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Viral Licensing: Ensuring the Public Interest When Taxpayers Fund Pharmaceutical Research

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VIRAL LICENSING: ENSURING THE PUBLIC INTEREST WHEN TAXPAYERS FUND PHARMACEUTICAL RESEARCH

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In recent years, the nation's drug development and delivery system has loomed in the forefront of pressing policy concerns. This piece suggests a relatively simple pathway that could provide opportunities for progress with aspects of the problem. Through the addition of a few choice provisions in their licensing agreements, research universities could improve consumer choices and access to the drugs developed with their government-funded research. Looking at the entire drug development system, universities play a complex set of roles. They are both the keepers of the academic flame and the stewards of public money. Beyond that, universities also may benefit from the substantial royalty dollars that flow when pharmaceutical companies purchase licenses. Like a well-oiled machine, universities should be able to smoothly and cleanly integrate these roles. Nevertheless, when the entire system is suffering shocks, these roles may come into conflict—particularly when the yearning for royalty green may be in tension with the responsible stewardship of largesse from the public purse. This piece suggests a way in which universities can be faithful to all of the disparate masters, serving as an elegant model of market efficiency and responsible action.

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With this perspective in mind, this piece suggests using university contracts as pathways for ensuring that innovations developed using federal funds sufficiently benefit those who have funded it. In brief, the paper identifies five potential ways in which contractual requirements could prove valuable and addresses navigating potential roadblocks to the implementation of these types of provisions.

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I. INTRODUCTION

In recent years, the United States' drug development and delivery system has loomed in the forefront of pressing policy concerns. Drug spending has risen to staggering levels and at a faster rate than any other aspect of health care spending, including hospitalization and nursing care.[1] Perverse incentives in the reimbursement system, including secretive rebates and clawbacks,[2] drive the system towards higher priced drugs, and drug companies increasingly find ways to delay generic

1. Aimee Picci, *Martin Skreheli-Style Drug Price Hikes are Everywhere*, CBS NEWS (Feb. 2, 2016), https://www.cbsnews.com/news/martin-shkreli-style-drug-price-hikes-are-everywhere/ (citing Robert Langreth & Rebecca Spalding, *Shkreli Was Right; Everyone's Hiking Drug Prices*, BLOOMBERG (Feb. 2, 2016), https://www.bloomberg.com/news/articles/2016-02-02/shkreli-not-alone-in-drug-price-spikes-as-skin-gel-soars-1-860) (noting that "[a]bout 20 of the top prescription drugs have at least quadrupled" their prices from 2014 to 2016); *see* Murray Aitken, *Understanding the Dynamics of Drug Expenditure*, QUINTILES IMS INSTITUTE, Sept. 2017, at 6-7 (noting that net drug expenditure in the U.S. increased from $335 per person in 1995 to $974 per person in 2015).

2. Instances in which Pharmacy Benefit Managers (PBMs) pay pharmacists too little to support wholesale acquisition of the drug or charge patients an inflated cost for drug. *See* ROBIN FELDMAN, DRUGS, MONEY, AND SECRET HANDSHAKES 49-50 (Cambridge 2019).

competitors and block competition.[3] Even some industry executives are beginning to acknowledge the problems and express discomfort with the current state of affairs.[4]

Despite calls for various solutions and arguments leveled against the proposals, the problem persists.[5] There is no magic bullet, and this piece does not claim to provide a remedy to all that ails the drug industry.

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3. *Id.* at 49-50 (noting that because of the perverse incentives in the reimbursement system, PBMs and drug companies can pressure insurance plans and pharmacies to pay more for drugs than they should); *id.* at 11 (showing that "invoice price increases on protected drug brands" have been "a significant driver of growth" in drug expenditures in the U.S. between 1996 and 2015); Aitken, *supra* note 1; FELDMAN, *supra* note 2; Jennifer L. Graber, *Excessive Pricing of Off-Patent Pharmaceutical: Hatch it or Ratchet?*, 92 N.Y.U. L. REV. 1146, 1180 (2017); *see* ALTARUM INST. CTR. FOR SUSTAINABLE HEALTH SPENDING, HEALTH SECTOR ECONOMIC INDICATORS: INSIGHTS FROM NATIONAL MONTHLY PRICE INDICES THROUGH JULY 2015 (Sept. 11, 2015), http://altarum.org/sites/default/files/uploaded-related-files/CSHS-Price-Brief_September_2015.pdf; *see also* Robin Feldman, *May Your Drug Price be Evergreen*, 5 J.L. & BIOSCIENCES 590, 601-04 (2018), https://doi.org/10.1093/jlb/lsy022 [hereinafter Feldman, *Evergreen*]; *see generally* Hannah Brennan, Amy Kapczynski, Christine H. Monahan & Zain Rizvi, *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J.L. & TECH. 275 (2016).

4. Caroline Chen & Robert Langreth, *Gilead Executive Says Pharmacy Benefit Managers Keep Prices High*, BLOOMBERG (Mar. 3, 2017), https://www.bloomberg.com/news/articles/2017-03-03/gilead-executive-says-pharmacy-benefit-managers-keep-prices-high (Gilead executive pointing to PBMs and saying that, "[i]f we just lowered the cost of Sovaldi from $85,000 to $50,000, every payer would rip up our contract"); *see, e.g.*, Anita Balakrishnan, *Mylan CEO on EpiPens: The System Rewards Higher Prices*, CNBC (Aug. 25, 2016) (Mylan CEO's saying, "No one's more frustrated than me . . . My frustration is, the list price is $608. There is a system. I laid out that there are four or five hands that the product touches, and companies that it goes through before it ever gets to that patient at the counter. Everyone should be frustrated. I'm hoping that this is an inflection point for this country.").

5. Thomas Sullivan, *Both Houses of Congress Investigating Prescription Drug Prices*, POL'Y & MED. (Nov. 6, 2015), https://www.policymed.com/2015/11/both-houses-of-congress-investigating-prescription-drug-prices.html (outlining the "bipartisan Senate investigation into pharmaceutical drug pricing"); Andrew Pollack, *Drug Prices Soar, Prompting Calls for Justification*, N.Y. TIMES (July 23, 2015), https://www.nytimes.com/2015/07/23/business/drug-companies-pushed-from-far-and-wide-to-explain-high-prices.html (discussing initiatives by various states to bring transparency and potentially even price controls); Joanna Shepherd, *The Prescription for Rising Drug Prices: Competition or Price Controls?*, 27 HEALTH MATRIX 315, 346 (2017) (noting that "[r]ecent surges in drug spending have provoked anger and prompted calls for reform" including demands for price controls); *see* Meg Tirrell & Dan Mangan, *Clinton Calls Drug Price Hike 'Outrageous,' Vows Plan*, CNBC (Sept. 21, 2015), https://www.cnbc.com/2015/09/21/clinton-calls-drug-price-hike-outrageous-vows-plan.html (noting Clinton's calls "to control the cost of skyrocketing prescription drugs"); *see also* Alison Kodjak, *One Way to Force Down Drug Prices: Have the U.S. Exercise Its Patent Rights*, NPR (Mar. 16, 2017), http://www.npr.org/sections/health-shot s/2017/03/16/520390026/one-way-to-force-down-drug-prices-have-the-u-s-exercise-its-patent-rights (describing Rep. Lloyd Doggett's calls for the government to exercise march-in rights); *see generally* ROBIN FELDMAN & EVAN FRONDORF, DRUG WARS: HOW BIG PHARMA RAISES PRICES AND KEEPS GENERICS OFF THE MARKET (Cambridge University Press 1st ed. 2017).

Rather, this piece suggests a pathway that could provide opportunities for progress with aspects of the problem. In contrast to the complex twists and turns of the Hatch-Waxman Act (for rapid entry of generic small molecule drugs), the convoluted byways of the Biosimilars Act (for entry of follow-on biologic drugs), and the truly impenetrable Affordable Care Act, this proposal is relatively simple. Through the addition of a few choice provisions in their licensing agreements, research universities could improve consumer choices and access to the drugs developed with their government-funded research.

Looking at the entire drug development system, universities play a complex set of roles. They are both the keepers of the academic flame and the stewards of public money.[6] Beyond that, universities also may benefit from the substantial royalty dollars that flow when pharmaceutical companies purchase licenses. Like a well-oiled machine, universities should be able to smoothly and cleanly integrate these roles. Nevertheless, when the entire system is suffering shocks, these roles may come into conflict—particularly when the yearning for royalty green may be in tension with the responsible stewardship of largesse from the public purse. This piece suggests a way in which universities can be faithful to all of the disparate masters, serving as an elegant model of market efficiency and responsible action.

II. FUNDING AND RESEARCH IN DRUG DEVELOPMENT

The notion begins at the cradle of pharmaceutical innovation. As a general matter, pharmaceutical companies are rather unsuccessful at developing breakthrough drugs, and most pharmaceutical innovation happens at research universities or smaller companies.[7] Moreover, a substantial amount of university research is subsidized by the government, with the federal government regularly providing grants to graduate programs at universities working on drug development or

6. Andrew K. Cordova & Robin Feldman, *Universities and Patent Demands*, 2 J.L. & BIOSCIENCES 717, 718 (2015).

7. Jonathan D. Rockoff, *Big Pharma, Short on Blockbusters, Outsources the Science*, WALL ST. J. (Dec. 6, 2016), https://www.wsj.com/articles/big-pharma-short-on-blockbusters-outsources-the-science-1481042583 (citing a Boston Consulting Group study stating that about 70 percent of drug industry's new sales in 2016 come from drugs originated in small companies, up from 30 percent in 1990); *see* Robert Kneller, *The importance of new companies for drug discovery: origins of a decade of new drugs*, NATURE REVIEWS DRUG DISCOVERIES 9, 867, 869 (2010) (comprehensive study of 252 drugs approved by the FDA between 1998 and 2007 stating that of drugs that were considered "scientifically novel," only 44% were from pharmaceutical companies, while 25% were from biotech companies and 31% were from universities); *see also* Aaron S. Kesselheim et al., *The Roles of Academia, Rare Diseases, and Repurposing in the Development of the Most Transformative Drugs*, 34 HEALTH AFFAIRS 286 (2015) (study finding that more than half of 26 transformative drugs approved by the 1984 and 2009 had origins in publicly funded research).

researching tools that aid in the drug development process.[8] Although the amount of federal funding has declined since a high in 2008, the federal government provided $24.6 billion in university research grants in 2013.[9] Meanwhile, universities also receive substantial funding from federal financial aid programs, like Pell Grants, as well as additional financial aid grants and general-purpose appropriations from state budgets.[10] In 2013, universities received over $120 billion in non-research specific funding from federal and state budgets.[11]

In addition to the benefit of public largesse through direct funding, universities also enjoy a special advantage benefit for any patents granted as a result of their research efforts. Since 2011, those who are accused of infringing a patent that originated through university research do not get the benefit of a "prior use" defense, in contrast to those accused of violating any other patents.[12] These funding and assertion benefits provide enormous value to universities, presumably with the hope that their research activities will redound to the benefit of the taxpayers who are funding this exploration.

All this being said, money from licensing remains a small part of overall funding, and in most cases it barely covers the cost of operating a tech transfer office.[13] According to a study from the Brookings Institute, at 13% of research schools the one-third of licensing fees that go to a university's general fund barely cover the cost of operating a tech

8. Stephen V. Frye et al., *Academic Drug Discovery in the US: A Survey and Analysis*, 10 NATURE REVS. DRUG DISCOVERY 409, 410 (2011) (stating that in a 2011 survey of Academic Drug Discovery centers, federal grants or contracts accounted for an average of 41% of total funding, by far the largest source of financial support for ADD centers); *see, e.g.*, Arti K. Rai & Bhaven N. Sampat, *Accountability in Patenting of Federally Funded Research*, 30 NATURE BIOTECHNOLOGY 953 (2012); *see also* NIH, NAT'L CANCER INST., PRECLINICAL THERAPEUTIC GRANTS BRANCH, (2018) (the NIH research grants arm that supports preclinical anticancer drug discovery and treatment strategies).

9. THE PEW CHARITABLE TRUSTS, FEDERAL AND STATE FUNDING OF HIGHER EDUCATION 3 (2015).

10. *Id.* at 3-4.

11. *Id.* Many medicines currently on our shelves began with government funded research. In fact, research funded by the NIH was associated with every one of the 210 new drugs approved by the FDA between 2010 and 2016. Pharmaceutical companies perform critical work in testing, approving, commercializing, and mass producing the innovation, the taxpayers have been there from the start. *See* Ekaterina Cleary et al., *Contribution of NIH funding to new drug approvals 2010-2016*, 115 PROC. NAT. ACAD. SCI. 2329 (2018).

12. *See* Arti K. Rai & Bhaven N. Sampat, *Accountability in Patenting of Federally Funded Research*, 30 NATURE BIOTECHNOLOGY 953, 953-54 (2012).

13. Walter D. Valdivia, *University Startups: Critical for Improving Technology Transfer*, CTR. FOR TECH. INNOVATION AT BROOKINGS (2013).

transfer office.[14] Moreover, the great majority of research schools fail to turn patents into an income stream.[15]

The system's design allows, and even encourages, universities to sell or license the intellectual property rights in their inventions to pharmaceutical companies.[16] After all, if the goal is to translate basic research into products for the public good, someone must actually do the translation, and universities are in the business of shaping minds, rather than producing products. As a result, the companies that develop these products ultimately benefit from taxpayer supported research funding as well, yet it is all part of a system intended to stimulate innovation and redound to the benefit of the public.

As the system winds its way from federal funds to private products, the government does not relinquish all its interests. University patents derived from government-funded research must include "government interest" statements as a result of information provided by the patent applicant.[17] Such statements provide notice that the patented invention was funded, at least in part, by federal dollars and that the government retains a so-called "march-in right," a rarely used patent provision allowing the government to ignore patent rights and grant a license to competitors to produce the drug.[18] Research has shown, however, that such notice and reporting are woefully incomplete, and these statements are frequently omitted.[19]

Although formal mention of the trailing government interest may slide into the dustbin, the public origin of these inventions remains. These innovations are imbued with the public interest—not just because they benefit from the government's grant of a patent, but more importantly, because their existence flows directly from the largesse of the public treasury. With this perspective in mind, using university

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14. *See id.* at 9. The other two-thirds of the funding goes to the researchers and their academic departments. *See id.*

15. *Id.*; *see also* Brian J. Love, *Do University Patents Pay Off? Evidence From a Survey of University Investors in Computer Science and Engineering*, 16 YALE J. L. TECH. 285, 301-05 (2014).

16. Chester G. Moore, Comment, *Killing the Bayh-Dole Act's Golden Goose*, 8 TUL. J. TECH. & INTELL. PROP. 151, 155 (2006) (noting "extraordinary growth" in university technology transfer since the enactment of the Bayh-Dole Act); *see* Robin Feldman & Mark A. Lemley, *Do Patent Licensing Demands Mean Innovation?*, 101 IOWA L. REV. 137, 174-75 (2015) (describing the changes in university licensing since the passage of the 1980 Bayh-Dole Act); *see also* Mark A. Lemley, *The Surprising Resilience of the Patent System*, 95 TEX. L. REV. 1, 36 n.170 (2016).

17. *See* U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-99-242, TECHNOLOGY TRANSFER: REPORTING REQUIREMENTS FOR FEDERALLY SPONSORED INVENTIONS NEED REVISION 4-6, 20 (1999), https://www.gao.gov/archive/1999/rc99242.pdf.

18. *See* 35 U.S.C. § 203 (2019).

19. *See, e.g.*, Rai & Sampat, *supra* note 8, at 954-55.

contracts as a pathway for ensuring that innovations developed using federal funds sufficiently benefit those who have funded it.

III. TRANSFERS OF INTELLECTUAL PROPERTY FROM UNIVERSITIES TO PHARMA COMPANIES

Under the Bayh-Dole Act of the early 1980s, Congress granted universities the opportunity to patent and license the inventions created with federal research money, reversing a long-standing policy in which the federal government served as the vehicle for such activity.[20] Prior to the Act, the federal government had proven less than stellar at intellectual property licensing.[21] The goal of the Act was to stimulate licensing of federally funded inventions and encourage the translation of those inventions into products, all for the benefit of the public.[22] The Bayh-Dole Act has been stunningly successful, resulting in a wealth of productivity.[23] One should not underestimate the breathtaking innovations that have resulted from university research translated into pharmaceutical products.

Stimulated by the potential for licensing revenue, research universities maintain technology transfer offices, which typically control the use of technology developed by the university and develop strategies to monetize such technologies.[24] This may be accomplished through licensing agreements requiring the payment of royalties.[25] While universities sometimes publish sample licensing agreements for reference, the terms of these agreements may be the subject of lengthy negotiations.[26] Among other possibilities, these negotiations can expand geographical regions, provide for exclusivity, or simply adjust the percentage of the royalty paid to the relevant university. These

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20. COUNCIL ON GOVERNMENTAL RELATIONS THE BAYH-DOLE ACT: A GUIDE TO THE LAW AND IMPLEMENTING REGULATIONS 1-2 (1999).

21. *Id.*

22. *Id.* at 2.

23. COUNCIL ON GOVERNMENTAL RELATIONS, THE BAYH-DOLE ACT: A GUIDE TO THE LAW AND IMPLEMENTING REGULATIONS 2 (1999), https://www.cogr.edu/sites/default/files/The_Bayh-Dole_Act-__A_Guide_to_the_Law_and_Implementing_Regulations.pdf.

24. Donald S. Siegel & Mike Wright, *University Technology Transfer Offices, Licensing, and Start-Ups*, *in* THE CHICAGO HANDBOOK OF UNIVERSITY TECHNOLOGY TRANSFER AND ACADEMIC ENTREPRENEURSHIP 1-2 (Albert N. Link, Donald S. Siegel, & Mike Wright eds., 2014).

25. *Id.* at 5.

26. *See* Markus Perkmann & Joel West, *Open Science and Open Innovation: Sourcing Knowledge from Universities*, *in* THE CHICAGO HANDBOOK OF UNIVERSITY TECHNOLOGY TRANSFER AND ACADEMIC ENTREPRENEURSHIP 51 (Albert N. Link, Donald S. Siegel, & Mike Wright eds., 2014) ("As university policies on intellectual property have become increasingly ambitious, negotiations over terms and conditions of the contracts between firms and universities can become arduous and long-lasting.").

provisions create the mechanism by which government policy and the public interest can be protected.[27]

From an institutional competence perspective, universities occupy an unusually advantageous position. At the end of the day, drug companies are profit-making enterprises that will operate according to the incentive structures within the system. Drug companies who eschew the highest profit opportunities may get hammered by their shareholders.[28] As one drug company executive noted, "[e]verybody has to make money. Should it be surprising? We do serve different stakeholders."[29]

Although Congress could respond by altering the incentive structure to which drug companies are responding, legislators are plagued by their own incentive structures, which may drive the system away from effective change. These include, quite simply, the modern need for extensive campaign funds and the power of the pharmaceutical industry's contribution efforts.[30]

Unlike Congress, universities stand in an unusual position. Universities are in the business of education, attracting the optimal mix of students and the optimal mix of faculty.[31] Education is a complex business, with competing pressures and incentives. For example, recent empirical research suggests that although university licensing frequently leads to new products and innovation, when universities behave in a manner similar to patent trolls—entities who make no products but assert patents against product-producing companies— the results lack those

27. *See id.* at 47.

28. For example, when AbbVie released Mavyret, a lower cost hepatitis C treatment to compete with Gilead's notoriously expensive Sovaldi, market analysts anticipated AbbVie's revenue contribution from Mavyret to be comparatively limited. *See* Emma Court, *AbbVie's new, cheaper hepatitis C drug could launch the drug world's own Hunger Games,* MARKETWATCH (Aug. 6, 2017), https://www.marketwatch.com/story/abbvies-new-cheaper-hepatitis-c-drug-could-launch-the-drug-worlds-own-hunger-games-2017-08-04.

29. *See* Robin Feldman, *Pharma Companies Fight Behind-the-Scenes Wars on Generic Drugs*, STAT (June 16, 2017), https://www.statnews.com/2017/06/16/generic-drugs-biosimilars-pharma/.

30. In the 2018 election cycle, Pharmaceutical companies have contributed nearly $18 million in PAC Contributions to Federal Candidates. Pharmaceuticals/Health Products, OPENSECRETS.ORG, https://www.opensecrets.org/pacs/industry.php?txt=H04&cycle=2018 [last visited Oct. 6, 2019]; *see also* Jay Hancock et al, *Follow The Money: Drugmakers Deploy Political Cash As Prices And Anger Mount*, KAISER HEALTH NEWS (July 24, 2017), https://khn.org/news/follow-the-money-drugmakers-deploy-political-cash-as-prices-and-anger-mount/.

31. Madey v. Duke Univ., 307 F.3d 1351, 1362 (Fed. Cir. 2002) (University-sanctioned research projects "further the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects" as well as "increas[ing] the status of the institution and lur[ing] lucrative research grants, students and faculty.").

positive indicia.[32] Nevertheless, as noted above, licensing income remains a less significant aspect of a university's business, either from the perspective of economics or mission.[33]

IV. SUGGESTED CONTRACTUAL PROVISIONS

If licensing provides a potential pathway, what types of provisions could research universities use to help rationalize a system that is experiencing such stress? In designing any such provision, one must be careful not to chill the pharmaceutical industry's incentive for licensing drugs and research technology from universities.[34] Rather, any provision should be designed to help correct the market imperfections that are impeding a healthy and robust pharmaceutical market.

The suggestions below build on research by one of the authors, regarding the drivers of incentive distortions within the industry.[35] They provide examples of the way in which the university pathway could be utilized.

A. Transparency

Competition is the backbone of U.S. industry.[36] The intellectual property system suspends competition for a period of time, conferring exclusivity for the express purpose of allowing innovators to recoup their investments and thereby creating the incentive for innovation. Nevertheless, once that period of exclusivity ends, competition should reign freely. Competitors should enter the market—driving prices down—and innovators should have the incentive to return to the lab and look for new discoveries that will initiate, once again, the cycle of innovation and profiting from exclusion.[37] The reality, however, defies this model.

To begin with, markets thrive on information, which is a key raw material of competition. In the pharmaceutical industry, however, information about the true pricing of drugs remains scarce.[38] The true

32. Robin Feldman & Mark A. Lemley, *The Sound and Fury of Patent Activity*, 103 MINN. L. REV. 1793, 1794-96 (2019).

33. Robin Feldman & Mark A. Lemley, *Do Patent Licensing Demands Mean Innovation?*, 101 IOWA L. REV. 137, 174-75 (2015).

34. *See* Kneller, *supra* note 7.

35. FELDMAN, *supra* note 2; *see* Feldman, *Evergreen*, *supra* note 3.

36. *Treating the Opioid Epidemic: The State of Competition in the Markets for Addiction Medicine: Hearing Before the H. Subcomm. on Reg. Reform, Com. & Antitrust L.*, 114th Cong. 55 (2016) (statement of Robin C. Feldman, Harry and Lillian Hastings Professor of Law, Director of the Institute for Innovation Law, UC Hastings College of the Law).

37. *See, e.g.*, FELDMAN & FRONDORF, *supra* note 5, at 138.

38. See generally FELDMAN, *supra* note 2, for an expanded description of the role of transparency in market innovation that is described in this paragraph.

prices of medications are hidden within the layers of complex contracts between pharmaceutical companies and middle players. These contracts are treated as fiercely guarded secrets, such that health insurance companies and even governmental payors, do not have full access to the information. Buying blind is never a good circumstance for markets, let alone for fostering competition. Lack of information creates distortions in the market. It hobbles small and medium-sized competitors, who have less ability than powerful, entrenched players to gain access to this key competitive material. Secrecy also creates barriers for state and federal authorities trying to find and repair their own policies that may be distorting markets. Neither circumstance promotes a full flowering of the competitive ideal. In recognition of the importance of transparency, numerous states are contemplating approaches for mandating transparency in various aspects of the pharmaceutical industry.[39] Other bills have contemplated stronger regulation of the pharmaceutical industry, for example, through price controls.[40]

University licensing could complement and enhance transparency efforts. For example, a standard university license could require that those who use university technology must agree to provide open-pricing information: either for a) the drug being licensed; b) any drugs innovated through use of a tool, if pharmaceutical technology is being transferred; or c) any improvements made to the core technology or innovation being licensed. Such open pricing information has the potential to generate competitive pressures in the market that will ultimately be more successful than public price controls.[41] Thinking even more expansively, an enlightened and enterprising university could establish a system for publishing and tracking such information, providing a service to competition and to government agencies wishing to track the success of their funding efforts.

B. Behavioral Limitations

In addition to stipulating transparency, universities could include behavioral limitations within their licensing agreements—limitations that could enhance the public interest and combat other types of market imperfections embodied in the pharmaceutical and health care industry.

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39. *State Legislative Action to Lower Pharmaceutical Costs*, NAT'L ACAD. FOR ST. HEALTH POL'Y (updated June 22, 2018), https://nashp.org/state-legislative-action-on-pharmaceutical-prices/ (listing states with bills or passed transparency legislation including Colorado, Hawaii, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, New Hampshire, New York, Oregon, Pennsylvania, Rhode Island, Vermont, Washington, and Wisconsin).

40. *Id.* at 2.

41. *See* FELDMAN, *supra* note 2, at 96-97 (discussing the merits of price transparency).

For example, empirical and anecdotal evidence suggests that pharmaceutical companies have developed a practice of utilizing additional patents and other exclusivities to extend their monopoly period and hold off what is known as the "patent cliff"— that is, the point at which generics will join the market.[42] A recent study by one of the authors found that "[O]f the roughly 100 best-selling drugs, more than 70% extended their protection at least once, with almost 50% extending the protection cliff more than once."[43] Moreover, "[a]lmost 40% of all drugs available on the market created additional market barriers by adding patents or exclusivities."[44] Other studies have documented troubling behavior in filing citizen petitions at the Food and Drug Administration (FDA) and in refusing to provide samples to generic companies applying for approval.[45]

Finally, the patent market in general has been plagued by non-practicing entities (NPEs), who make no products but assert patents against product-producing companies.[46] NPEs are known colloquially as "patent trolls."[47] Academic works have described the way in which such entities exploit market imperfections to extract returns above the value of their patents.[48] A recent National Science Foundation (NSF)-funded

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42. *See generally* Robin Feldman, *May Your Drug Price be Evergreen*, J. OF L. & BIOSCIENCES 590 (Dec. 2018).

43. *Id.* at 597, 618.

44. *Id.*

45. Robin Feldman, Evan Frondorf, Andrew K. Cordova, & Connie Wang, *Empirical Evidence of Drug Pricing Games - A Citizen's Pathway Gone Astray*, 20 STAN. TECH. L. REV. 39, 44 (2017) (empirical study detailing the extent to which citizen petitions filed at the FDA are used as last-ditch efforts by pharmaceutical companies to hold off generic entry); Michael A. Carrier & Daryl Wander, *Citizen Petitions: An Empirical Study*, 34 CARDOZO L. REV. 249, 251-52 (2012) (empirical study finding that brand drug companies filed the majority of total citizen petitions filed between 2001-2010); *see* FELDMAN & FRONDORF, *supra* note 5, at 81-90 (discussing game-playing related to providing samples for generics).

46. *See* ROBIN FELDMAN, RETHINKING PATENT LAW 38 (2012) [hereinafter FELDMAN, RETHINKING].

47. Brenda Sandburg, *You May Not Have a Choice. Trolling for Dollars*, THE RECORDER (July 30, 2001).

48. Robin Feldman, *Intellectual Property Wrongs*, 18 STAN. J.L., BUS., & FIN. 250, 264 (2013); Robin Feldman, Tom Ewing & Sara Jeruss, *The AIA 500 Expanded: The Effects of Patent Monetization Entities*, 17 UCLA J.L. & TECH. 1, 1-2 (Fall 2013); Colleen V. Chien, *Of Trolls, Davids, Goliaths, and Kings: Narratives and Evidence in the Litigation of High-Tech Patents*, 87 N.C. L. REV. 1571, 1573-74 (2009); James E. Bessen, Jennifer Ford & Michael J. Meurer, *The Private and Social Costs of Patent Trolls*, REGULATION, 26 (Winter 2011-2012); Brian J. Love, *An Empirical Study of Patent Litigation Timing: Could A Patent Term Reduction Decimate Trolls Without Harming Innovators?*, 161 U. PENN. L. REV. 1309, 1310-12 (2013); Fiona M. Scott Morton & Carl Shapiro, *Strategic Patent Acquisitions*, 79 ANTITRUST L.J. 463, 482-83 (2014); *see* Tom Ewing & Robin Feldman, *The Giants Among Us*, 1 STAN. TECH. L. REV. 1, 1 (2012); *see also* Mark A. Lemley, *Are Universities Patent Trolls?*, 18 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 611, 629-30 (2008) (distinguishing between universities as non-practicing entities and trolls).

study by one of the authors demonstrated that patent assertion by NPEs rarely leads to new products or markers of innovation.[49] Most important, the study showed that when universities behave in a manner similar to patent trolls—engaging in ex post assertion of patents against product-producing companies—the results also lack markers of innovation.[50]

University licensing provisions could be crafted to discourage any of these types of behaviors. On a granular level, university licenses could be drafted to forbid particular behaviors, such as obtaining follow-on patents on the invention that make minor modifications, refusing to provide samples to generic hopefuls, or filing citizen petitions to block generic entry. On a broader level, universities could choose to follow the lead of companies that have entered into patent consortiums in which the relevant licenses allow use of the patent, but do not allow the licensees to bring any claims for patent infringement.[51] Other potential license provisions—not to mention university policies—could provide that the technology must be used for creating a product or service, rather than for monetization through an NPE. Measures such as these could help ensure that publicly funded research goes to the production of products for the benefit of society, rather than getting lost in weaponization.

Although the thrust of the transparency and behavioral suggestions is aimed at ensuring the public interest for publicly funded research, competition benefits the public in all circumstances. Thus, although most appropriate for publicly funded research, a forward-thinking university could choose to include these provisions in the licensing of any university technology. Such an approach would reflect the leadership role that universities play, not only in shaping young minds, but also in shaping the future.

V. IS PATENT MISUSE A ROADBLOCK?

While the United States justice system typically supports the rights of private parties to contract, there are limitations. For contracts involving patents, one such limitation is imposed by the doctrine of patent misuse. The doctrine of patent misuse forbids patent misuse, which occurs when a patent holder attempts to improperly extend the

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49. *See* Feldman & Lemley, *supra* note 16.

50. *See id.*

51. *See, e.g.*, Ina Fried, *Google Joins Stable of Tech Companies Licensing their LTE Patents as a Group*, RECODE (Apr. 9, 2015), https://www.recode.net/2015/4/9/11561306/google-joins-stable-of-tech-companies-licensing-their-lte-patents-as; *see also* U.S. DEP'T OF JUSTICE & F.T.C., ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY (1995) at 28 (in which pooling arrangements are looked upon favorably as potentially having "procompetitive benefits").

time and scope of its patent beyond that given by the grant.[52] As an equitable defense to a claim of patent infringement, the doctrine does not invalidate a patent.[53] Instead, it renders the patent unenforceable until the misuse ends and the effects of the behavior have dissipated.[54]

Patent misuse is a longstanding doctrine, originally invoked over a hundred years ago by infringement defendants who alleged that the patent holder was attempting to improperly extend its monopoly through the enforcement of its patent right.[55] Since that time, courts have repeatedly used the doctrine to keep a patent holder's patent power in check, particularly in the licensing context.[56] While patent misuse has been largely a judicially created defense, Congress has articulated five categories of conduct that do not constitute patent misuse.[57] Today, the types of contractual agreements that can constitute patent misuse include royalty payments beyond the scope or term of the patent,[58] grant back

52. *See, e.g.*, Blonder-Tongue Labs. Inc. v. Univ. of Ill. Found., 402 U.S. 313, 343-44 (1971).

53. *See, e.g.*, C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1372 (Fed. Cir. 1998) ("Patent misuse arises in equity, and a holding of misuse renders the patent unenforceable until the misuse is purged; it does not, of itself, invalidate the patent.").

54. *Id.*

55. Motion Picture Patents Co. v. Universal Film Mfg., 243 U.S. 502, 518 (1917) (refusing to enforce a patent where the licensees were obligated to require purchasers of the patented film projector to use only film made by patent owner: "[T]o enforce it would be to create a monopoly in the manufacture and use of moving picture films, wholly outside of the patent in suit and of the patent law as we have interpreted it.").

56. *See* FELDMAN, RETHINKING, *supra* note 46, at 137-42 (citing Motion Picture Patents Co. v. Universal Film Mfg., Co., 243 U.S. 514–18 (1917)).

57. *See* 35 U.S.C. § 271(d) (2019).

58. *See, e.g.*, Brulotte v. Thys Co., 379 U.S. 29, 30, 32 (1964) (held that an agreement licensing a patented hop-picking machine to farmers in exchange for royalties from hop crops harvested both before and after the patents' expiration dates was "unlawful *per se*" to the extent it provided for the payment of royalties that "accrue after the last of the patents incorporated into the machines had expired.").

arrangements,[59] price regulation,[60] and where market power is shown, tying arrangements[61] and compulsory packaging licensing.[62]

Here, most of the suggested Good Behavior provisions bear no resemblance in form or substance to these traditional forms of potential patent misuse conduct.[63] Yet arguably, the university would be using its patent to obtain something beyond the physical scope of its patent: the licensee's Good Behavior. Does a Good Behavior License run afoul of the patent misuse doctrine?

A. The Purpose of the Patent Misuse Doctrine

The primary purpose of the patent system is to promote the progress of science for the public benefit.[64] This purpose is longstanding; in 1945

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59. A grantback agreement or clause requires the licensee to give the patent holder rights in products that the licensee develops. While the Supreme Court has held that grantbacks are not per se unlawful, see Transparent-Wrap Machine Corp. v. Stokes & Smith Co., 329 U.S. 637, 648 (1947), where courts tend to find misuse where the grantback provision reaches too broadly. *See, e.g.*, Duplan Corp. v. Deering Milliken, Inc., 444 F. Supp. 648, 712-13 (D.S.C. 1977) (finding patent misuse where grantback provision would have included patents developed by the licensee that could not be characterized as a mere improvement on the licensor's invention), *aff'd in part, rev'd in part on other grounds*, 594 F.2d 979 (4th Cir. 1979); United States v. Imperial Chemical Indus., 105 F. Supp. 215, 232 (S.D.N.Y. 1952) (use of nonexclusive grantback license to perpetuate patent monopoly after patent expiration is unlawful); Transitron Elec. Corp. v. Hughes Aircraft Co., 487 F. Supp. 885, 893, 904-05 (D. Mass. 1980) (describing overbroad grantbacks as classic patent misuse and citing *Transparent-Wrap* for the proposition that a license provision requiring that the licensee grant back all its own patents to the licensor might constitute patent misuse), *aff'd* 649 F.2d 871 (1st Cir. 1981).

60. *See* Bauer & Cie v. O'Donnell, 229 U.S. 1, 8, 18 (1913) (stating that a patentee cannot fix the price at which a patented article lawfully purchased from the patentee could be resold as the original sale exhausted the patent right).

61. In a tying agreement, a patent holder requires licensees to buy unpatented goods (tie-in) or prevent licensees from using, producing or selling a competitor's product (tie-out). Historically, tie-in and tie-out arrangements have been held to be misuse *per se* based on an assumption that a patent confers market power on the patent holder. *See* Morton Salt Co. v. G.S. Suppiger Co., 314 U.S. 488, 493-94 (1942). In 1988, Congress amended the patent law to require a showing of market power in the relevant market for the patented product for tie-in arrangements to constitute misuse. *See* Patent Misuse Reform Act of 1988; *see also* Ill. Tool Works v. Independent Ink, 547 U.S. 28, 46 (2006) ("[I]n *all* cases involving a tying arrangement, the plaintiff must prove that the defendant has market power in the tying product.") (emphasis added).

62. Compulsory packaging licensing occurs when a licensee is forced to accept a broader package of unwanted patents in order to get the desired patent. In other words, the availability of the desired patent is conditioned on acceptance of unwanted patents. Such coercive packaging licensing can constitute patent misuse, and a showing of market power is required to establish misuse. *See* 35 U.S.C. § 271(d)(5); *see also* Zenith Radio Corp. v. Hazeltinen Research, Inc., 395 U.S. 100, 134, 139-40 (1969) (package license in which licensor refused to grant licenses to individual patents but insisted on granting license to any of the company's 500-odd patents could constitute patent misuse).

63. *See infra* notes 90-105 and accompanying text.

64. U.S. CONST., art. I, § 8.

the United States Supreme Court explained, "[t]he primary purpose of our patent system is not reward of the individual but the advancement of the arts and sciences. Its inducement is directed to disclosure of advances in knowledge which will be beneficial to society; it is not a certificate of merit, but an incentive to disclosure."[65]

To help achieve this ultimate goal, patent law confers on a patent holder a limited monopoly or right, for twenty years, to exclude others from "making, using, offering for sale, or selling [his] invention."[66] The extent of a patent holder's exclusionary right is limited by the definition of the invention and the twenty-year term.[67] In crafting the patent laws, Congress attempted to strike a balance "between fostering innovation and ensuring public access to discoveries."[68]

In this nation's history, Congress's choice to allow an inventor to temporarily exclude others is a decidedly utilitarian endeavor. We are not led down this pathway because of the inherent natural right of an inventor; we travel that road for the purpose of bringing benefit to all by incentivizing innovation. The effect of this choice is inherently anticompetitive, at least in the short term. In this anticompetitive grant, patents run smack up against antitrust law, which promotes competition more directly and in the short term.[69] In order to mark the boundary line between the two domains—patent and antitrust—the Supreme Court developed the doctrine of patent misuse in a series of cases, beginning with *Motion Picture Patents Co. v. Universal Film Mfg.*[70] The doctrine sought to prevent the use of patents as an end-run around antitrust laws.[71] Without the doctrine, patent holders were able to claim that any anticompetitive behavior was insulated by virtue of the presence of a patent in the transaction.[72] As the Supreme Court has explained, without the doctrine, "[p]rivate business would function as its own patent office and impose its own law upon its licensees."[73] The boundary drawn was

65. Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 330-31 (1945).

66. 35 U.S.C. § 154(a) (2019).

67. *See* Ethyl Gasoline Corp. v. United States, 309 U.S. 436, 456 (1940).

68. Kimble v. Marvel Entm't, 135 S. Ct. 2401, 2406-07 (2015).

69. *See generally* Herbert J. Hovenkamp, *The Intellectual Property-Antitrust Interface*, 3 ISSUES IN COMPETITION L. & POL'Y 1979, 1979 (2008); Robin Feldman, *Patent & Antitrust: Differing Shades of Meaning,* 13 VA. J.L. & TECH. 1 (2008).

70. 243 U.S. 502 (1917); *see also* Morton Salt v. G.S. Suppiger, 314 U.S. 488, 494 (1942), overruled on other grounds by Ill. Tool Works v. Indep. Ink, 547 U.S. 28 (2006); Leitch Mfg. v. Barber Co., 302 U.S. 458, 462-63 (1938); Carbice Corp. of Am. v. Am. Patents Dev. Corp., 283 U.S. 27, 33-35 (1931).

71. *See* FELDMAN, RETHINKING, *supra* note 46, at 137-42.

72. *Id.*

73. Mercoid Corp. v. Mid-Continent Inv. Co., 320 U.S. 661, 667 (1944).

patent misuse, defined as "attempts to broaden the physical or temporal scope of the patent monopoly."[74]

The Supreme Court has held repeatedly that patent misuse should be tested under patent law principles, not those of antitrust.[75] The notion is that when a patent holder acts within the scope of the patent, the law would stay the hand of antitrust; when a patent holder acts outside its scope, antitrust could have full rein.[76] The core of the notion was simply that patent law would be allowed to limit competition and foster exclusion in the service of the greater good of long-term innovation; secure in the knowledge that the suppression of competition would be limited in both time and scope.[77] In time, upon the patent's expiration, competition would come roaring back, bringing the promise of even greater follow on innovation and competition. After all, patents are not trade secrets. Society asks patent holders to pay for their temporary right to exclude by facilitating the next generation of innovation, those who can quickly knock the originator off its lofty perch.[78]

While certain behaviors might violate both patent law and antitrust law, the showing of an antitrust violation is not required to establish patent misuse.[79] The standards for patent misuse are different from the standards of an antitrust violation, which generally requires market power and a showing of anticompetitive harm.[80] Misuse is behavior determined by patent law.[81] The inquiry focuses on whether the behavior expands the time or scope of a patent in a manner that is inconsistent with patent law policy.[82]

B. The Proper Use of Patent Power: Restraining Competition Within

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74. Blonder-Tongue Labs. Inc. v. Univ. of Ill. Found., 402 U.S. 313, 343 (1971).

75. *See, e.g.*, Transparent-Wrap Machine Corp. v. Stokes & Smith Co., 329 U.S. 637, 641 (1947); *Morton Salt*, 314 U.S. at 493-94; Motion Picture Patents Co. v. Universal Film Mfg., 243 U.S. 502 (1917).

76. *See Carbice Corp.*, 283 U.S. at 34 n.4 (noting that an attempt to use a patent to unreasonably restrain commerce is both beyond the scope of the patent and a direct violation of the antitrust laws); *see also* Int'l Salt Co. v. United States, 332 U.S. 392 (1947); *Mercoid*, 320 U.S. at 661; United States v. Masonite Corp., 316 U.S. 265 (1942); Morton Salt Co. v. G.S. Suppiger Co., 314 U.S. 488 (1942).

77. *See* FELDMAN, RETHINKING, *supra* note 46, at 137-42.

78. *See generally* Robin Feldman, *The Inventor's Contribution,* 9 UCLA J.L. & TECH. 6 (2005).

79. *See, e.g.*, *Morton Salt*, 314 U.S. at 494 (held on public policy grounds that patent was unenforceable where patented machine was leased to lessees on condition that lessees use an unpatented product from patentee; it was "unnecessary" to determine whether an antitrust violation existed).

80. *Id.*

81. *See* FELDMAN, RETHINKING, *supra* note 46, at 137-42.

82. *See* Robin Feldman, *The Open Source Biotechnology Movement: Is It Patent Misuse?*, 6 MINN. J.L. SCI. & TECH. 117, 135 (Dec. 2004).

the Scope of the Patent Grant

As noted in the past, "[a]t a fundamental level, the intellectual property system exudes a deep faith in the power of competition. Competition may be held in abeyance, but those who receive the benefit of a patent or exclusivity must pay for that privilege by disclosing sufficient information such that competitors will be able to step into the market."[83]

Patent law's notion of competition, however, is quite different from that of antitrust law. Antitrust is concerned with the clash of the mighty. Only when a party holds sufficient market power does antitrust deign to enter.[84] In contrast, patent law is concerned with the proper use of the patent power—regardless of whether market power exists.[85] Patent misuse operates against bad behavior even by the mouse, not just by the mighty.

Nevertheless, the wrong tested with patent misuse is still related to the harms that antitrust law aims to combat.[86] For patent misuse, the question is whether the patent holder is using its precious and temporary right to exclude competitors beyond the power in the four corners of the grant.[87] In other words, is the patent holder leveraging its patent to restrain competition beyond what is permitted?[88]

Here, the patent holder who writes a Good Behavior License cannot be said to be restraining competition beyond what is permitted. Good Behavior provisions that require the licensee to cooperate or not impede in the generic entry process, for example, would have the procompetitive effect of accelerating the entry of generic pharmaceuticals into the marketplace, thereby simulating competition. Likewise, a provision discouraging the licensee from extending a patent cliff would stimulate competition because the period of exclusivity would not extend beyond the patent term. The artificial barrier to competition (the patent) would

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83. Robin Feldman, *May your drug price be evergreen*, J.L. & BIOSCIENCES 590, 592 (peer review) (2018).

84. *See* Robin Feldman, *Patent and Antitrust: Differing Shades of Meaning*, 13 VA. J.L. & TECH. 1, 10, 18-19 (2008) [hereinafter Feldman, *Differing Shades*].

85. *See generally* Robin Feldman, *The Insufficiency of Antitrust Analysis for Patent Misuse*, 55 HASTINGS L. J. 399 (2003) (describing patent misuse explaining that only in the case of a tying or compulsory packaging licensing claim does patent misuse require market power) [hereinafter Feldman, *Insufficiency*].

86. *See generally* Feldman, *Differing Shades*, *supra* note 84.

87. *See Zenith Radio*, 395 U.S. at 136 (discussing the limits of patent power, or "patent leverage," as when "the patentee seeks to extend the monopoly of his patent to derive a benefit not attributable to use of the patent's teachings."); *see also* Princo Corp. v. Int'l Trade Com'n, 616 F.3d 1318, 1331 (Fed. Cir. 2010) ("What patent misuse is about, in short, is 'patent leverage . . . .' ").

88. Feldman, *Differing Shades*, *supra* note 84, at 4.

be removed at an earlier time than it would have been had the patent cliff been extended.

Procompetitive effects also can result from a price transparency requirement. As previously discussed, the lack of information on the true price of drugs helps to suppress competition and creates distortions in the market. Through a price transparency provision, a Good Behavior License has the potential to generate competitive pressures that would likely result in lower prices for the end user. And, such provision would help to mitigate against increased prices that are a natural negative consequence of the monopoly granted through a patent.[89]

Far from attempting to restrain competition, the patent holder through a Good Behavior License is trying to allow competition to flourish and to ensure that those who use its invention do not over-enthusiastically or inappropriately constrain others. It is the essence of a pro-competitive provision.[90]

C. Does a Good Behavior License Support the Patent Policy of Innovation for the Public Good?

Innovation is the ultimate goal of our nation's patent system. This goal is enshrined in our Constitution that authorizes Congress the power to grant patents for a single purpose: "[t]o promote the Progress of Science and the useful Arts . . . ."[91] Innovation is desirable for many reasons, not the least of which is its ability to drive growth in the economy.

Patent misuse concerns the extension of patent rights that hamper innovation. The importance of innovation to the misuse doctrine is illustrated in *Transparent-Wrap Machine Corp. v. Stokes & Smith Co.*,[92] where the licensee granted the patent holder a royalty-free license to use the improvement. The Supreme Court held that although the grant back agreement extended the patent term, the agreement did not constitute patent misuse because it did not diminish the licensee's incentive to innovate.[93] Thus, while the behavior extended the scope of

89. Feldman, *Insufficiency*, *supra* note 85, at 433 (identifying higher prices charged by patent holders as a negative effect of patent system).

90. To the extent that a good behavior patent license can be analogized to an open source software license, the U.S. Court of Appeals for the Seventh Circuit has found that an open source license "does not restrain trade." *See* Wallace v. Int'l Bus. Machines Corp., 467 F.3d 1104, 1107 (7th Cir. 2006) (affirming dismissal of complaint alleging that defendants conspired to eliminate competition in the operating system market by making Linux, a free open-source software, in violation of the federal antitrust laws).

91. U.S. CONST., art. I, § 8.

92. *Transparent-Wrap Machine Corp.*, 329 U.S. at 638-40.

93. *Id.* at 645-46.

the patent, such behavior was not impermissible under patent law because it was not contrary to the public policy of innovation.

Ironically, the patent system produces some negative effects that may actually hinder innovation, the very process it is intended to foster and the reason for its existence. The Good Behavior provisions tend to lessen these negative effects and thereby promote innovation. Thus, even if a Good Behavior License were said to expand the scope of the patent, it seeks to support innovation and therefore, should not offend the patent misuse doctrine.

By the very nature of the twenty-year patent term, delays in new inventions are common, if temporary. "[D]elaying the point at which inventions enter the public domain reduces the benefits society may gain in terms of a foundation for future innovation."[94] Rather than delay the entry of inventions, Good Behavior provisions that require the licensee to cooperate in the generic application process or to forgo extending a patent cliff would accelerate the entry of new inventions, and thereby spur future innovation.

Another negative effect of the patent system is the over-proliferation of patent rights and the resulting "patent thicket."[95] A patent thicket has been defined as "a dense web of overlapping intellectual property rights that a company must hack its way through in order to . . . commercialize new technology."[96] Patent thickets disincentivize downstream inventors by burdening them with the hassle and attendant costs in obtaining or attempting to obtain permission from patent holders of overlapping rights.[97] In this manner, patent thickets frequently impede rather than promote innovation.[98]

Avoiding or minimizing patent thickets would help downstream inventors create new products and process for the common good. A Good Behavior provision that bars a licensee from bringing a patent

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94. Feldman, *Insufficiency*, *supra* note 85, at 435.

95. *See* Stu Woolman, Elliot Fishman & Michael Fisher, *Evidence of Patent Thickets in Complex Biopharmaceutial Technologies*, 53 IDEA at 1, 7 (2013); *see also* Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, 1 INNOVATION POL'Y & THE ECON. 119, 119 (2001) (a patent thicket is "an overlapping set of patent rights requiring that those seeking to commercialize new technology obtain licenses from multiple patentees.").

96. Shapiro, *Navigating the Patent Thicket*, *supra* note 95, at 120.

97. *See* FEDERAL TRADE COMMISSION, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY 6 (2003).

98. Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1629 (2003) (in discussing the problem of patent thickets, concludes that "[r]ather than promoting innovation, patents threaten to impede it or, at best, are deployed to counter the impeding patent rights of competitors."); *see, e.g.*, Woolman, et al., *Evidence of Patent Thickets*, *supra* note 95, at 1, 27 (empirical study shows that patent thickets tend to impede innovation in complex biopharmaceuticals).

infringement claim serves to minimize the thicket. By eliminating the threat of an infringement lawsuit, such provision would allow downstream inventors to commercialize their improvements faster and less expensively, without the trouble and expenses of "cutting through" the thicket.

Yet another negative effect of the patent system is its encouragement of duplicative activity, as parties try to invent around patents held by others rather than build on that work.[99] A patent holder's voluntary relinquishment of an infringement suit would reduce this unfavorable effect in the same manner as in the patent thicket context.

In addition to mitigating against negative effects of the patent system, a Good Behavior License tends to promote innovation in other respects. Take for example a Good Behavior provision that grants the patent holder the right to use improvements made by the licensee. This type of grant-back provision promotes innovation because it enables the patent holder to learn about how its invention has been used and to gain others' knowledge that can be used by the patent holder for future inventions.[100]

The rise of patent trolls and NPEs have moreover shaped the patent landscape.[101] Studies have shown that licenses with NPEs do not facilitate the development or use of new technology.[102] And NPEs are responsible for costly and unmeritorious patent litigation.[103] Given the high cost of litigation, a rational company may choose to pay a license fee to a NPE rather than incur the costs and risks of a lawsuit. "The patent in that case is not benefitting society at all but rather serving as a drag on innovation."[104] Because licenses with NPEs/PAEs generally do not promote innovation and do not benefit society as a whole, they are inconsistent with patent policy. Therefore, banning such licenses – as a Good Behavior License would do – would be consistent with patent policy.

Rather than impede innovation, a Good Behavior License would have the effect of alleviating many negative consequences of the patent

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99. *See* Feldman, *Insufficiency*, *supra* note 85, at 434.

100. *See, e.g.*, Jacobsen v. Katzer, 535 F.3d 1373, 1382 (Fed. Cir. 2008) ("by requiring that changes made by downstream user be visible to the copyright holder and others, the copyright holder learns about the uses of his software and gains others' knowledge that *can be used to advance future* software releases"; allowing copyright right infringement claim based on alleged breaches of an open source software license) (emphasis added).

101. *See generally* Robin Feldman & Mark A. Lemley, *Do Patent Licensing Demands Mean Innovation?*, 101 IOWA L. REV. 137, 139 (2015).

102. *See, e.g.*, *id.*, at 156-66, 173; *see also* Robin Feldman & Mark A. Lemley, *Is Patent Enforcement Efficient?*, 98 B.U. L. REV. 649, 655-58 (2018).

103. *See, e.g.*, Feldman & Lemley, *supra* note 101, at 152-54.

104. *Id.* at 140, 152-54.

system. Such license should not constitute patent misuse because it seeks to promote innovation.

VI. CONCLUSION

Federal funding of university life science research is an important part of the system that has produced life-saving innovations and helped preserve the nation's dominant position in the pharmaceutical industry worldwide. Spending in this manner is unequivocally a public good, and the translations spurred by the Bayh-Dole Act have brought great benefit to patients and the health care system. Just as universities have served as a driving force in research, so too can universities serve as a driving force for guiding the drug development system out of its current morass.

The challenge in shifting from a for-profit mindset is indeed substantial. The lure of gold from technology transfer offices can easily illuminate a less humble path. Nevertheless, without the pressures of shareholder constraints and political winds, universities are uniquely situated to act in the highest philosophical and ethical traditions that are deeply embedded in the academic mission. And indeed, there is a modicum of self-interest at play, as well. Federal funding continues to provide a significant source of support for research universities. Right now, public fury over the cost of medication is aimed at drug companies and health insurers. If that fury were to turn toward universities and morph into a movement to kill spending, universities have much to lose. In an era in which public anger manifests itself in a manner that is fast, furious, and not always rational, the high ground may be safer, as well.