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Daniel J. Hemel1 & Lisa Larrimore Ouellette2

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U.S. taxpayers provide over $100 billion each year in direct support for scientific research through grants and government labs. Under the Bayh–Dole Act, grant recipients can obtain patents on inventions that result from this public support. This framework has been replicated in many other countries, though it has been widely criticized here and abroad. The most salient charge against Bayh–Dole is that it forces consumers to “pay twice” for patented products—first through the tax system and again when the patentee charges a supracompetitive price. Supporters of Bayh–Dole counter that patents promote commercialization of inventions generated by government grantees, but it is doubtful that the commercialization benefits can justify the Act’s present scope.

One important feature of Bayh–Dole, however, has been overlooked in the debate thus far—a feature that arises from the global-public-good nature of knowledge. Unless government grantees can obtain patent protection for inventions generated by government-funded research, the United States would have no practical way of internalizing the positive externalities conferred on consumers in other countries who use products produced through U.S. taxpayer-financed research. Put differently, the charge that Bayh–Dole forces U.S. consumers to “pay twice” misses the point that eliminating some Bayh–Dole patents would permit non-U.S. consumers—in particular, consumers in other rich-world countries—to avoid paying at all. By allowing the United States as a whole to internalize some benefits that federally funded inventions bring to consumers in other rich-world countries, the Bayh–Dole regime arguably yields attractive distributional effects and plausibly leads to greater direct research support within the United States.

To be sure, this “internalization theory” of Bayh–Dole was not the rationale upon which sponsors of the Act relied. And like commercialization theory, internalization theory cannot justify the Act’s present scope. Rather than relying on internalization theory to defend Bayh–Dole, we highlight ways in which this novel theory can inform debates over Bayh–Dole reform. Internalization theory suggests that patents on products generated by government-sponsored research have a role to play in a global marketplace—although not quite the role that they play under the status quo.

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Introduction

Universities, national laboratories, and other recipients of federal funding for research and development receive over $100 billion each year from U.S. taxpayers.1 Under the Bayh–Dole Act of 1980, grant recipients can patent inventions stemming from this public support.2 Proponents say that Bayh–Dole has been a success beyond the “wildest dreams” of its drafters,3 creating hundreds of thousands (or millions) of jobs4 and “say[ing]—literally—millions of lives.”5 One prominent columnist has placed Bayh–Dole among the “three policies that gave us the jobs economy.”6 The Economist magazine—a publication not generally prone to hyperbole—has gone a step further, calling Bayh–Dole “[p]ossibly the most inspired piece of legislation to be enacted in America over the past half-century.”7

Bayh–Dole’s detractors, for their part,8 attack the Act from many angles. We focus here on two lines of criticism. The first takes the perspective of consumers and taxpayers within the United States. The argument is that it is inefficient—and unfair—to force U.S. taxpayers to “pay twice” for patented products: once when they fund the initial grant, and again when they pay

6 Amity Shales, Commentary, Three Policies that Gave Us the Jobs Economy, WALL ST. J., Oct. 17, 2011, at A17. The other two, according to Shales, are the preferential tax treatment for capital gains and the laws allowing pension plans to invest in start-ups.
7 Opinion, Innovation’s Golden Goose, ECONOMIST TECH. Q., Dec. 14, 2002, at 3. This oft-quoted statement almost certainly qualifies as hyperbole, however. Even Bayh–Dole’s most ardent backers might balk before placing it above the Civil Rights Act of 1964, the Voting Rights Act of 1965, the landmark environmental legislation of the 1970s, and the Americans with Disabilities Act of 1990. One might also wonder whether the editors of The Economist would stand by the statement today, given the magazine’s more pessimistic current view of the patent system overall. See Time To Fix Patents, ECONOMIST, Aug. 8, 2015, at 9.
supracompetitive prices for the patented product. A second line of attack highlights the effect of Bayh–Dole (and university patenting more broadly) on the developing world. Federal grant recipients may seek patent protection under the laws of any jurisdiction, and U.S. universities have patented life-saving treatments in developing countries. Access-to-medicine advocates are concerned that such patents may drive prices of essential products out of reach for some consumers in the developing world.

In our view, both of these critiques have considerable force. And yet there is a significant segment of the market for patented products to which neither argument applies: consumers in other rich-world countries. When a website in Germany pays a higher price to its server because the server uses a technology covered by a patent granted to MIT, the website owner is not paying “twice” for the technology because the website owner never paid a first time: U.S. taxpayers, not German taxpayers, provided the funding for the

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9 See, e.g., Rochelle Cooper Dreyfuss, Collaborative Research: Conflicts on Authorship, Ownership, and Accountability, 53 VAND. L. REV. 1161, 1194 (2000); Rebecca S. Eisenberg, Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research, 82 VA. L. REV. 1663, 1666 (1996); Bhaven N. Sampat & Frank R. Lichtenberg, What Are the Respective Roles of the Public and Private Sectors in Pharmaceutical Innovation?, 30 HEALTH AFF. 332, 333 (2011); cf. Bd. of Trs. of Leland Stanford Jr. Univ. v. Roche Molecular Sys., 131 S. Ct. 2188, 2201 (2011) (Breyer, J., dissenting) (arguing that there must be some compensating benefit of Bayh–Dole because otherwise, “Why should the public have to pay twice for the same invention?”).

10 Not all university patents are Bayh–Dole patents, and vice versa, although there is significant overlap. See Nat’l SCI. FOUND., supra note 1, at 4-29 tbl. 4-3 (noting that universities receive over half their R&D funding from the federal government, and ninety-five percent of their R&D funding from other government and nonprofit sources). We focus on university patenting for simplicity, but the benefit we will describe is more broadly applicable to federally funded research at other institutions (including other nonprofit organizations, for-profit firms, and national laboratories) and to non-federally funded research at universities.

11 The text of the Bayh–Dole Act does not distinguish between U.S. and foreign patents, see 35 U.S.C. § 202(a), and the regulations implementing Bayh–Dole make quite clear that grantees can seek patent protection in foreign jurisdictions as well as the United States. See 37 C.F.R. § 401.14(a), cl. (b) (setting forth the general rule that a grantee “may retain the entire right, title, and interest throughout the world to each subject invention”).


research at MIT. Meanwhile, the global distributive justice concerns that come to mind when, say, patients in sub-Saharan Africa pay higher prices for a first-generation HIV treatment patented by Yale are less compelling when patients in Norway pay more for a hair loss treatment patented by the University of Central Florida. Indeed, in the latter context, allowing U.S. universities to claim patent protection (as Bayh–Dole does) might seem attractive from a distributive justice perspective: why should taxpayers in the United States pay for the development of the treatment while beneficiaries in (much richer) Norway pay nothing at all?

To be clear, one might still argue that the combination of federal grants and Bayh–Dole patent revenues results in “excessive” rewards for knowledge good producers. By “excessive,” we mean that the reward exceeds the amount needed to induce a potential innovator to pursue a project. The social costs of excessive rewards are fourfold. First, insofar as rewards are funded through behavior-distorting taxes (such as taxes on income or consumption), then excessive rewards distort behavior more than the minimum degree necessary to produce the corresponding innovation benefits. Second, and similarly, insofar as rewards come in the form of patent rents, then excessive rewards result in greater deadweight loss than necessary to motivate the innovator. Third, if rewards exceed the social benefits of innovation, then excessive rewards might induce innovators to pursue socially wasteful projects. And fourth, even insofar as excessive rewards amount to pure transfers from taxpayers or consumers to innovators, then excessive rewards might shift resources from individuals with higher marginal utilities of income to individuals with lower marginal utilities of income, thus reducing overall welfare.

Our argument here is that U.S. public and private investment in knowledge production might fall (further) below the level that maximizes global welfare if the U.S. federal government and U.S. firms did not have the opportunity to capture a portion of the benefits that U.S.-generated knowledge goods confer on foreign consumers—an opportunity that the Bayh-Dole regime facilitates. Of course, if one believes that the current level of U.S. public and private investment in knowledge production is supraoptimal, then that might be a reason to oppose a regime such as Bayh-Dole that facilitates further investment. Moreover, our argument is explicitly not that the internalization theory can justify U.S. patents for federally funded research. On the latter point, see note 120 and accompanying text.

This overlooked international dimension of the Bayh–Dole regime may provide a novel—though partial—justification for allowing universities to obtain patents on publicly supported inventions. In addition to yielding arguably attractive distributional consequences, such patents may also increase efficiency: By allowing the U.S. federal government and U.S. firms to internalize some of the benefits that federally funded inventions bring to foreign consumers, Bayh–Dole may induce higher levels of U.S. public and private spending on research in the first place. Universities and other nonprofits are required to reinvest Bayh–Dole patent revenues in science research and education, and those universities with successful technology transfer programs have been able to devote substantial resources to new research projects. It is also possible that lobbying by universities and their domestic licensees who benefit from Bayh–Dole patent rents could cause Congress to increase research grant appropriations. This theory applies with similar force to other countries considering the enactment (or refinement) of Bayh–Dole-like laws: Patents on publicly supported inventions allow the nation-state that sponsors the research to capture a larger share of the global benefits generated by its efforts, with potentially positive effects on the overall level of public R&D funding. We call this the “internalization theory” of Bayh–Dole, and as far as we know, it is an aspect of the Bayh–Dole regime that has gone unmentioned in the literature thus far.

Our primary goal here is to describe the internalization theory, but we also seek to identify the questions that must be answered to evaluate its strength. For example: How often do federally funded research institutions seek patent protection in foreign jurisdictions? How much of this overseas patenting activity occurs in high-income countries and how much occurs in middle- and low-income countries? And when foreign sales of a product that resulted from federally funded R&D generate supracompetitive profits, where do these profits go? We offer a first cut at answering these questions, but we do not think there is yet sufficient evidence to offer a full-throated defense of the claim that Bayh–Dole actually serves a valuable benefit-internalization function on either efficiency or distributive grounds. Rather, we hope to lay the groundwork for universities and other Bayh–Dole proponents who are in a better position to bolster this claim empirically.

Our analysis proceeds in four short parts. Part I reviews the uneasy case for patents on federally funded inventions. Part II sets out the internalization theory and describes how Bayh–Dole may allow the United States to capture a portion of the benefits that federally funded R&D brings to consumers in other (and especially other rich-world) countries. Part III presents new data on the reach of university patents beyond the United States, with a particular focus on patents in industrialized nations that are not the focus of the “paying twice”

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critique or the access-to-medicines movement. Finally, Part IV explores how internalization theory should affect the ongoing Bayh–Dole debate in the United States, as well as debates in other countries where governments are considering similar regimes.

I. The Uneasy Case for Bayh–Dole Patents

Prior to 1980, federal agencies maintained inconsistent policies as to whether recipients of research grants could take title to inventions that sprung from federally funded projects. This uncertainty, as well as increases in the costs of bringing pharmaceuticals to market, led Congress to pass the Bayh–Dole Act of 1980. The stated goals of the Act include promoting “utilization of inventions arising from federally supported research” and “collaboration between commercial concerns and nonprofit organizations, including universities.”

To accomplish these goals, the Bayh–Dole Act allows contractors such as universities that receive federal grants to “retain title to” (i.e., obtain patents on) inventions created under those grants. Once university patent administrators learn of a federally funded invention, a university has two months to notify the agency and two years to decide whether to retain title, and then another one year to file a patent—with shorter deadlines if the inventor has made any public disclosure (e.g., by publishing the invention) that limits the period of patentability.

The agency may file any patents that a contractor chooses not to pursue, including patent applications in other countries. Thus, if the

22 See Eisenberg, supra note 9, at 1671–91; Peter Lee, Patents and the University, 63 DUKE L.J. 1, 30–32 (2013). As these and other scholars have explained, universities often sought patents on federally funded inventions before Bayh–Dole, and an important motivation for the Act was to standardize these practices. See id.; see also DAVID C. Morrow ET AL., IVORY TOWER AND INDUSTRIAL INNOVATION: UNIVERSITY–INDUSTRY TECHNOLOGY TRANSFER BEFORE AND AFTER THE BAYH–DOLE ACT 1 (2004) (describing evidence that “the Bayh–Dole Act was one of several factors that contributed to the growth of patenting and licensing by U.S. universities during the 1980s and 1990s” in that it “provided a strong congressional endorsement” of university patenting “and simplified the formerly complex administrative process through which U.S. universities gained title to the intellectual property resulting from publicly funded research”).


26 35 U.S.C. § 202(a). Funding agreements may provide otherwise only in a limited number of circumstances. Id. The default right to take title applies “throughout the world.” 37 C.F.R. § 401.14(a), cl. (b).

27 37 C.F.R. § 401.14(a), cl. (c); see 35 U.S.C. § 202(c). For details on the one-year grace period for filing a patent after a public disclosure such as a publication, see 35 U.S.C. § 102(b).

contractor files a patent application in the United States but not the United Kingdom, the agency may file in the United Kingdom. If a contractor chooses to patent, “the Federal agency shall have a nonexclusive, nontransferable, irrevocable, paid-up license” to the patents, and any U.S. patent application must specify “that the Government has certain rights in the invention.” Agencies may further “require periodic reporting on the utilization” of the invention. As a matter of law, agencies also may exercise “march-in” rights to issue additional licenses to the invention if the contractor is not taking “effective steps to achieve practical application” or “to alleviate health or safety needs.” In practice, however, march-in rights have never been exercised.

Universities are required to reinvest their patent rents in research. The statute specifies that any grant agreement must contain a “requirement that the balance of any royalties or income earned by the contractor with respect to subject inventions, after payment of expenses (including payments to inventors) incidental to administration of subject inventions, be utilized for the support of science research or education.” The Bayh–Dole Act also includes an explicit preference for federally funded inventions to be manufactured in the United States. Any exclusive licensee of a Bayh–Dole patent must agree “that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States” unless domestic manufacture is infeasible.

The justification for the Bayh–Dole Act generally offered by its supporters is materially different from the standard justification for the patent system overall. As Rebecca Eisenberg writes in her landmark analysis of the Bayh–Dole Act, “a standard instrumental argument” for patents is that they provide “incentives to invest in the costly and risky enterprise of making inventions,” but this argument “loses much of its force in the case of inventions made with public funding” where taxpayers have already “absorbed the risk that nothing will come of [their] investment.” (This is the foundation of the

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30 35 U.S.C. § 202(c)(5); 37 C.F.R. § 401.14(a), cl. (h).


35 Eisenberg, supra note 9, at 1668; see also Mark A. Lemley, Ex Ante Versus Ex Post Justifications for Intellectual Property, 71 U. Chi. L. REV. 129, 129 (2004) (“The standard justification for intellectual property is ex ante . . . .”). While the standard argument loses much of its force in the context of publicly funded innovations, the argument does not lose all of its force. For example, even when a federal grant fully covers out-of-pocket costs, it may not compensate the researcher fully for the opportunity cost of her time. A researcher who devotes years of work to a project at below-market pay does in that sense absorb part of the risk that nothing will come of her time investment, and the possibility of patent rewards may incentivize her to make that investment. On the other hand, there is no empirical evidence that Bayh–
“paying twice” critique: if U.S. taxpayers are already funding university research to the optimal level, then adding patent rights to the incentive package gives an excessive reward.36 Instead of relying on theories based on ex ante incentives, Eisenberg writes, Bayh–Dole advocates “shift the focus from the initial costs of making an invention to the subsequent costs of developing an existing invention into a commercial product.”37 The “commercialization theory” posits that the Bayh–Dole framework facilitates cooperation between university researchers and the private-sector firms capable of bringing the products of university research to market. The idea that patents are needed for commercialization is the first goal listed in the statutory text,38 is pervasive throughout the legislative history,39 and has been noted by both the Supreme Court and the Federal Circuit.40 Commentators have focused on this theory when defending Bayh–Dole, pointing to the number of patent licenses and start-up firms that the Act has produced.41

Dole spurs federally funded researchers to produce more or better inventions, and it is even theoretically possible that the financial incentives of Bayh–Dole could lead to less innovation if they “crowd out” intrinsic rewards. Cf. Yochai Benkler, THE WEALTH OF NETWORKS: HOW SOCIAL PRODUCTION TRANSFORMS MARKETS AND FREEDOM 92–98 (2006). Our argument here does not depend on which of these theories is correct. For further discussion of this and other possible justifications for Bayh–Dole patents, see Ian Ayres & Lisa Larrimore Ouellette, A Market Test for Bayh–Dole Patents, 102 CORNELL L. REV. 271 (2017).

36 See supra note 9 and accompanying text.
37 Eisenberg, supra note 9, at 1669. Note that “ex post theories” such as the commercialization theory are not limited to the Bayh–Dole context. See Ayres & Ouellette, supra note 35 (manuscript at 13-15) (reviewing literature); see also Edmund W. Kitch, The Nature and Function of the Patent System, 20 J.L. & ECON. 265 (1977); Staff of Subcomm. on Patents, Trademarks & Copyrights of the S. Comm. on the Judiciary, 85th Cong., An Economic Review of the Patent System, Study No. 15, at 36 (Comm. Print 1958) (prepared by Professor Fritz Machlup).
38 35 U.S.C. § 200 (2012) (“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 . . . .”).
39 See, e.g., H.R. REP. NO. 96-1307, pt. 1, at 3 (1980) (“[T]he existing melange of 26 different agency policies on vesting of patent rights in government funded research is replaced by a single, uniform national policy designed to cut down on bureaucracy and encourage private industry to utilize government funded inventions through the commitment of the risk capital necessary to develop such inventions to the point of commercial application.”); 124 CONG. REC. S 122 (1978) (statement of Sen. Bayh) (expressing concern about the “[h]undreds of valuable medical, energy, and other technical discoveries” that were “sitting unused”).
A typical example cited by advocates of the commercialization theory is that of a cancer researcher at a university whose work is funded by a federal grant; the researcher develops a cutting-edge therapy but cannot possibly afford to pay the millions of dollars required to put the therapy through clinical trials. So the researcher obtains a patent on the therapy and licenses it to a pharmaceutical company on an exclusive basis. The pharmaceutical company pays for the clinical trials and brings the therapy to market, improving the lives of patients and reaping profits that the company shares with the university and the researcher. Bayh–Dole is an essential link on this causal chain, say its supporters, because if the researcher could not have obtained the patent, then she could not have licensed the invention to the pharmaceutical company on an exclusive basis. And the pharmaceutical company would not have spent millions of dollars on clinical trials if, once those trials were completed, any other pharmaceutical company could copy the therapy and sell it as a generic product.\textsuperscript{42} Note that this “commercialization theory” is focused on increasing dissemination of federally funded inventions, not increasing their initial supply.

The evidence surrounding the commercialization theory is mixed. One study found that almost a third of scientifically novel drugs are discovered by universities and then transferred to pharmaceutical and biotechnology companies for commercialization.\textsuperscript{43} This data point might suggest that Bayh–Dole plays an important role in bringing inventions from the lab to the market (although it is unclear how many of these novel drugs would have been commercialized absent Bayh–Dole). On the other hand, data collected by the Association of University Technology Managers indicates that over sixty percent of patent licenses issued by universities are nonexclusive.\textsuperscript{44} That statistic calls into question the commercialization-theory account, in which the promise of exclusivity is what incentivizes a private-sector firm to invest in

\textsuperscript{42} See, e.g., de Parry, supra note 5 (“Have you or a loved one taken Tamoxifen or Herceptin for breast cancer? How about Revlimid for multiple myeloma? Bexxar for non-Hodgkin lymphoma? Gleevac for chronic myelogenous leukemia? Did Neulasta ever keep you safe from infection while undergoing chemotherapy? Then you have benefited from bipartisanship, because these and nearly 200 other drugs are available today as a result of the 96th Congress passing a little-known bill that . . . became known as the Bayh–Dole Act.”). On the need for sufficient patent life to incentivize clinical trials, see Benjamin N. Roin, Unpatentable Drugs and the Standards of Patentability, 87 TEX. L. REV. 503, 545–47 (2009). Of course, pharmaceutical companies also benefit significantly from nonpatent incentives such as regulatory exclusivity, tax preferences, and the direct federal grants that are the focus of this paper. See Lisa Larrimore Ouellette, Patentable Subject Matter and Nonpatent Innovation Incentives, 5 UC IRVINE L. REV. 1115, 1128–37 (2015).

\textsuperscript{43} Robert Kneller, The Importance of New Companies for Drug Discovery: Origins of a Decade of New Drugs, 9 NATURE REVIEWS DRUG DISCOVERY 867, 896 tbl.1 (2010); see also Sampat & Lichtenberg, supra note 9, at 334–35 (reporting that of the 135 drugs granted “priority review” by the FDA from 1988 to 2005—reserved for “drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists”—seventeen percent had a patent assigned to the government or acknowledging government support, and two-thirds at least indirectly relied on government-funded research).

commercializing inventions coming out of publicly funded labs. As Eisenberg writes, “nonexclusive licenses do little or nothing to give licensees an advantage over their competitors and thus are unlikely to enhance the profitability of product development.”45 To be sure, one should be cautious about inferring that all nonexclusive licenses have no commercialization value: for instance, universities might maximize profits through cartel rather than monopoly arrangements.46 Yet at the very least, the pervasiveness of nonexclusive licenses creates a chink in the commercialization theory’s armor. And a number of prominent innovation scholars—including Arti Rai, Suzanne Scotchmer, Bhaven Sampat, and Mark Lemley, have echoed Eisenberg’s critique: the validity of commercialization theory depends on the technology in question, and it is not convincing for many Bayh–Dole patents.47

In several high-profile cases of Bayh–Dole patents that ultimately ended up in litigation, the commercialization-theory account seems to carry little force. For example, Boston University made headlines—and earned the label of “patent troll”—by successfully suing thirty of the largest tech firms over a nonexclusively licensed patent on blue LEDs,48 which was the product of research partially funded by the National Science Foundation (NSF).49 Given the rapid adoption of this technology without exclusivity, Boston University’s

45 Eisenberg, _supra_ note 9, at 1710.

46 For example, if a licensee firm thinks a university is profit maximizing, it might accept a nonexclusive license for a percentage of its profits on the condition that the university demand the same percentage from any future licensee. A purely profit-motivated university would have an incentive to grant a second nonexclusive license only if the first firm turns out to be bad at commercializing the invention (because a fixed percentage of monopoly profits is greater than that same percentage of duopoly profits). We are unaware of universities that have followed such a strategy, rather than making nonexclusive licenses available to all interested parties.


patent does not seem to have been necessary to make blue LEDs publicly available. A similar conclusion applies to several high-profile inventions in the biological sciences. Stanford’s widely licensed (and now expired) Cohen–Boyer patents on recombinant DNA technology—a foundation of the modern biotechnology industry—are often cited as an example of inventions that did not need patents for commercialization.\textsuperscript{50} As another example, a report on ten genetic diagnostic tests requested by the Department of Health and Human Services found that in no case “was the test developed by the exclusive rights holder the first to market.”\textsuperscript{51} This included the test covered by the (now invalid) breast cancer gene patent owned by the University of Utah, the United States, and Myriad Genetics.\textsuperscript{52} The research underlying this patent was financed in part by grants from the National Institutes of Health (NIH) and intramural research at the National Institute of Environmental Health Sciences.\textsuperscript{53}

When a product would have been invented even without the prospect of a patent and would have been commercialized even without exclusivity, then allowing a patentee to charge a supracompetitive price for the product might seem like it imposes an unnecessary tax on consumers.\textsuperscript{54} One of us has argued that if commercialization theory is the justification for Bayh–Dole patents, then universities ought to be required to license patents to the party willing to commit to commercialization for the shortest period of exclusivity so as to minimize the welfare loss from higher prices.\textsuperscript{55} If a twenty-year patent life is not necessary to incentivize investment ex ante and not required for commercialization ex post, then what possible justification might there be for allowing exclusivity throughout the full patent term?

We do not claim to have a complete answer to the last question. Quite likely, many readers will reach the end of this piece and conclude that Bayh–Dole patent rights should be limited to cases in which exclusivity is necessary for commercialization. Yet there is one dimension of the Bayh–Dole regime that our analysis so far has ignored—and, indeed, that the academic literature on Bayh–Dole has ignored as well. Bayh–Dole patent rights affect not only

\textsuperscript{50} See, e.g., Ayres & Ouellette, supra note 35; Eisenberg, supra note 9, at 1710; Rai & Eisenberg, supra note 47, at 300; Sampat, supra note 47, at 783; So et al., supra note 13, at 2079.

\textsuperscript{51} SEC’Y’S ADVISORY COMM. ON GENETICS, HEALTH, AND SOC’Y, U.S. DEPT HEALTH & HUMAN SERVS., GENE PATENTS AND LICENSING PRACTICES AND THEIR IMPACT ON PATIENT ACCESS TO GENETIC TESTS 31 n.82 (2010).

\textsuperscript{52} See Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013) (invalidating U.S. Patent No. 5,747,282 (filed June 7, 1995)).

\textsuperscript{53} See SEC’Y’S ADVISORY COMM. ON GENETICS, HEALTH, AND SOC’Y, supra note 51, at A-11; Susan L. Neuhausen et al., Haplotype and Phenotype Analysis of Six Recurrent BRCA1 Mutations in 61 Families: Results of an International Study, 58 AM. J. HUM. GENETICS 271, 279 (1996); Donna Shattuck-Eidens et al., BRCA1 Sequence Analysis in Women at High Risk for Susceptibility Mutations, 278 JAMA 1242, 1250 (1997); Donna Shattuck-Eidens et al., A Collaborative Survey of 80 Mutations in the BRCA1 Breast and Ovarian Cancer Susceptibility Gene, 273 JAMA 533, 541 (1995).

\textsuperscript{54} For an explanation of how patents act as a “shadow tax” on patented products, see Daniel J. Hemel & Lisa Larrimore Ouellette, Beyond the Patents-Prizes Debate, 92 TEX. L. REV. 303, 312–14, 371–73 (2013).

\textsuperscript{55} Ayres & Ouellette, supra note 35.
consumers in the United States (the focus of the “paying twice” critique) but also consumers in foreign countries (who have yet to “pay once”). And while access-to-medicine advocates have drawn attention to Bayh–Dole patenting activity in the developing world, much less is known about Bayh–Dole activity in other high-income countries. The following Part explains why patents on publicly funded research in high-income non-U.S. countries might matter to the Bayh–Dole debates.

II. The Internalization Theory of Bayh–Dole

To understand the potential benefits of foreign Bayh–Dole patents, we begin in Section II.A by considering why one might expect underinvestment in public funding for research grants in first place, and how the Bayh–Dole regime might offer a partial solution to this problem by allowing the United States to internalize foreign benefits of publicly funded inventions. Section II.B considers the mechanisms through which this internalization of foreign benefits might feed back into direct research spending. Finally, Section II.C discusses some important caveats to this internalization theory of Bayh–Dole.

A. Bayh–Dole and Global Benefit Internalization

We begin with a simplified model of how policymakers set funding levels for grants and national laboratories. If the goal of U.S. policymakers is to maximize U.S. welfare, then they should invest up to the point that the marginal cost equals the marginal benefit to U.S. citizens (and perhaps U.S. residents as well). Yet the scientific knowledge that results from this investment often benefits non-U.S. citizens and non-U.S. residents. If U.S. policymakers do not consider these non-U.S. benefits, then they will invest in knowledge subsidies at less than the globally optimal level. To be clear, we are not claiming that federal grant appropriations are explicitly based on detailed cost–benefit analyses, nor are we claiming that U.S. lawmakers always act so as to maximize national welfare. We adopt the national welfare maximization assumption—which is standard in the international political economy literature—as a reasonable first approximation to explain U.S. policy, but we interrogate and relax this assumption in Section II.B.56

Similarly, if policymakers abroad fail to account for the benefits to consumers in the United States and other countries when setting their spending levels for grants and other knowledge subsidies, they will also invest less than the optimum level. As Nobel laureate Joseph Stiglitz explains, “[k]nowledge is a global public good,” and “global public goods provide a central rationale for

international collective action.” But there is no comprehensive international agreement requiring nation-states to support research through public finance at any particular level. Rather, the solution nation-states have found to the problem of global underinvestment in technical knowledge is an IP solution. Most significantly, almost all nation-states have ratified the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which requires signatories (except least-developed countries) to offer twenty-year patents in “all fields of technology” to inventors from all other signatory states. TRIPS allows producers of knowledge goods to internalize some of the benefits resulting from use of those knowledge goods abroad.

Innovation economist Suzanne Scotchmer worried that international coordination on patents rather than on non-patent incentives leads to “too little public sponsorship and too much intellectual property” at the domestic level. Yet the existence of patent law treaties such as TRIPS may actually help solve the problem of too little domestic spending on non-patent incentives when combined with Bayh–Dole regimes. The key to this argument is that Bayh–Dole allows federal government grantees to obtain patents not only in the United States, but in foreign jurisdictions as well. In this way, Bayh–Dole patents allow the United States to internalize some of the benefits that its own direct public spending on innovation brings to consumers overseas. Foreign consumers benefit from the inventions generated by federally funded research at U.S. universities. And when foreign consumers pay supracompetitive prices on these patented inventions, much of this patent “shadow tax” flows back to the United States. Some of this benefit goes to government labs and public universities; some goes to nonprofit research universities and foundations that

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57 See Joseph E. Stiglitz, Knowledge as a Global Public Good, in GLOBAL PUBLIC GOODS: INTERNATIONAL COOPERATION IN THE 21ST CENTURY 308, 320 (Inge Kaul et al. eds., 1999). In a separate Article, we complicate this account of global knowledge production: We explain that not all knowledge goods are global public goods and that nation-states may have other motivations to invest in knowledge production besides increasing the welfare of their own citizens. Daniel J. Hemel & Lisa Larrimore Ouellette, Knowledge Goods and Nation-States, 101 MINN. L. REV. 167 (2016). But we do not dispute that there is a global underinvestment problem; rather, our analysis simply limits the range of knowledge goods for which this problem is likely to be severe.


60 See supra note 54 and accompanying text.

61 In 2014, six of the top ten universities ranked by life sciences licensing income were public universities. See Brady Huggett, Top US Universities, Institutes for Life Sciences in 2014, 33 NATURE BIOTECHNOLOGY 1131 (2015).
the federal government has chosen to support through tax exemptions; and some goes to U.S. manufacturers like Myriad Genetics (and then to the U.S. government through taxation of these profits).

As noted above, the Bayh–Dole Act even incorporates an explicit preference for keeping profits within the United States. Thus, for example, the University of Utah could not exclusively license its breast cancer gene patent to a firm that would conduct genetic testing abroad. This limitation ensured that foreign consumers would have to obtain their tests for breast cancer gene mutations from a U.S. firm (or, at least, a firm with a substantial presence in the United States).

B. The Relationship Between Bayh–Dole Patents and Direct R&D Spending

While it seems clear that Bayh–Dole serves a benefit-internalization function, it is less obvious how this feature affects the overall amount of direct research funds within the United States. We hypothesize two plausible mechanisms through which such funding may be increased: (1) greater support from internal university research funds generated from Bayh–Dole patent revenues, and (2) higher federal grant appropriations.

First, Bayh–Dole patentees are required to reinvest patent revenues in science research and education. Successful university technology transfer offices have been able to recycle significant revenues back into new university projects. For example, the Wisconsin Alumni Research Foundation (the independent licensing arm of the University of Wisconsin at Madison) boasts of providing an inflation-adjusted total of “$2.3 billion in cumulative direct grants.” At Stanford, excess licensing revenue is transferred to the “Research Incentive Fund” to support early-stage projects by junior science faculty; this fund received over $10 million in the 2013 to 2014 academic year.

To be sure, many universities do not generate much (if any) net income from their technology transfer programs, and we are not aware of any data that separates foreign patent revenues from domestic income. It is therefore

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62 Supra note 34 and accompanying text.

63 For our purposes, it makes little difference whether such funding is recycled through the federal budget or not. If universities receive additional revenues from Bayh–Dole patents and that are reinvested in research, this is functionally equivalent to a tax on Bayh–Dole patent revenues that is returned to universities for new research projects.

64 Supra note 33 and accompanying text.

65 Frequently Asked Questions About WARF’s Purpose and Functions, supra note 21.


68 See Ayres & Ouellette, supra note 35 (surveying the literature on Bayh–Dole revenues).
difficult to evaluate how successful this “revenue recycling” hypothesis is in practice. (Though even when legal fees outstrip licensing income, Bayh–Dole patents may encourage additional grant spending; lawyers are often successful lobbyists.) What we can say, based on annual survey data from the Association for University Technology Managers (AUTM), is that the gross licensing income reported by U.S. universities and nonprofit research institutes has been increasing faster than their legal fees, as illustrated in Figure 1.69 The trajectory for net income that can be reinvested into university research thus appears positive. And at least some universities, such as Wisconsin and Stanford, have long been recycling their patent revenues—likely including foreign patent revenues—back into their research programs.

Figure 1. Licensing Income and Legal Fees at U.S. Universities and Nonprofits

Furthermore, these licensing revenues do not include damages awards from patent infringement lawsuits brought by universities. For patent lawsuits filed between 2006 and 2009 with a U.S. university as a party, total damages awarded were over $3 billion.70 More recently, university patent litigants have won impressive damages awards, such as the Wisconsin Alumni Research

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69 Statistics Access for Technology Transfer (STATT) Database, supra note 44. The number of U.S. institutions reporting this data ranged from 157 to 192 over the years shown. AUTM also surveys Canadian institutions, but they were removed before the cumulative numbers reported in Figure 1 were calculated.

One estimate concluded from the 2012 AUTM survey data that 84% of reporting universities did not generate enough licensing income to cover their operating costs. WALTER D. VALDIVIA, UNIVERSITY START-UPS: CRITICAL FOR IMPROVING TECHNOLOGY TRANSFER 9 (Ctr. for Tech. Innovation at Brookings, 2013).

70 We conducted a search on August 29, 2016, at LEX MACHINA, http://lexmachina.com. Of course, large portions of these rewards likely went to university licensees and to the lawyers litigating the cases, rather than to university coffers.
Foundation’s $234 million award against Apple (appeal pending),\(^71\) and Carnegie Mellon University’s $1.5 billion award against Marvell Semiconductor (reduced to $750 million in a settlement).\(^72\) These lawsuits do not seem to have much connection to commercialization of the underlying technologies, but if large portions of these rewards are recycled into new research projects, the net welfare effect may well be positive. To be clear, given the confidential nature of most university patent license agreements and litigation fee arrangements, it is difficult to draw any strong conclusions. Rather, we hope our argument will encourage universities to analyze and share their own data so that this claim may be evaluated more rigorously.

The second mechanism through which the internalization function of Bayh–Dole might increase grant-funded U.S. research is through higher grant appropriations from Congress. Because their constituents benefit from Bayh–Dole patents filed abroad, lawmakers interested in increasing U.S. welfare may have a greater incentive to invest public funds in research in the first place. If the United States invests up to the point that the marginal cost of research spending equals the expected marginal benefit within the United States, then bringing the marginal U.S. benefit per unit of investment closer to the marginal global benefit will also increase U.S. investment closer to the global optimum.\(^73\)

Of course, the assumption that Congress will provide funding for scientific research up to the point that the marginal cost equals the marginal benefit to U.S. citizens is an oversimplification—even observers with a highly optimistic view of legislators’ motives would concede as much. And yet the hypothesis remains plausible even if one adopts a more cynical view of congressional action. Public choice theory suggests that members of Congress will support federal funding for scientific research so long as the political benefits (in particular, the benefits to well-organized interest groups) exceed the political costs (in the form of higher taxes).\(^74\) Interest-group support for federal research spending will be stronger when well-organized domestic constituencies stand to profit from federally funded inventions. Universities have successfully


\(^73\) This logic should be familiar from any course in introductory economics. See, e.g., PAUL KRUGMAN ET AL., ESSENTIALS OF ECONOMICS 266–67 (2d ed. 2010). The other common solution from introductory economics for underinvestment in goods that produce positive externalities is a Pigouvian subsidy: a government payment to increase supply of the good. See, e.g., id. at 275. But there is no global mechanism for subsidizing governments that invest in knowledge goods; rather, the only comprehensive international coordination mechanism for knowledge-good production is the system of IP treaties. See generally Hemel & Ouellette, supra note 57 (discussing this puzzle).

lobbied both for increased research appropriations and against any curtailment of their patent rights. Moreover, many of the beneficiaries of federally funded research (even research that occurs at universities) are private-sector firms such as faculty spinoffs, which may be capable of influencing lawmakers through more traditional methods (e.g., political contributions). This is not to suggest that interest-group politics will produce an outcome in which public funding for scientific research exactly equals the national-welfare-maximizing amount. It is to suggest, though, that the amount of funding seems likely to be positively correlated with domestic benefits, even if the correlation is far from perfect.

We will discuss numerous caveats to this account in the following Section, but first, a concrete example may help illustrate the basic case. Suppose Congress is debating how much to appropriate to the U.S. Department of Energy (DOE) for scientific research related to energy efficiency, which may lead to inventions such as cheaper methods of sealing wasteful leaks in building air ducts. If these inventions could not be patented, then consumers in other countries could free-ride off the duct-sealing knowledge that stems from DOE-funded research. If members of Congress are focused on benefits to only their constituents, they will not account for these benefits outside the United States when setting DOE's

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77 On faculty spinoffs, see Andy Lockett et al., The Creation of Spin-off Firms at Public Research Institutions: Managerial and Policy Implications, 34 RES. POL’Y 981 (2005).

78 To be sure, it is conceivable that federal funding for scientific research may be negatively correlated with Bayh–Dole patent rents reaped by universities. Perhaps lawmakers will look at the additional revenues that Bayh–Dole brings to universities and decide to reduce the amount of federal grants commensurately. Yet even in that scenario, the Bayh–Dole regime would serve a benefit-internalization function: by replacing taxpayer dollars with foreign licensing fees, Bayh–Dole would be reducing the burden that science research spending places on the federal fisc. Put differently, if Bayh–Dole leads to foreign consumers paying for research that would otherwise be funded by taxpayer dollars, then Bayh–Dole—by ensuring that foreign consumers pay once—results in U.S. taxpayers paying less.


80 See U.S. Patent No. 5,522,930 col. 1 l. 5–9 (filed Nov. 4, 1994) (noting support from the U.S. Department of Energy); see also Duct Sealing, ENERGY STAR, http://www.energystar.gov/index.cfm?fuseaction=home_improvement.hm_improvement_ducts (last visited Mar. 4, 2016) (“In a typical house . . . about 20 to 30 percent of the air that moves through the duct system is lost due to leaks, holes, and poorly connected ducts. The result is higher utility bills and difficulty keeping the house comfortable, no matter how the thermostat is set.”).

81 For example, suppose that DOE adopts the market test proposed in Ayres & Ouellette, supra note 35, and firms prove eager to commercialize these inventions without exclusivity.
research budget. At the margin, there may be some energy-related research projects that would not be funded even though they are welfare enhancing from a global perspective.

Bayh–Dole allows DOE grant recipients to patent these inventions abroad so that some of the benefits to consumers in other countries flow back to the United States. Imagine (though the example is far from imaginary) that a DOE-funded U.C. Davis professor creates a new duct-sealing method and the University of California’s technology transfer office obtains a patent on this invention in the United States and in foreign jurisdictions.82 The University of California then licenses its worldwide patent rights to Aeroseal, Inc., a startup company created to commercialize the technology.83 Aeroseal, in turn, licenses the technology to dealers across the United States, Canada, and 19 other countries.84 Dealers reap profits from their customers; Aeroseal reaps profits from the dealers; and the University of California reaps profits from Aeroseal. Bayh–Dole makes this possible by allowing the University of California to patent the duct-sealing technology: if anyone could use the technology, then the dealers would have no incentive to pay Aeroseal and Aeroseal would have no incentive to pay the University of California.

The key point is that Bayh–Dole patents allow U.S. universities to earn licensing revenues that, at least indirectly, come from the foreign consumers who benefit from the products of U.S. university research. The profits earned by the University of California can be redirected back into research. And if some congressmembers consider these licensing revenues in their own cost-benefit calculus, then Congress may increase funding for energy-related projects. This increased funding is of course a benefit from the perspective of the grant recipients who share in these patent rents, but it is also a benefit from a global perspective: if some welfare-enhancing projects that would not have been pursued without Bayh–Dole are now funded, then consumers worldwide can benefit from technologies that would otherwise not exist. And note again that the flow of Bayh–Dole revenue to the University of California may increase research funding even if the prospect of foreign patent rents does not affect congressional appropriations choices, because of the revenue-recycling requirement embedded in the Bayh–Dole statute.85


85 See supra notes 65-67 and accompanying text.
C. Caveats to the Internalization Theory

The prior two Sections have described the internalization theory of Bayh–Dole: By allowing the United States to internalize some of the benefits that foreign consumers receive from publicly funded technologies, Bayh–Dole may increase grant-funded research within the United States closer to the globally efficient level that accounts for these external benefits. But there are important caveats to consider before concluding that this is in fact a significant net efficiency benefit of the Bayh–Dole regime. Here, we discuss three such complications: (1) the results of government-funded research cannot always be patented; (2) investment in some kinds of research grants may not be suboptimal even without internalization of foreign benefits; and (3) even if Bayh–Dole yields the internalization benefit that Part III describes, the costs associated with these patents may not outweigh this benefit.

First, it is worth noting that the benefit we describe is inapplicable to knowledge that cannot be patented. For example, scholars have identified a number of medical innovations that are not protectable under most IP laws, ranging from hygiene checklists for intensive-care units\(^86\) to the complex computational models known as “black-box medicine”\(^87\) to information about failed research projects.\(^88\) The Bayh–Dole regime will not help the United States internalize foreign benefits from its subsidies for these kinds of projects, and other forms of global coordination may be necessary to prevent underinvestment. But this observation does not necessarily translate into an argument against Bayh–Dole patents: when knowledge cannot be patented, there are no patent-related costs, either. And the fact that Bayh–Dole does not solve all problems related to underinvestment in non-IP incentives does not mean that it doesn’t solve some problems.

One might argue that patent protection for knowledge goods that can be patented negatively affects investment in knowledge goods that cannot be patented, because capital is diverted from unpatentable technologies to patentable technologies.\(^89\) Yet if capital can move freely across sectors, then protection for patentable technologies will have only an incidental effect on investment in unpatentable technologies (insofar as the increased rewards for investment in patentable technologies boosts the market-wide rate of return and thus the market-wide cost of capital). Put differently, protection for patentable technologies will divert capital away from investment in

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87 See W. Nicholson Price II, Black-Box Medicine, 28 HARV. J.L. & TECH. 419 (2015). Price defines “black-box medicine” as “the use of opaque computational models to make decisions related to health care,” and he explains that the cost-intensive components—aggregated data, algorithms, and validation studies—generally cannot be protected with patent law. Id. at 421, 443–46.
89 See Kapczynski & Syed, supra note 86, at 1945 (“[P]atents may not only fail to incentivize some net-beneficial goods, but also affirmatively jeopardize the creation of such goods by diverting resources away from them.”).
unpatentable technologies to the same extent that it diverts capital away from investment in any other sector. Patent protection for a new HIV drug reduces investment in black-box medicine to the same extent that it reduces investment in shoe factories and sports arenas.

The capital diversion story is compelling only insofar as the factors of knowledge production are in limited supply. Of course, capital and labor are always in limited supply, but greater investment in patentable technologies has at most a rounding-error impact on investment in unpatentable technologies unless capital and labor are trapped in (and locked out) of the knowledge sector. This might be true if, say, the number of scientists is fixed (such that increasing the rewards for science research won’t stop scientists from becoming traders\(^90\)) or the availability of venture capital funding is limited (such that increasing returns to venture capital won’t lead investors to shift over from, e.g., hedge funds). And yet one can just as easily tell a story in which increasing the rewards for patentable technologies will lead to greater investment in unpatentable technologies. To the extent that Bayh–Dole enriches universities, it results in more money being available for non-federally-funded research endeavors (including research yielding products that are not protected under intellectual property laws).

This leads to the second caveat: Internalization of global spillovers is a benefit only to the extent that there is otherwise a problem with underinvestment in innovation. This is not necessarily the case in all circumstances. In the context of domestic IP law, Mark Lemley has argued that innovators will often have sufficient incentives to create even when others can free-ride on their discoveries.\(^91\) Similarly, in the context of international IP law, nation-states may have sufficient incentives to subsidize knowledge-good production even when other states can free-ride on the resulting knowledge. As we explain in a separate article, not all knowledge goods are global public goods, and governments have many motivations to invest in knowledge production that the conventional economic account fails to capture—including motivations that might take into account foreign benefits.\(^92\) And yet the theoretical underpinnings of the underinvestment hypothesis are strong, and the existing evidence does little to falsify the hypothesis.\(^93\)

\(^90\) Cf. Landon Thomas Jr., Traders with Ph.D.s, N.Y. TIMES, Feb. 23, 2016, at B1 ("Harnessing Ph.D.-toting mathematicians to the most powerful computers money can buy has become the accepted way for hedge funds and banks to get a trading edge these days . . . ").


\(^92\) Hemel & Ouellette, supra note 57. For example, the United States may receive prestige-based awards from developing solutions to problems like Ebola that primarily afflict developing countries.

\(^93\) See id. (manuscript at 37). Also note that coordination may be required even for some inframarginal goods: If multiple countries have independent incentives to invest in the same project, they may strategically choose to wait and hope the others will pursue the project first, much like the classic game-theory scenario of “chicken.” See id. (manuscript at 48).
As a final caveat, it is worth noting that even if internalization theory is an important overlooked benefit of Bayh–Dole patents, this does not mean that these patents are always welfare enhancing. As others have described at length, Bayh–Dole patents may have numerous costs, including increased deadweight loss, transaction costs, and negative changes in the practice and norms of science.94 These costs are particularly significant if one focuses on patenting on a global scale, where obtaining and enforcing patent rights is often prohibitively expensive.95 Even if the Bayh–Dole Act increases direct U.S. spending on scientific research, this benefit might not outweigh the costs of the associated patents. This is a specific example of a more general point about IP laws made by Brett Frischmann and Mark Lemley: “even where internalizing externalities increases incentives to invest, the social costs of relying on property rights to do so still may exceed the benefits.”96

Note, though, that Frischmann and Lemley’s argument is quite different from the “paying twice” critique of Bayh–Dole. The standard argument for patents is that patents allow for positive externalities to be internalized; the “paying twice” critique counters that the standard account is inapplicable in the context of publicly funded research because externalities have already been internalized. Frischmann and Lemley’s general point casts doubt on the standard argument at the first step; the internalization theory casts doubt on the “paying twice” critique at the second step. The two points are entirely consistent with one another: the social costs of relying on property rights sometimes exceed the benefits from internalizing positive externalities and Bayh–Dole sometimes allows the United States to internalize positive externalities from federally funded research. Of course, if the IP system cannot be justified on internalization grounds, then neither can Bayh–Dole be. Yet the standard account of patents—with all the caveats that come with it—applies to the Bayh–Dole context to a greater extent than exponents of the “paying twice” critique tend to acknowledge.

III. The Global Reach of U.S. University Patents

So far, we have considered how Bayh–Dole might serve to internalize foreign benefits in theory; here, we consider the global reach of Bayh–Dole patents in practice. As noted in the Introduction, access-to-medicines advocates

94 See Ayres & Ouellette, supra note 35 (reviewing the literature on these costs); Margo A. Bagley, Academic Discourse and Proprietary Rights: Putting Patents in Their Proper Place, 47 B.C. L. REV. 217 (2006); Rai, supra note 47. Note, though, that the enforcement of Bayh–Dole patents abroad does not necessarily lead to any deadweight loss, because governments in consumer states can choose to buy licenses from the patentee and then distribute the relevant knowledge good to domestic consumers at marginal cost. See Hemel & Ouellette, supra note 57 (manuscript at 42–44); Benjamin N. Roin, Intellectual Property Versus Prizes: Reframing the Debate, 81 U. CHI. L. REV. 998, 1012–13 (2014).

95 See, e.g., MARKETA TRIMBLE, GLOBAL PATENTS: LIMITS OF TRANSNATIONAL ENFORCEMENT 35 (2012) (explaining why “obtaining parallel patents is difficult and costly” and only feasible for large companies).

96 Frischmann & Lemley, supra note 91, at 258.
have raised concerns about the distributive impact university patents on consumers in low-income countries.\footnote{Supra notes 10–13 and accompanying text.} For example, in advocating for an “equitable access license” for free use of university technologies in low- and middle-income countries, Amy Kapczynski, Samantha Chaifetz, Zachary Katz, and Yochai Benkler have stressed the grave human cost that such patents might have:

Perhaps patent-based costs account for only a few percent of preventable deaths from diseases in low- and middle-income countries. Perhaps open access to university-based technologies would only avert a fraction of these deaths and free up a fraction of the research tools relevant to neglected diseases. But preventing even a fraction of one percent of deaths in low- and middle-income countries would translate into saving tens of thousands of lives every year.\footnote{Kapczynski et al., supra note 13, at 1114.}

A high-profile example of a university patent that limited access to an essential medicine abroad is Yale’s South African patent on the AIDS medicine stavudine (or d4T).\footnote{Id. at 1034.} When Yale and its exclusive licensee decided to permit the sale of generic stavudine in South Africa, the price dropped from $1600 to $55 per year.\footnote{Id.; see Ouellette, supra note 16, at 309.} There is surprisingly little data, however, about the extent to which universities in fact seek patents abroad. Was it anomalous for Yale to patent stavudine in South Africa, or was it in line with typical university patent acquisition? Kapczynski et al. lamented that “there is no comprehensive data and no easy way to determine patent status in the majority of [low- or middle-income] countries.”\footnote{Kapczynski et al., supra note 13, at 1083.}

Bhaven Sampat took a first cut at this problem in his 2009 study of the academic patents on new drugs approved by the FDA between 1988 and 2005.\footnote{Sampat, supra note 12. His definition of “academic” includes universities, nonprofit research institutes, government laboratories, and research hospitals, id. at 11, all of which are subject to the same patent policy considerations we are discussing here.} By examining the U.S. patents that drug companies submit with their FDA applications, he found seventy-two drugs with at least one academic patent and ninety-six academic patents in total (due to multiple patents per drug).\footnote{Id. at 11.} Using an international patent search tool known as the Derwent Innovation Index, he concluded that eighteen of these ninety-six patents had counterparts in low- and middle-income countries—a group that included India, Brazil, and China.\footnote{Id. at 11, 14–15. The full list of countries was India, Kenya, North Korea, Mongolia, Malawi, Nigeria, Vietnam, Zambia, Zimbabwe, Bulgaria, Brazil, China, Colombia, Cuba, Egypt, Indonesia, Iraq, Iran, Jordan, Sri Lanka, Morocco, Moldova, Peru, Philippines, Thailand, Tunisia, and the Ukranian Republic. Id. at 11.}
While useful for showing that stavudine is not unique, Sampat’s study is limited to a small set of pharmaceutical inventions, it does not specify which developing countries those inventions were patented in or whether there were any patents in low-income countries (as opposed to middle-income countries), and it does not discuss patenting in any high-income foreign countries. We are unaware of any other public data on the extent to which U.S. universities have sought patents abroad.

To shed light on this question, we obtained data from the Economics and Statistics Division of the World Intellectual Property Organization (WIPO), an agency of the United Nations that administers IP treaties and serves as a reference source for IP information. WIPO provided a dataset of patent filings by U.S. university applicants based on the PATSTAT database, which is compiled by the European Patent Office (EPO) and which combines data from over one hundred national and regional patent offices. The data contains counts of the number of distinct patent “families” filed at each patent office from 2000 to 2011. A patent family is a group of patents—in the same or different countries—that protect a single invention. For example, Boston University sought to protect its blue LED invention with multiple patent applications in each of the United States, Japan, and the European Patent Office, but in WIPO’s data these would count as one filing for this family in each of those three jurisdictions. If Boston University had instead only sought to patent this invention in the United States, its three U.S. patents on this invention would count as one patent family filed only in the United States. Families are counted if any of the applicants are U.S. universities as coded by WIPO; the data thus includes filings made by U.S. universities in conjunction with other entities such as for-profit firms.

Table 1 shows the number of patent families filed by U.S. universities from 2000 to 2011 in different jurisdictions, with countries sorted by World

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107 The year of filing is the date when the first member of the patent family was filed at any office. For example, if the first filing for a patent family was at the EPO in 2010, then a 2011 filing in that family at India’s patent office would appear as a 2010 filing in India. 2011 is the last year of the dataset because it is the last year for which subsequent filings dating to that year should be complete.


109 See Highly Insulating Monocrystalline Gallium Nitride Thin Films, GOOGLE PATENTS, https://patents.google.com/patent/US5686738A (last visited Mar. 7, 2016) (containing links under “Also published as” to a number of applications with the same “priority” or first filing date; supra notes 48–49 and accompanying text (discussing this invention).

110 The blue LED patents are not in WIPO’s data because the priority date was 1991.

Bank income groups.\textsuperscript{112} Next to each country (or regional office) are three numbers: the raw number of patent families filed by U.S. universities, and that number expressed as a percentage of the filings at each of the U.S. Patent and Trademark Office (USPTO) and the EPO. It seems unlikely that many U.S. universities filed patents abroad without seeking to patent the same invention domestically, so it is reasonable to conclude, for example, that about one-third of patents filed domestically were also filed at the EPO, and about one-quarter were also filed in Canada. Note that counting patent filings for Europe is complicated because applicants may file patents either with directly with a country’s national patent office or with the European Patent Office, which simplifies application procedures for thirty-eight member states, some of which joined mid-way through the period studied.\textsuperscript{113} We present the national filing numbers for those European countries with the largest numbers of filings.

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</tr>
<tr>
<td>Russian Federation</td>
<td>600</td>
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</tr>
<tr>
<td>Hong Kong</td>
<td>450</td>
<td>1.2%</td>
<td>3.4%</td>
</tr>
</tbody>
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\textsuperscript{113} See Member states of the European Patent Organisation, EUROPEAN PATENT OFFICE, https://www.epo.org/about-us/organisation/member-states.html (last visited Mar. 17, 2016) (listing the following member states and their dates of accession: Albania, Austria, Belgium, Bulgaria, Switzerland, Cyprus, Czech Republic, Germany, Denmark, Estonia, Spain, Finland, France, United Kingdom, Greece, Croatia, Hungary, Ireland, Iceland, Italy, Liechtenstein, Lithuania, Luxembourg, Latvia, Monaco, Former Yugoslav Republic of Macedon, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Sweden, Slovenia, Slovakia, San Marino, Turkey).
<table>
<thead>
<tr>
<th>Country</th>
<th>Filings</th>
<th>% of US</th>
<th>% of EPO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Singapore</td>
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<tr>
<td>Argentina</td>
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<td>1.7%</td>
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<tr>
<td>Uruguay</td>
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<td>0.1%</td>
</tr>
<tr>
<td>Chile</td>
<td>12</td>
<td>0.0%</td>
<td>0.1%</td>
</tr>
<tr>
<td>Estonia</td>
<td>6</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Luxembourg</td>
<td>2</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Portugal</td>
<td>2</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>GCC Member States (<em>Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates</em>)</td>
<td>2</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
</tbody>
</table>

**Upper-Middle Income Economies**

<table>
<thead>
<tr>
<th>Country</th>
<th>Filings</th>
<th>% of US</th>
<th>% of EPO</th>
</tr>
</thead>
<tbody>
<tr>
<td>China</td>
<td>5,675</td>
<td>15.4%</td>
<td>43.1%</td>
</tr>
<tr>
<td>Mexico</td>
<td>1,765</td>
<td>4.8%</td>
<td>13.4%</td>
</tr>
<tr>
<td>Brazil</td>
<td>1,128</td>
<td>3.1%</td>
<td>8.6%</td>
</tr>
<tr>
<td>South Africa</td>
<td>523</td>
<td>1.4%</td>
<td>4.0%</td>
</tr>
<tr>
<td>Eurasian Patent Organization (<em>Turkmenistan, Belarus, Tajikistan, Russian Federation, Kazakhstan, Azerbaijan, Kyrgyz, Armenia, Moldova</em>)</td>
<td>215</td>
<td>0.6%</td>
<td>1.6%</td>
</tr>
<tr>
<td>Malaysia</td>
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<td>0.3%</td>
<td>0.9%</td>
</tr>
<tr>
<td>Peru</td>
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<td>0.4%</td>
</tr>
<tr>
<td>Colombia</td>
<td>46</td>
<td>0.1%</td>
<td>0.3%</td>
</tr>
<tr>
<td>Costa Rica</td>
<td>39</td>
<td>0.1%</td>
<td>0.3%</td>
</tr>
<tr>
<td>Ecuador</td>
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<td>0.2%</td>
</tr>
<tr>
<td>Romania</td>
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<td>0.1%</td>
</tr>
<tr>
<td>Panama</td>
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<td>0.1%</td>
</tr>
<tr>
<td>Dominican Republic</td>
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<td>0.0%</td>
</tr>
<tr>
<td>Cuba</td>
<td>4</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Jordan</td>
<td>3</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Tunisia</td>
<td>3</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Belize</td>
<td>2</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Thailand</td>
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<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Algeria</td>
<td>1</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Montenegro</td>
<td>1</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
</tbody>
</table>

**Lower-Middle Income Economies**

<table>
<thead>
<tr>
<th>Country</th>
<th>Filings</th>
<th>% of US</th>
<th>% of EPO</th>
</tr>
</thead>
<tbody>
<tr>
<td>India</td>
<td>2,483</td>
<td>6.7%</td>
<td>18.8%</td>
</tr>
<tr>
<td>Philippines</td>
<td>216</td>
<td>0.6%</td>
<td>1.6%</td>
</tr>
<tr>
<td>Ukraine</td>
<td>86</td>
<td>0.2%</td>
<td>0.7%</td>
</tr>
<tr>
<td>Vietnam</td>
<td>50</td>
<td>0.1%</td>
<td>0.4%</td>
</tr>
<tr>
<td>Egypt</td>
<td>39</td>
<td>0.1%</td>
<td>0.3%</td>
</tr>
<tr>
<td>Georgia</td>
<td>29</td>
<td>0.1%</td>
<td>0.2%</td>
</tr>
<tr>
<td>Morocco</td>
<td>27</td>
<td>0.1%</td>
<td>0.2%</td>
</tr>
<tr>
<td>Honduras</td>
<td>6</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Uzbekistan</td>
<td>6</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
</tbody>
</table>
At least three important observations can be drawn from this data:

First, the majority of inventions at U.S. universities—perhaps as many as two-thirds—do not appear to be patented abroad. Why wouldn’t a university always file worldwide patents? The main obstacle is cost. As one benchmark, Stanford’s technology transfer office explains that comprehensive foreign patent protection can cost over $200,000 due to legal, translation, and filing fees, and that “under normal circumstances” it does not obtain foreign protection “unless a licensee is reimbursing patent costs.”114 Foreign patents can also be more difficult to obtain: the United States gives inventors a one-year grace period to file a patent application after disclosing their inventions (such as at a conference or in a paper),115 but such a disclosure will destroy patentability in most other countries.116

Second, although U.S. universities do not seek foreign patents on a majority of their patentable inventions, they do file many patent applications abroad. The sum of all foreign patent families sought over this twelve-year period is 72,370—almost twice the 36,943 patent families sought in the United States. This does not mean that more inventions are patented by U.S. universities abroad than at home; rather, it means that for each patent family filed by a university in the United States, the university files—on average—a family in two more jurisdictions.

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Third, perhaps unsurprisingly, the number of patents filed in a given foreign jurisdiction correlates strongly with the size and strength of the local economy. U.S. universities sought 59,750 patent families in high-income economies, 9,616 in upper-middle income economies, 2,952 in lower-middle income economies, and only 52 in low-income economies. And almost all of the patenting outside of high-income economies is in four large upper-middle-income economies—China (5,675), Mexico (1,765), Brazil (1,128), and South Africa (523)—and one large lower-middle-income economy, India (2,483). No other country outside the high-income world received more than 1% of USPTO filings. While these five countries have significant poverty, they also have large economies: China has the second-highest gross national income in the world, India is seventh, Brazil is eighth, Mexico is fifteenth, and South Africa is thirty-first.\footnote{GNI, Atlas Method (Current US$), World Bank, http://data.worldbank.org/indicator/NY.GNP.ATLS.CD (last visited Aug. 29, 2016) (sorting by 2015 data).}

These patent applications in middle- and low-income countries are worthy of further study, both to examine universities’ rationales for seeking patents in these jurisdictions and to determine the extent to which these patents are limiting access to poor consumers.\footnote{It is not necessarily true that such patents limit access; in theory, they could encourage investment in local development costs. See generally Keith E. Maskus, Intellectual Property Rights in the Global Economy 136–41 (2000).} But while developing-world patents have been the focus of the literature on Bayh–Dole’s impact abroad, note that most foreign patents sought by U.S. universities are in other rich-world countries. More patent families were filed in each of Europe, Canada, Japan, and Australia than in the middle-income countries discussed above. Given that the former economies more closely mirror that of the United States, we think most readers will find it less objectionable on distributional grounds—and perhaps distributionally desirable—to ask consumers in these jurisdictions to pay for some of the benefits they receive from technologies funded by U.S. taxpayers.

With a more complete picture of how often universities seek patent protection in foreign jurisdictions, we turn in Part IV to the implications of these patents for the debate over Bayh–Dole regimes.

\section{IV. Rethinking Bayh–Dole Theory and Practice}

What does internalization theory mean for the Bayh–Dole Act? As noted above, this was not the theory under which Bayh–Dole was enacted.\footnote{See supra notes 38–39.} And like commercialization theory, internalization theory cannot justify the Act’s present scope, even under the most optimistic account. Recognizing the potential internalization benefit, however, has at least four payoffs for the ongoing debates over Bayh–Dole patents. This Part explains how internalization theory might affect discussions of (1) Bayh–Dole Act reform in
the United States; (2) whether other countries should adopt similar frameworks; (3) how international trade law should view these regimes; and (4) whether Bayh–Dole regimes are problematic from the perspective of global distributive justice.

First, to evaluate the impact of internalization theory on the Bayh–Dole reform debate in the United States, consider those patents that cannot be justified under commercialization theory. We have argued that an overlooked benefit of allowing U.S. research institutions to patent inventions stemming from federal funding is that such patents allow the United States to internalize some of the benefits that foreign consumers have received from these inventions. But note that this benefit applies only to patents filed abroad—it does nothing to justify the U.S. patents filed by these institutions, or the associated lawsuits. Perhaps the clearest implication of the internalization theory is that in some cases, U.S. lawmakers might consider limiting Bayh–Dole’s scope to foreign patents. To be sure, this kind of split Bayh–Dole implementation might raise practical challenges if arbitrageurs can buy goods in the United States at marginal cost and then sell them abroad to undercut the higher prices of patented goods. In most high-income countries, however, patentees can block parallel imports, thus limiting the extent of arbitrage.

A Bayh–Dole regime that applied only to foreign patenting would not prevent some consumers from paying twice—specifically, U.S. citizens who pay federal income taxes but live overseas. This category encompasses several million people (just how many million is not clear). Most readers will agree that this problem—while real—is not so serious as to undermine the case for a modified Bayh–Dole regime that focuses on foreign patents. Insofar as U.S. citizens living abroad are unfairly disadvantaged, the problem could be corrected through tax law (e.g., a deduction or credit for out-of-pocket spending on patented products generated by federally funded research and purchased abroad). Our intuition is that the administrative costs of such a fix would be high relative to whatever fairness benefits it might bring. In any

120 Cf. Ayres & Ouellette, supra note 35 (noting that if the internalization theory advocated here is correct, then the “market test” proposal might be limited to domestic patents).


event, the question of how to treat U.S. taxpayers living overseas strikes us as a second-order consideration in the broader Bayh–Dole debate.

Second, although we have framed the internalization theory as a justification for the U.S. Bayh–Dole Act, a similar argument applies to other countries considering the adoption of Bayh–Dole-like regimes. Just as the Bayh–Dole Act allows the United States to internalize some of the benefits to consumers in other countries resulting from U.S. taxpayer-funded research, Bayh–Dole analogues abroad allow taxpayers in other countries that provide public support for the production of global knowledge goods to internalize some of the benefits that their investment yields for U.S. consumers. As we have emphasized elsewhere, the international IP regime provides a framework for allocating the cost of knowledge good production across borders. Domestic laws that allow for the patenting of government-financed research are one element within that larger framework.

Indeed, the internalization theory seems to apply with even more force in other high-income countries with smaller populations than the United States, such as Norway or Switzerland. Although these two countries have among the highest gross national incomes per capita in the world, they each represent less than one percent of cumulative global income. The United States, in contrast, produces nearly a quarter of global income, so far more of the global benefit of any investment in knowledge production is already internalized. If Norway and Switzerland invested in direct science funding only up to the point that the marginal cost equaled the marginal benefit to their own citizens—without any ability to internalize benefits to foreign consumers from their science investments—then these countries would have weak incentives to become major players in global knowledge good production. Bayh–Dole-like regimes in small rich-world countries may play a significant role in bringing these countries’ science investments closer to the global optimum.

Third, even though domestic manufacture provisions might seem like the result of protectionist rent-seeking by U.S. industry, the overlooked benefit we have highlighted might inform how such provisions are viewed under international trade law. The domestic manufacture provisions of the U.S. Bayh–Dole Act were challenged by Brazil in 2001 as a violation of various requirements of treaties administered by the World Trade Organization (WTO). Brazil ultimately suspended this challenge as part of settlement.

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125 See Hemel & Ouellette, *supra* note 57 (manuscript at 37–42).


128 See *id*.

that the WTO never had an opportunity to evaluate the merits of Brazil’s claims.\textsuperscript{130} Evaluating the legal status of domestic manufacture provisions under international trade law is beyond the scope of this piece; we simply note that as a practical matter, domestic manufacture provisions may serve as mechanisms for benefit internalization rather than pure protectionism.

Finally, we suggest that our analysis highlights an overlooked distributive implication of the Bayh–Dole regime. The argument against Bayh–Dole from a global distributive justice perspective is that Bayh–Dole enriches already well-endowed U.S. universities at the expense of foreign consumers—including consumers in the very least developed countries. It is easy to see why one might object to a regime that results in transfers from consumers in Burundi and Malawi to the coffers of Stanford and MIT. Yet the critique of Bayh–Dole on global distributive justice grounds is not as straightforward as it might initially seem. In a hypothetical scenario in which Congress repealed or curtailed Bayh–Dole and required universities to license the products of federally funded research on a nonexclusive basis worldwide, consumers in Burundi and Malawi would benefit—but so too would their counterparts in Luxembourg and Norway (countries in which per capita gross domestic product is considerably higher than in the United States).\textsuperscript{131} Repealing Bayh–Dole is an extremely scattershot way of addressing global wealth inequality, as the benefits would flow not only to consumers in the world’s poorest countries but also to consumers in the world’s richest.

We are sympathetic to the argument that the United States should redistribute more of its wealth to the world’s poor. We are less persuaded that this argument counts as a strike against Bayh–Dole. If the motivation for curtailing Bayh–Dole is that the United States should redistribute more of its wealth to the world’s poor, then the more logical conclusion is that the United States should preserve Bayh–Dole and redistribute more of its wealth to the world’s poor via foreign aid. To be sure, advocates of increased foreign aid face considerable political obstacles. But so too do critics of Bayh–Dole. The relevant question is whether, in a scenario in which the political will for Bayh–Dole repeal or significant scale-back exists, the political will for retention of Bayh–Dole plus a substantial increase in the foreign aid budget would also exist. Note that the benefits of Bayh–Dole are relatively concentrated (with the pharmaceutical industry and the higher education sector being the most notable winners) while the costs of foreign aid spending are diffuse (spread across all taxpayers). Standard public choice logic would suggest that repealing or significantly scaling back Bayh–Dole may be politically more difficult than keeping Bayh–Dole and increasing foreign aid. Advocates of global wealth redistribution who now target Bayh–Dole might consider resetting their sights.

\textsuperscript{130} See Keith E. Maskus, \textit{Trade-Related Intellectual Property Rights}, in \textit{THE OXFORD HANDBOOK ON THE WORLD TRADE ORGANIZATION} 408 (Amrita Narlikar et al. eds., 2012) (noting that the United States withdrew its WTO complaint about Brazil’s local-working requirement based in part on Brazil’s agreement “to suspend its counter-dispute against the United States” regarding the Bayh–Dole Act’s domestic manufacture provision).

\textsuperscript{131} For arguments that the Bayh–Dole Act should be repealed, see supra note 8.
For these reasons, advocates of global wealth redistribution (and we consider ourselves members of this camp) might consider the possibility of pursuing redistributive objectives within the Bayh–Dole framework rather than arguing for Bayh–Dole repeal or reform on (shaky) distributional grounds. One possibility is to allow federal government grantees to pursue patent protection in other rich-world countries but not in the least developed ones. In fact, such a change might not amount to a dramatic deviation from the status quo. As noted above, U.S. universities are much more likely to seek patent protection under the laws of industrialized nations than under the laws of the least developed countries.

Additionally, universities (perhaps spurred by access-focused activists within university communities) may be able to use their patents as leverage to help rather than hurt consumers in poorest countries. Over one hundred universities and other nonprofit institutions have declared that “responsible [patent] licensing includes consideration of the needs of people in developing countries and members of other underserved populations,” and a smaller group has more recently articulated specific ways in which they are “committed to implementing effective technology transfer strategies that promote the availability of health-related technologies in developing countries.” Access-to-medicine objectives might be better achieved by having universities take an active role in the allocation of knowledge goods across borders, rather than by having universities exit the arena entirely and allow patents to become the province of the private sector alone.

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132 For example, the group Universities Allied for Essential Medicines issues an annual report card that grades universities on their global health impact, including their patent policies. University Report Card: Global Equity & Biomedical Research, UNIV. ALLIED FOR ESSENTIAL MEDS., http://globalhealthgrades.org (last visited Aug. 29, 2016).


Conclusion

Our contribution here is both theoretical and empirical. In theory, the Bayh–Dole Act and its overseas analogues can allow nation-states that produce global knowledge goods to capture a share of the benefits that their investments yield for consumers abroad. This feature plausibly encourages further public spending on scientific research, though we are the first to acknowledge that this effect is as yet unproven. What we can and do show here is that U.S. universities file a significant number of Bayh–Dole patents abroad—primarily in high-income countries and a handful of upper-middle-income countries, though rarely in lower-middle-income countries aside from India and almost never in the lowest-income countries. The primary effect of the Bayh–Dole Act beyond the United States’ borders is to allow U.S. taxpayer-funded research institutions to claim a share of the benefits that their efforts yield for consumers elsewhere in the rich world.

Does this account immunize Bayh–Dole from critics who charge that it forces U.S. consumers to “pay twice” for innovations and that the Act’s commercialization benefits are overstated? Certainly not. But it does suggest an added and as-yet-overlooked dimension to the Bayh–Dole debate. Our modest conclusion is that supporters and critics of Bayh–Dole alike ought to consider the Act’s role within the broader framework of policies allocating the costs of knowledge good production across borders. While it is too soon to say that Bayh–Dole deserves a place within that framework, we also think that the contrary conclusion is likewise premature.