Contracting to Preserve Open Science: The Privatization of Public Policy in Patent Law

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Patents on biomedical research tools—technological inputs to experimentation—may inhibit scientific inquiry and the development of life-enhancing therapies. Various "public law" approaches to address this challenge, such as a common law experimental use exception to patent infringement, have achieved limited success. In the wake of these shortcomings, this Article argues that institutions that fund and support biomedical research are resorting to an underappreciated model of private ordering to resolve research holdup. Increasingly, federal and state agencies, universities, non-profits, and disease advocacy groups are conditioning the provision of vital research support on requirements that recipients of this support make resulting patented inventions widely available for noncommercial research purposes. In essence, these institutions are contractually constructing a biomedical research commons.

These efforts represent a significant shift towards "privatizing" patent regulation. Through a new model of "consideration-based patent regulation," public institutions are embedding policy objectives in contractual quid pro quos with individual recipients of research support. This model provides public institutions with considerable freedom to effectuate norms favoring wide dissemination of research technologies. This Article greets this development with cautious optimism, providing prescriptions for how public institutions may effectively manage the contractual construction of a biomedical research commons. It concludes by exploring the significant ramifications of this development for patent law, institutions, and theory.

Contents

Introduction

In an era of great concern that patents may inhibit biomedical research,[1] the intellectual property policies of the California Institute for Regenerative Medicine ("CIRM") suggest a promising solution.[2] CIRM, a state agency, will provide $3 billion over ten years for human embryonic stem cell research in California.[3] Under CIRM's regulations, grantees may patent inventions arising from state funds.[4] However, as a condition of receiving public money, non-profit grantees must make patented inventions "readily available" to California institutions for noncommercial research purposes.[5] In essence, CIRM is contractually creating a research commons within the state of California. While CIRM's regulations are not ideal (from a national perspective) in that they only benefit research institutions of one state, they illustrate an important mechanism for mitigating the exclusionary effects of patents. Amidst great anxiety that patents may exclude scientists from using critical technologies, public institutions are leveraging their significant support for biomedical research to "contract" for enhanced access to such technologies.

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[1] *See infra* Part I; s*ee generally* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 698–701 (1998); Suzanne Scotchmer, *Standing on the Shoulders of Giants: Cumulative Research and the Patent Law*, 5 J. ECON. PERSP. 29, 39-30 (1991); Peter Yun-hyoung Lee, *Inverting the Logic of Scientific Discovery*, 19 HARV. J.L. & TECH. 79, 81 (2005) [hereinafter Lee, *Inverting the Logic of Scientific Discovery*]; Christopher D. Hazuka, *Supporting the Work of Lesser Geniuses: An Argument for Removing Obstructions to Human Embryonic Stem Cell Research*, 57 U. MIAMI L. REV. 157, 157-58 (2002); Lori Andrews et al., *When Patents Threaten Science*, 314 SCIENCE 1395, 1395-96 (2006).

[2] *See* 17 Cal. Code Reg. § 100300-100310, § 100400-100410.

[3] *See infra* Part IV.B.

[4] CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE, INTELLECTUAL PROPERTY POLICY FOR NON-PROFIT ORGANIZATIONS 2, 22 (2006), *available at* http://www.cirm.ca.gov/faq/pdf/IPPNPO.pdf (last visited July 30, 2007) [hereinafter CIRM, NON-PROFIT POLICY]; CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE, POLICY FOR FOR-PROFIT ORGANIZATIONS 29 (2006), *available at* http://www.cirm.ca.gov/faq/pdf/ForProfitOrg.pdf (last visited July 30, 2007) [hereinafter CIRM, FOR-PROFIT POLICY].

[5] 17 Cal Code Regs. § 100306(a); CIRM, NON-PROFIT POLICY, *supra* note 4, at 18, 37.

Patents, which are twenty-year grants of exclusive rights on inventions, embody an intrinsic tradeoff. While they provide incentives to invent and develop new technologies, they also constrain access to those technologies. These constraints can have several deleterious effects. In the research context, patents on "research tools"[6]—vital inputs to experimentation such as gene fragments and extracted, purified human embryonic stem cells—may inhibit scientific inquiry and the development of life-enhancing therapies. In other contexts, exclusive rights can substantially raise the price of essential medicines[7] and hinder commercialization of existing inventions.[8]

The standard retort to this critique is that access constraints are necessary to motivate investment in new technology. However, this retort does not hold in all contexts.[9] It is particularly questionable in the political economy of biomedical research, where government, academic, and non-profit institutions provide enormous support for research leading to patented inventions.[10] Many patented research tools, for example, arise from taxpayer-funded investigations conducted at non-profit universities. This support undermines the notion that

[6] The National Institutes of Health ("NIH") defines research tools as "tools that scientists use in the laboratory, including cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry and DNA libraries, clones and cloning tools (such as PCR), methods, laboratory equipment and machines." Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice, 64 Fed. Reg. 72,090, 72,092 n.1 (Dec. 23, 1999) [hereinafter NIH, *Principles and Guidelines*].

[7] *See, e.g.*, Madhavi Sunder & Anupam Chander, *The Romance of the Public Domain*, 92 CAL. L. REV. 1331, 1332 (2004) (emphasizing distributional concerns in intellectual property law); Keith Aoki, *Distributive and Syncretic Motives in Intellectual Property Law (with Special Reference to Coercion, Agency, and Development)*, 40 U.C. DAVIS L. REV. 717, 726–38 (2007); Amy Kapczynski et al., *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, 20 BERKELEY TECH. L.J. 1031, 1046-51 (2005); Michael E. Gluck, Federal Policies Affecting the Cost and Availability of New Pharmaceuticals, July 2002; Note, *Patents for Critical Pharmaceuticals: The AZT Case*, 17 AM. J.L. & MED. 145, 168-69 (1991).

[8] *See* eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 396 (2006) (Kennedy, J., concurring) (discussing "patent trolls," firms that assert patents but do not produce any goods or services); *see also* ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY 939-40 (4th ed. 2007) (noting that trolls may play a valuable role as "market makers").

[9] *See* Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289, 300 (2003).

[10] While some public institutions take financial interests in inventions, they do not fund research *primarily* to maximize returns on investment. *See infra* Part IV.

patent exclusivity is necessary to provide incentives to invent.[11] Of course, exclusivity may still be required to encourage private firms to further develop existing inventions into commercial products.[12] The policy challenge is to strike an appropriate balance between access and exclusivity for publicly-supported inventions.[13] Various "public law"[14] mechanisms to address this challenge, such as a common law experimental use exception to patent infringement,[15] have only achieved partial success.

This Article argues that an underappreciated model of private ordering is actively enhancing access to patented research tools and that expanding this model promises significant gains.[16] Specifically, it argues that public institutions are increasingly conditioning their contributions to biomedical research on requirements that recipients of those contributions share resulting patented inventions widely for noncommercial research purposes. In essence, these institutions are building, through contract-like quid pro quos, a research commons for biomedicine. This Article suggests that the most effective solution to patent holdup may come not from exogenous government regulation, but from contractual arrangements crafted by institutions in the biomedical sector. Exclusive rights on research tools are problematic because these assets are foundational inputs to a wide range of downstream uses. However, these inputs

[11] Rai & Eisenberg, *supra* note 9, at 300; Adam B. Jaffe, *The U.S. Patent System in Transition: Policy Innovation and the Innovation Process*, 29 RESEARCH POLICY 531, 552 (2000); *cf.* Katherine J. Strandburg, Users as Innovators: Implications for Patent Doctrine, (Mar. 2007) (unpublished manuscript), *available at* http://ssrn.com/abstract=969399 [hereinafter Strandburg, *Users as Innovators*].

[12] F. Scott Kieff, *Property Rights and Property Rules for Commercializing Inventions*, 85 MINN. L. REV. 697 (2001) [hereinafter Kieff, *Property Rights and Property Rules*]; *but see* John M. Golden, *Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System*, 50 EMORY L. J. 101, 166 (2001) (arguing that patents on processes or refined products render patents on foundational research tools unnecessary).

[13] Rai & Eisenberg, *supra* note 9.

[14] In this context, "public law" initiatives refer to broadly-applicable congressional enactments, judicial decisions, and administrative rules. In contrast, "private law" arrangements create rights and obligations between individual parties. *Cf.* Orin S. Kerr, *Rethinking Patent Law in the Administrative State*, 42 WILLIAM & MARY L. REV. 127, 129 (2000).

[15] *See infra* Part II.

[16] While several of these initiatives, such as reserved research exceptions by universities, enhance access to *all* patented inventions for noncommercial research, this Article focuses on research tools, primarily because of their centrality to scientific inquiry. *See infra* Parts II & IV.C.

have inputs, too. By attaching conditions to assets even anterior to research tools—such as the money, patent rights, and materials necessary to develop them—public institutions can help ensure the widespread availability of patented research tools for scientific inquiry.

This leveraging of valuable consideration to ensure access to patented technologies illustrates a general phenomenon that I call "consideration-based patent regulation." This contractually-driven practice is often swifter, nimbler, and more precise than traditional patent regulation,[17] and holds significant implications for patent law. While this Article focuses on maintaining a robust research commons, institutions are also utilizing consideration-based patent regulation to enhance access to essential medicines[18] and preempt the threat of "patent trolls."[19]

This Article represents the first systematic analysis of the creation of a biomedical research commons by public institutions, by which I include federal and state agencies, universities, non-profit organizations, and disease advocacy groups.[20] Within this effort, the National Institutes of Health ("NIH") is leveraging its funds to strongly encourage and arguably compel grant recipients to share patented inventions with noncommercial scientists. CIRM explicitly requires such sharing within California. Universities are reserving research exceptions for non-profit institutions when licensing technology to industry. Non-profit organizations and disease advocacy groups are conditioning receipt of money and tissue samples on assurances that patented inventions arising from these inputs will be freely available for research purposes.

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[17] *Cf.* Arti K. Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77, 142 (1999) [hereinafter Rai, *Regulating Scientific Research*] ("[M]odifying patent doctrine in order to address specific difficulties in basic biotechnology research is a very blunt approach.").

[18] *See, e.g.*, 17 Cal Code Regs. § 100306(d) (requiring non-profit grantees to provide therapies and diagnostics to uninsured California patients at discounted prices); 17 Cal. Code Reg. § 100407 (requiring for-profit grantees to provide drugs to uninsured California patients at discounted prices).

[19] *See, e.g.*, Lori Pressman et al., *The Licensing of DNA Patents by U.S. Academic Institutions: An Empirical Study*, 24 NATURE BIOTECH. 31, 37 (2006) (describing "diligence milestones" in licenses requiring commercial development of inventions).

[20] *Cf.* Kapczynski et al., *supra* note 7, at 1037. Where necessary, I will distinguish among these "public" institutions.

While the common property regimes arising from these efforts vary in size and scope, their potential to enhance access to patented research tools is enormous.[21]

Commentators (including this one) naturally look for public law solutions to public policy challenges. However, the enormous role of particular institutions in supporting biomedical research suggests that their intellectual property policies—which span the governmental and non-governmental realms—warrant examination. Some of these actors, such as the NIH and CIRM, fall within the realm of democratic accountability and represent underappreciated avenues for policy intervention. But policymakers must also account for the activities of other players in the biomedical research sector. At the very least, such awareness counsels for a cautious approach to centralized patent reform, as institutional working solutions can curb some of the most egregious instances of patent holdup without the need for legislative, doctrinal, or regulatory innovations.

Before proceeding, some distinctions are in order. In some cases, biomedical research is best advanced by simply relegating foundational technologies to the public domain.[22] However, in many other cases, optimal exploitation of biomedical research tools requires both access and exclusivity. Many of these inventions, such as extracted and purified human embryonic stem

[21] While others have argued for the NIH and universities to safeguard noncommercial research, this Article situates these institutions within a much broader regulatory paradigm. *See, e.g.*, Rai & Eisenberg, *supra* note 9; Mark A. Lemley, *Are Universities Patent Trolls?*, FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 611 (2008) [hereinafter Lemley, *Are Universities Patent Trolls?*]; Yochai Benkler, *Commons-Based Strategies and the Problem of Patents*, 305 SCIENCE 1110, 1110-11 (2004) [hereinafter Benkler, *Commons-Based Strategies*]. Furthermore, unlike arguments for maintaining open access to *data* through contracts, this Article focuses on the very different challenge posed by patented biomedical inventions. *See* J.H. Reichman & Paul F. Uhlir, *A Contractually Reconstructed Research Commons for Scientific Data in a Highly Protectionist Intellectual Property Environment*, 66 L. & CONTEMP. PROBS. 315 (2003).

[22] *Cf.* Lee, *Inverting the Logic of Scientific Discovery*, *supra* note 1. On efforts to preempt patents, see Robert P. Merges, *A New Dynamism in the Public Domain*, 71 U. CHI. L. REV. 183 (2004) [hereinafter Merges, *A New Dynamism in the Public Domain*]. The erosion of the public domain represents a significant problem. *See generally* Jessica Litman, *The Public Domain*, 39 EMORY L.J. 965 (1990); James Boyle, *The Second Enclosure Movement and the Construction of the Public Domain*, 66 LAW & CONTEMP. PROBS. 33 (2003); Pamela Samuelson, *Enriching Discourse on Public Domains*, 55 DUKE L.J. 783 (2006) [hereinafter Samuelson, *Enriching Discourse*]; *cf.* Leslie A. Kurtz, *Copyright: The Scenes a Faire Doctrine*, 41 FLA. L. REV. 79, 83-84 (1989).

cells, are "dual status" resources—they are both fully-functioning research tools in their current state as well as precursors to value-added commercial products. Even where public support has satisfied the incentive to invent the underlying tool, targeted exclusivity may still be necessary to motivate additional private investment in product development.[23] Accordingly, in certain circumstances, such assets should be widely available for high-value uses such as noncommercial research[24] while subject to context-specific exclusive rights for commercialization and sale.[25] Unlike broad-brush public law approaches, contractual approaches are well-suited to draw these distinctions, thus optimizing exploitation of these technologies.[26]

This inquiry adds a new dimension to "private ordering" that has long sought to resolve intellectual property holdup.[27] It reveals that such behavior is not the exclusive domain of for-profit entities; governments, universities, and non-profits are dominant players in innovation markets, and they are actively engaged in private ordering as well. This model of private ordering relies on three defining elements. In consideration-based patent regulation, institutions: 1) contribute valuable research support leading to patented inventions; 2) advance norms

[23] This was the rationale behind the Bayh-Dole Act, which allows private parties to patent taxpayer-financed inventions to encourage developing them into marketable products. Rai & Eisenberg, *supra* note 9, at 299; Kieff, *Property Rights and Property Rules*, *supra* note 12; *but see* Golden, *supra* note 12.

[24] Noncommercial research includes investigations conducted by non-profit institutions as well as preliminary "internal" investigations at for-profit firms that are not directly commercialized

[25] While this Article distinguishes between noncommercial research use and commercial sale, that is not the only distinction that is relevant to the optimal licensing of patented research tools. *See* NIH, *Principles and Guidelines*, 64 Fed. Reg. at 72094 (describing: 1) primary usefulness as a tool for discovery; 2) range of downstream activities enabled; and 3) immediate usefulness without further development as factors to consider in licensing a patented biomedical resource).

[26] Along similar lines, this Article does not advocate a noncommercial research exception for *privately-developed* research tools. Tools such as polymerase chain reaction (PCR), a process for copying DNA, may not have developed as robustly absent market exclusivity. Joe Fore, Jr., et al., *The Effects of Business Practices, Licensing, and Intellectual Property on Development and Dissemination of the Polymerase Chain Reaction: Case Study*, 1 J. BIOMEDICAL DISCOVERY AND COLLABORATION 7 (July 3, 2006). Other mechanisms are available to liberalize access to such tools that have achieved "infrastructural" status. Peter Lee, *The Evolution of Intellectual Infrastructure*, 83 Wash. L. Rev. 39 (2008) [hereinafter Lee, *The Evolution of Intellectual Infrastructure*].

[27] *See generally* Merges, *A New Dynamism in the Public Domain*, *supra* note 22.

emphasizing access to resulting technologies rather than strict exclusivity; and 3) implement these norms through "contractual" mechanisms to enhance access to patented inventions.

These efforts are notable both substantively and procedurally. At a substantive level, they reveal the vast importance of institutional norms in the patent system. While patent theory presumes that actors in the patent system are profit-maximizing entities,[28] this overlooks many public institutions that provide enormous research support. Consideration-based patent regulation both reveals and exploits the unique upstream-downstream "normative hierarchy" of the biomedical field.[29] Subject to exceptions,[30] public institutions that provide "upstream" support for investigations leading to research tools are also generally committed to widely disseminating them.[31] Alternatively, "downstream" entities that develop commercial products, such as pharmaceutical and biotechnology firms, tend to favor exclusivity and profit maximization.[32] The confluence of significant upstream support and norms favoring access creates a situation ripe with possibility.[33] Normative considerations thus represent a powerful reason why the initial allocation of patent rights on research tools (or contractual claims on those rights) matters a great deal.[34]

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[28] *See* Giles S. Rich, *The Relation between Patent Practices and the Anti-Monopoly Laws*, 24 J. Pat. Off. Soc'y 159, 164 (1942).

[29] While this upstream-downstream structure is a useful schematic, the distinctions among basic research, applied research, and development are increasingly blurry. *See, e.g.*, Golden, *supra* note 12, at 119. Nevertheless, public institutions still support an inordinate amount of basic research that feeds private sector development.

[30] *See infra* Part IV.

[31] *Cf.* Golden, *supra* note 12, at 110 (2001) ("[O]ver-emphasis on patent protection risks displacing a system of public sector values that appears to have served science and society well.").

[32] *Id*. at 106, 131, 133.

[33] *Id*. at 109 ("[Legal commentators] have largely ignored the details of the multi-billion dollar system of investment, mostly public and university-based, that provides most of the researchers and basic research that drives modern biotechnology.").

[34] See R.H. Coase, *The Problem of Social Cost*, 3 J.L. & ECON. 1 (1960) (positing that without transaction costs, the initial allocation of property rights does not matter because costless transfers will produce efficient outcomes); Clarisa Long, *Proprietary Rights and Why Initial Allocations Matter*, 49 EMORY L.J. 823, 823 (2000) (noting that transactions are costly and so initial allocations matter). I suggest that the initial allocation of property rights also matters based on the *normative* character of the entities controlling them. Quite simply, the life of a patented research tool will unfold differently if it is controlled by the NIH as opposed to a biotechnology company. *Cf.* Fore, Jr. et al., *supra* note 26, at *2.

At a procedural level, consideration-based patent regulation reflects an important shift from property to contract as a means for implementing patent policy. One could call this the privatization of public policy in patent law. I use the term "contract" broadly to include both informal quid pro quos as well as explicit contracts, such as funding agreements and licenses. While patents traditionally promote technological development through giving inventors a right to exclude, public institutions are advancing policy objectives by curtailing this exclusivity through contracts. This approach offers public institutions considerable freedom to operate. Because it awards federal funds, the NIH can "negotiate" with its grantees for much greater access to patented research tools than the Patent Act or current doctrine requires. This approach also permits valuable context-specific distinctions. Ideally, patents on biomedical research tools function less like simple rights to exclude and more as complex governance regimes involving selective exclusion and access.[35] These governance regimes, and the high information costs they entail, are better managed through *in personam* contractual relationships rather than *in rem* property rules.[36]

Of course, the contractual creation of a biomedical research commons faces several limitations. Such a commons is only coextensive with the web of grantor-grantee and licensor-licensee relationships defining it. Furthermore, a poorly managed research exception could chill private incentives to develop existing inventions. Accordingly, technical competence issues loom large. Finally, conflicts may arise between an institution's commitment to widely disseminate research tools and its desire to reap profits through exclusivity. Notwithstanding

[35] See Henry E. Smith, *Exclusion Versus Governance: Two Strategies for Delineating Property Rights*, 31 J. LEG. STUD. S453 (2003).
[36] On the distinction between *in rem* and *in personam* rights, see Thomas W. Merrill & Henry E. Smith, *The Property/Contract Interface*, 101 COLUM. L. REV. 773, 780-89 (2001).

these challenges, through carefully crafted agreements and faithful adherence to self-articulated values, public institutions can effectively construct a commons for biomedical research.

In addition to addressing patent holdup, this development holds several broader implications for patent law. The shift from a property to contract regulatory paradigm is itself significant, but it also illustrates a mechanism by which institutions can inject access norms in a patent system often criticized as narrowly preoccupied with exclusivity. This model also vastly widens the range of "policy levers"[37] available to effectuate patent policy to include federal and state funding agencies, universities, non-profit foundations, and disease advocacy groups. In an era where parallel processing and open source software have revealed the immense potential for decentralized production,[38] the efforts described here illustrate decentralized *regulation.* Significantly, consideration-based patent regulation provides "upstream" contributors with a greater role in managing the fruits of innovation, historically the exclusive province of downstream patentees.[39]

Part I examines access constraints inherent in the patent system and shows how patents may impede biomedical research. Part II explores the unique challenges posed by patents on publicly-supported inventions and assesses the limitations of public law mechanisms to address them. Part III examines the role of private ordering in tempering the excesses of intellectual property and explores a model by which public institutions can assert their normative commitments in market-based, contractual relationships. Part IV examines the creation of a biomedical research commons by public institutions. Applying the three-part model of consideration-based patent regulation, it considers the enormous contributions of public

[37] *Cf.* Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575 (2003).
[38] Yochai Benkler, *Coase's Penguin, or, Linux and the Nature of the Firm*, 112 YALE L.J. 369 (2002) [hereinafter Benkler, *Coase's Penguin*].
[39] *See* JAMES BOYLE, SHAMANS, SOFTWARE, AND SPLEENS 119-143 (1996); Madhavi Sunder, *IP*^{3}, 59 STAN. L. REV. 257, 284 (2006).

institutions to biomedical research, their normative commitments to open science, and contractual practices that limit the exclusive rights of downstream patentees to advance this objective. Part V assesses the opportunities and challenges posed by this endeavor and offers prescriptions for effectively managing it. Part VI explores the significant implications of this phenomenon for patent law, institutions, and theory.

Part I. The Role of Patents in Inhibiting Biomedical Research

Patents embody an intrinsic conflict; they increase the supply of new inventions by constraining access to them.[40] As is well-recognized, the technical knowledge inherent in an invention is a public good, which is nonrival[41] (multiple parties can use it without diminishing its availability) and nonexcludable[42] (absent legal intervention, it is difficult if not impossible to exclude others from appropriating it).[43] Public goods such as new innovations are subject to undersupply in the absence of exclusive rights because non-innovating firms could simply free-ride on the research and development of others. Patents allow inventors to exclude free riders, thus enabling an adequate return on investment.[44] The necessary trade-off is that exclusive rights may constrain access to patented inventions.[45]

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[40] Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 282 (1977); Rai, *Regulating Scientific Research*, *supra* note 17, at 117; FREDERIC M. SCHERER, INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE 442 (2d ed. 1980).

[41] *See* VI THE WRITINGS OF THOMAS JEFFERSON 180–81 (H.A. Washington ed., 1871) (describing ideas as "expansible over all space, without lessening their density in any point").

[42] While firms may protect valuable information as a trade secret, without legal intervention such as enforceable nondisclosure agreements, it may be difficult to maintain the secrecy of information and still exploit it.

[43] *See generally* Kenneth J. Arrow, *Economics of Welfare and the Allocation of Resources for Invention*, *in* NATIONAL BUREAU OF ECONOMIC RESEARCH, THE RATE AND DIRECTION OF INVENTIVE ACTIVITY (1962).

[44] The patent system also promotes efficiency by providing an incentive to disclose technical knowledge instead of protecting it as a trade secret. Additionally, patents decrease wasteful, duplicative effort by granting one entity the exclusive right to develop a technological "prospect." *See generally* Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1024-44 (1989) [hereinafter Eisenberg, *Patents and the Progress of Science*] (surveying prevailing patent theories); A. Samuel Oddi, *Un-Unified*

While access constraints on patented end-user goods may be problematic,[46] access constraints on the technological *inputs* to research and development are particularly troublesome.[47] In the biomedical realm, patents on upstream "research tools"[48] may inhibit downstream productive activity. A significant challenge of legislative and doctrinal attempts to enhance access to research tools is that no clear definition of that term exists.[49] For the purposes of this Article, I define a research tool as a broadly enabling tool for discovery useful to many scientists as an input to experimentation.[50] Examples of patented tools include: extracted and purified human embryonic stem cells; DNA sequences coding for specific proteins, called expressed sequence tags (ESTs); DNA sequences that serve as genetic disease markers, such as single nucleotide polymorphisms (SNPs); genetically modified disease models, such as the OncoMouse; and techniques for transferring genes from one organism to another, known as recombinant DNA technology.[51] Status as a research tool is context-specific; a genetic diagnostic test is a medical product when used to diagnose a patient, but a research tool when used to study a disease mechanism.[52] Furthermore, a research tool may be functional in its

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Economic Theories of Patents—The Not-Quite-Holy-Grail, 71 Notre Dame L. Rev. 267 (1996) (same); Kitch, *supra* note 40 (elaborating prospect theory).

[45] *Cf.* Carol M. Rose, *The Moral Subject of Property*, 48 WM. & MARY L. REV. 1897 (2007) (characterizing private property as a "second-best" approach to resource management).

[46] For example, patents on pharmaceuticals contribute to higher prices and decreased availability. *See supra* note 7.

[47] *See* Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 Yale L.J. 177, 225 [hereinafter Eisenberg, *Proprietary Rights and the Norms of Science*]; Rebecca S. Eisenberg, *Patents and Data-Sharing in Public Science*, 15 INDUSTRIAL & CORPORATE CHANGE, 1013, 1016 [hereinafter Eisenberg, *Patents and Data-Sharing in Public Science]*; *cf.* Mark A. Lemley, *Patenting Nanotechnology*, 58 STAN. L. REV. 601, 619-20 (2005) [hereinafter Lemley, *Patenting Nanotechnology*].

[48] See *supra* note 6.

[49] These definitional difficulties are mitigated in contractual approaches to regulating patent tools, as parties can negotiate the meaning of terms in specific contexts over time. *Cf.* Robert E. Scott & George G. Triantis, *Incomplete Contracts and the Theory of Contract Design*, 56 CASE W. RES. L. REV. 187 (2005).

[50] *Cf.* NIH, *Principles and Guidelines*, 64 Fed. Reg. at 72,094.

[51] For additional examples, see John P. Walsh et al., *Research Tool Patenting and Licensing and Biomedical Innovation*, *in* PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285, 296 (2003) [hereinafter Walsh et al., *Research Tool Patenting and Licensing*].

[52] Charles Clift, *Patenting and Licensing Research Tools*, *in* INTELLECTUAL PROPERTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATION: A HANDBOOK OF BEST PRACTICES 82 (A. Krattinger et al. eds., 2007) [hereinafter HANDBOOK OF BEST PRACTICES].

current state while also representing a precursor to a "value-added" product, such as a commercial therapy or even a more highly refined research tool. For example, a gene that codes for a therapeutic protein is both an object of study as well as a candidate for a marketable therapy.[53] Crucially, many research tools do not arise from applied, commercial research, but arise quite directly from basic biomedical investigations.

Many developments have coalesced to significantly increase the patenting of research tools.[54] First, courts have taken an expansive view of patentable subject matter,[55] such that in some cases the direct fruits of basic research can be patented.[56] Second, advances in molecular biology have revealed a relatively clear path from "basic" discoveries to commercial products, thus enhancing their patentability.[57] Third, the 1980 passage of the Bayh-Dole Act allowed and encouraged federal grantees to patent taxpayer-financed inventions, thus leading to an explosion in university patenting.[58] Finally, there is much money to be made. Biomedical patents are essential to the pharmaceutical and biotechnology industries,[59] and profit expectations have motivated patenting up and down the research and development chain.[60]

Patents on research tools can hinder scientific inquiry in a variety of ways.[61] First, a patent on a critical, "keystone" asset can singlehandedly hold up research.[62] As I have argued

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[53] *See also* Katherine J. Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain*, 2004 Wis. L. Rev. 81 (distinguishing between experimenting *on* research tools and experimenting *with* research tools) [hereinafter Strandburg, *What Does the Public Get?*].
[54] *See* Rai & Eisenberg, *supra* note 9, at 291-95.
[55] *See* Diamond v. Chakrabarty, 447 U.S. 303 (1980); *infra* notes and accompanying text.
[56] Richard R. Nelson, *The Market Economy, and the Scientific Commons*, 33 RESEARCH POLICY 455, 462 (2004).
[57] Rebecca S. Eisenberg, *Patents and Data-sharing in Public Science*, *supra* note 47, at 1014.
[58] *See infra* Part IV.A.C.
[59] *See* Golden, *supra* note 12, at 106.
[60] Further exacerbating the problem of patents on cutting-edge biomedical research tools, these patents tend to be quite broad. *See* Rai & Eisenberg, *supra* note 9, at 296; Burk & Lemley, *supra* note 37, at 1656; Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 848-49 (1990); Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 TEX. L. REV. 989, 1072-73 (1997). Patrick L. Taylor, *Research Sharing, Ethics and Public Benefit*, 24 NATURE BIOTECH. 398, 399 (2007).
[61] *See* Robert C. Levin et al., *Appropriating the Returns from Industrial Research and Development*, 1987 Brookings Papers on Economic Activity, 783, 788 (1987).

elsewhere, patents on technological "infrastructure" [63] such as extracted and purified human embryonic stem cells have the potential to impede wide arrays of scientific inquiry.[64] Second, the need to bundle multiple licenses for various patented assets can generate transaction costs that render such investigations prohibitively expensive.[65] This may produce a "tragedy of the anticommons" wherein too many upstream exclusive rights leads to wasteful underexploitation of resources, represented here by foregone research.[66] For example, if a scientist needs to bundle many licenses for patented expressed sequence tags (ESTs), aggregate costs may render an intended course of research unduly expensive.[67] Third, similar to but distinct from the anticommons scenario is the challenge of patent thickets, where multiple overlapping patents cover a single technology.[68] This is most likely to occur in component industries, where, for example, a single semiconductor may infringe hundreds of patents.

The degree to which patents inhibit noncommercial biomedical research is a widely-debated empirical question. In a recent survey, Professor John Walsh and colleagues found that only 1% of academic researchers suffered a project delay of more than one month due to patents on necessary inputs, and none had completely abandoned a project.[69] An earlier survey found

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[62] *See* Merges & Nelson, *supra* note 60, at 882 (discussing the Selden patent, which was used to control development of the automobile); *see generally* Scotchmer, supra note 1.
[63] *See* Brett M. Frischmann, *An Economic Theory of Infrastructure and Commons Management*, 89 MINN. L. REV. 917, 956 (2005).
[64] Lee, *The Evolution of Intellectual Infrastructure*, *supra* note 26, at ; Lee, *Inverting the Logic of Scientific Discovery*, *supra* note 1, at 90.
[65] For a discussion of the challenges of negotiating technology licenses, see Lee, *The Evolution of Intellectual Infrastructure*, *supra* note 26, at 97-99.
[66] Heller & Eisenberg, *supra* note 1; National Research Council, Intellectual Property Rights and Research Tools in Molecular Biology (1997); *see generally* Michael A. Heller, *The Tragedy of the Anticommons: Property in the Transition from Marx to Markets*, 111 HARV. L. REV. 621 (1998).
[67] *See* Heller & Eisenberg, *supra* note 1.
[68] *See generally* Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting* 119, i*n* ADAM B. JAFFE ET AL. EDS. 1 INNOVATION POLICY AND THE ECONOMY (2001); Burk & Lemley, *supra* note 37, at 1627.
[69] John P. Walsh et al., Patents, Material Transfers and Access to Research Inputs in Biomedical Research, Final Report to the National Academic of Sciences' Committee [on] Intellectual Property Rights in Genomic and Protein-Related Inventions, Sept. 20, 2005, at 2 [hereinafter Walsh et al., Patents, Material Transfers and Access to Research

"almost no evidence" that the presence of multiple upstream rights holders led to the complete cessation of projects.[70] Similarly, royalty stacking from multiple licenses did not represent a significant or pervasive threat to such activity.[71] Commentators observe a *de facto* experimental use exception whereby patentees "rationally forbear" from suing university scientists.[72] Private firms wish to avoid the negative publicity and ill-will that arises from suing universities (especially since they routinely seek licenses from them). Furthermore, university research on patented assets that does not lead directly to a competing product may have little financial impact on for-profit patentees, who may actually seek to free ride on unlicensed academic research.[73] For their part, non-profit researchers are often oblivious as to whether they are using patented inputs in their experiments,[74] and universities have incentives not to monitor such practices closely.[75]

While rare, the potential for hindering noncommercial research is nonetheless significant. For example, restrictive licensing of critical tools such as the OncoMouse[76] and polymerase

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Inputs]. The authors conclude that "friction" arising from material transfer agreements for *physical* property posed a much greater impediment to basic science. *Id*.

[70] Walsh et al., *Research Tool Patenting and Licensing*, *supra* note 51, at 298.

[71] *Id*. at 299.

[72] Rai & Eisenberg, *supra* note 9, at 296; *see* Walsh et al., *Research Tool Patenting and Licensing*, *supra* note 51, at 324-26; Cristina Weschler, *Note, The Informal Experimental Use Exception: University Research after* Madey v. Duke University, 79 N.Y.U. L. REV. 1536 (2004); Leon Rosenberg, *Perspectives from Different Sectors: Major Pharmaceutical Company*, *in* Nat'l Research Council, INTELLECTUAL PROPERTY RIGHTS AND RESEARCH TOOLS IN MOLECULAR BIOLOGY 61, 63 (1997), *available at* http://books.nap.edu/html/property. This also reflects private ordering, where a norm has developed of ignoring patents and patentees tolerate it.

[73] Ariad Pharmaceuticals is the exclusive licensee of a patent on NH-kB, a signaling protein. After the company sued Eli Lilly for infringement, Ariad CEO Harvey Berger stated, "We entirely encourage noncommercial use without a license." Walsh et al., *Patents, Material Transfers and Access to Research Inputs in Biomedical Research*, *supra* note 69, at 30.

[74] John P. Walsh et al., *View from the Bench: Patents and Material Transfers*, 309 SCIENCE 2002, 2002 (2005).

[75] Doing so may expose them to enhanced damages for willful infringement. Eisenberg, *Patents and Data-Sharing in Public Science*, *supra* note 47, at 1019.

[76] Fiona Murray, *The Oncomouse that Roared: Resistance & Accommodation to Patenting in Academic Science*, March 2006, available at http://web.mit.edu/fmurray/www/papers/THE%20ONCOMOUSE%20THAT%20ROARED_FINAL.pdf ; Eliot Marshall, *NIH Cuts Deal on Use of OncoMouse*, 287 Science 567 (2000). Ultimately, the NIH negotiated with DuPont to ease these restrictions. *See infra* Part IV.A.

chain reaction (PCR)[77] initially threatened to inhibit basic research. One study cited above concluded that the burden of paying multiple license fees, while manageable for for-profit companies, could be onerous for university labs, "making it impossible for them to license particular research tools."[78] Additionally, evidence suggests that industry's willingness to forbear from enforcing patents against universities is waning.[79] Furthermore, proprietary claims can chill noncommercial research in ways other than through licensing fees and injunctions. DuPont initially licensed the OncoMouse widely throughout the academic community but insisted on prepublication reviews of academic papers, reach-through royalties on future commercial products, and limitations on sharing such animals. Many scientists balked at these restrictions, refraining from using this important tool.

One reason that upstream patents have not severely inhibited research is because of the NIH's aggressive intervention to enhance access to taxpayer-financed research tools, a practice illustrating consideration-based patent regulation. For example, the NIH negotiated greater access to patented human embryonic stem cells as well as patented techniques for transferring genes into mammalian cells.[80] Additionally, private ordering by the NIH and Merck has helped preempt patents on expressed sequence tags (ESTs), thus averting a potential tragedy of the anticommons.[81] Given that biomedical research generates immense spillovers benefitting society at large,[82] even slight disruptions can have significant effects. Such research occupies "Pasteur's Quadrant:" while it strives for deep understanding, it is also intrinsically oriented towards

[77] *See Cetus To Exact Royalties from PCR Sales; Probe Absolves Convicted Rapist*, BIOTECH. NEWSWATCH, Sept. 5, 1988, at 7.
[78] *Id*. at 302.
[79] Nelson, *supra* note 56, at 467; *see also* National Research Council, Reaping the Benefits of Genomic and Proteomic Research (2006).
[80] *See infra* Part IV.A.I.
[81] *See* Heller & Eisenberg, *supra* note 1, at 699.
[82] *See* Mark A. Lemley & Brett M. Frischmann, *Spillovers*, 100 COLUM. L. REV. 257, 257 (2007)

practical applications.[83] Much hangs in the balance, and accordingly many have decried the privatization of the scientific research commons.[84]

Part II. The Challenges of Regulating Access to Biomedical Research Tools

While many observers argue for wide access to biomedical research tools, constructing an appropriate commons faces several complications. From the demand side,[85] the "infrastructural" ability of these resources to enable myriad downstream uses weighs in favor of allowing unfettered access to them.[86] In general, society is better off when scientists have ready access to gene fragments, disease models, and basic laboratory procedures. However, two supply-side considerations render open access to research tools problematic. First, generating research tools is a capital intensive endeavor and without some degree of exclusivity, private firms would have little incentive to invent them.[87] While many scientists—including private sector scientists—routinely develop research tools simply for their own use,[88] patent exclusivity still provides additional incentives for firms to support this development. These concerns over private incentives are mitigated in the public sphere, where taxpayer funding and non-profit universities produce many research tools. Given that public support has already satisfied the incentive to invent these technologies, perhaps such tools should be openly available to all.

[83] D. STOKES, PASTEUR'S QUADRANT: BASIC SCIENCE AND TECHNOLOGICAL INNOVATION (1996); Nelson, *supra* note 56, at 455, 57; Francis Narin et al., *The Increasing Linkage Between U.S. Technology and Public Science*, 26 RESEARCH POLICY 317, 317 (2000).
[84] *See, e.g.*, Nelson, *supra* note 56, at 455; Andrews et al., *supra* note 1, at 1396.
[85] In economic terms, demand-side considerations relate to resource consumption while supply-side considerations relate to resource production.
[86] *See* Frischmann, *supra* note 63; Frischmann & Lemley, *supra* note 82, at 282.
[87] *See supra* note 26; Lee, *The Evolution of Intellectual Infrastructure*, *supra* note 26, at 110.
[88] Strandburg, *Users as Innovators*, *supra* note 11.

However, this proposal implicates the second supply-side complication. While open access may be appropriate for some research tools, it is not appropriate for all of them. Many research tools are "dual status" inventions: they both facilitate scientific research in their present state as well as represent precursors to value-added commercial products.[89] Human embryonic stem cells are an example: these cells are highly useful inputs in basic scientific investigations, but are also promising candidates for commercial therapies. Although public support has satisfied the incentive to invent the underlying tool, exclusive rights may still be necessary to encourage private investment to develop that tool into a marketable product.[90] This was the rationale behind the Bayh-Dole Act, which provides exclusive rights to taxpayer-financed inventions precisely to motivate private investment in commercialization. The challenge is to design a property regime that: 1) can differentiate between publicly-supported research tools that warrant exclusive rights to spur additional investment in "optimization" and those that do not; and 2) for the former, to ensure that such tools are widely available for high-value activities (such as basic research) while maintaining requisite exclusivity to encourage private development.

Not surprisingly, this public policy challenge has elicited a number of actual and proposed "public law" responses.[91] By "public law" mechanisms, I refer to traditional modes of patent regulation arising from broadly-applicable judicial decisions, legislative enactments, and administrative rules. For reasons that will become clear, I distinguish these public law mechanisms from private law mechanisms, characterized by contracts establishing particular

[89] Such products include therapies or even more highly refined research tools.
[90] Kieff, *Property Rights and Property Rules*, *supra* note 12, at .
[91] For proposals dealing with gene patents, see Jordan Paradise et al., *Patents on Human Genes: An Analysis of Scope and Claims*, 307 SCIENCE 1566, 1567 (2005).

rights and obligations between individual parties.[92] Common law and statutory experimental use exceptions, patentable subject matter doctrine, the statutory requirements of patentability, compulsory licenses, and remedies analysis all represent policy levers for tempering patent rights,[93] but none offers a complete solution. As an exhaustive review of all of these mechanisms is beyond the scope of this Article, I will focus on several prominent devices before briefly surveying others. As we will see, the gaps left by public law initiatives define a valuable role for private law approaches to play a supplementary role.

A. The Common Law Experimental Use Exception

A doctrine aimed directly at allowing unlicensed use of patented inventions for noncommercial purposes is the common law experimental use exception.[94] Traditionally, the doctrine distinguished "philosophical," noncommercial uses of patented inventions from commercial ones, exempting the former from infringement.[95] While theoretically this exception

[92] As Professors Thomas Merrill and Henry Smith make clear, the distinction between *in rem* and *in personam* rights is one of degree rather than kind. *See* Merrill & Thomas, *supra* note 36, at 777.
[93] *See also* Oskar Liivak, *Maintaining Competition in Copying: Narrowing the Scope of Gene Patents*, 41 U.C. DAVIS L. REV. 177 (2007); Maureen A. O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177 (2000).
[94] The doctrine has attracted voluminous academic commentary, much of it positive. *See, e.g.*, Eisenberg, *Patents and the Progress of Science*, *supra* note 44; Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1 (2001); Rochelle Dreyfuss, *Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense Arrived?*, 46 ARIZ. L REV. 457 (2004); Strandburg, *What Does the Public Get?*, *supra* note 53; Jeffrey R. Armstrong, *Bayh-Dole Under Siege: The Challenge to Federal Patent Policy as a Result of* Madey v. Duke University, 30 J.C. & U.L. 619 (2004); Nelson, *supra* note 56, at 466. However, the doctrine has attracted negative commentary as well. *See, e.g.*, Elizabeth A. Rowe, *The Experimental Use Exception to Patent Infringement: Do Universities Deserve Special Treatment?*, 57 HASTINGS L.J. 921 (2006); Jordan P. Karp, *Experimental Use as Patent Infringement: The Impropriety of a Broad Exception*, 100 YALE L.J. 2169 (1991); *Michael S. Mireles, An Examination of Patents, Licensing, Research Tools, and the Tragedy of the Anticommons in Biotechnology Innovation*, 38 U. MICH. J.L. REFORM 141, 201-05, 211-16 (2004) [hereinafter Mireles, *Patents, Licensing, Research Tools*].
[95] Whittemore v. Cutter , 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600) ("[I]t could never have been the intention of the legislature to punish a man, who constructed such a[n allegedly infringing] machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects."); s*ee* Sawin v. Guild, 21 F. Cas. 554, 555 (C.C.D. Mass. 1813) (No. 12,391); Poppenhusen v. Falke, 19 F.

might have safeguarded university research from patent infringement, recent court decisions have largely foreclosed that possibility.[96]

Most prominently, in *Madey v. Duke University*, the Federal Circuit construed the experimental use exception extremely narrowly.[97] In that case, Duke University used the patented laser of a recently-departed scientist for research purposes, and the scientist sued for infringement. The Federal Circuit rejected Duke's experimental use defense, holding that "so long as the [suspect] act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense."[98] Duke's "legitimate business" involved educating students and attracting research grants and faculty, and using the patented laser advanced those objectives. In the wake of *Madey*, universities may no longer invoke the common law experimental use exception to shield research uses of patented inventions from infringement.[99]

It is important to note that even if courts recognized a robust experimental use exception, it would be overly inclusive. As discussed, a general noncommercial research exception would

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Cas. 1048, 1049 (C.C.S.D.N.Y. 1861) (No. 11,279); Roche Products, Inc. v. Bolar Pharmaceutical Co., 733 F.2d 858, 862-63 (Fed. Cir. 1984); see 3 WILLIAM C. ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS § 898, at 56 (1890).

[96] *See, e.g.*, Pitcairn, 547 F.2d 1106, 1125-26 (Ct. Cl. 1976); Roche Prods., 733 F.2d at 863; Deuterium Corp. v. United States, 19 Cl. Ct. 624, 633 (Ct. Cl. 1999); Embrex v. Serv. Eng'g Corp., 216 F. 1343, 1349 (Fed. Cir. 2000); *see generally* Armstrong, *supra* note 94.

[97] 307 F.3d 1351 (Fed. Cir. 2002).

[98] 307 F.3d at 1362. Several observers note that *Madey* simply extended previous Court of Claims and Federal Circuit jurisprudence on the experimental use exception to university research and did not truly "narrow" the exception. See *supra* note .

[99] *See* Strandburg, *What Does the Public Get?*, *supra* note 53, at 84 ("[R]ecent decisions from the U.S. Court of Appeals for the Federal Circuit threaten to shrink the experimental-use exemption to extinction."); s*ee also* Applera Corp. v. MJ Research, Inc., 311 F. Supp. 2d 293, 296 (D. Conn. 2004) (affirming *Madey's* "very narrow" and "strictly limited" interpretation of the experimental use exception); Brief for Association of American Medical Colleges, et al, as Amici Curiae in Support of Petitioner at 14, Duke Univ. v. Madey, 123 S. Ct. 2639 (2003) (No. 02-1007); Suz Redfearn, *The Madey Decision and Academic Research: Has the Sky Fallen?*, 1 PRECLINICA 230, 231(Nov./Dec. 2003). In addition, sovereign immunity is not a reliable mechanism for shielding state university researchers from infringement. *See generally* Gary Pulsinelli, *Freedom to Explore: Using the Eleventh Amendment to Liberate Researchers at State Universities from Liability for Intellectual Property Infringements*, 82 WASH. L. REV. 275 (2007).

discourage private companies from committing resources to develop and market research tools primarily used by non-profit scientists.[100]

B. The Statutory Experimental Use Exception

While Congress has enacted a *statutory* experimental use exception, it is relatively narrow in scope. The 1984, Congress passed the Hatch-Waxman Act, which expedited the process by which firms may introduce generic versions of patented drugs.[101] The act also created a statutory research exception from patent infringement "for uses reasonably related to the development or submission of information under a Federal law which regulates the . . . use . . . of drugs."[102] The Act, however, does not establish a true experimental use exception. First, the act's narrow safe harbor only applies to research activities leading to submitting information to the FDA or other regulatory body. Second, the Act exempts from infringement uses of patented materials that are decidedly *commercial*—studies leading to drug development—and may not reach far enough upstream to apply to foundational basic research. Recently, the Supreme Court liberally construed the safe harbor, holding that it applies to the use of patented materials in

[100] *See* Integra Lifesciences I Ltd. v. Merck KGaA, 331 F.2d 860, 878 (Fed. Cir. 2003) (Newman, J., dissenting); Federal Trade Comm'n, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy, at ch. 4, at 36 (2003) ("Inventors of tools used by researchers need an income stream from those who use their inventions."); *see also* Kieff, *Property Rights and Property Rules*, *supra* note 12, at 703.

[101] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended in scattered sections of 21 U.S.C. and 35 U.S.C.). The act responded to the Federal Circuit's decision in *Roche Products Inc. v. Bolar Pharmaceuticals*, 733 F.2d 858 (Fed. Cir. 1984), which held that use of a patented pharmaceutical for investigations related to FDA submission requirements did not qualify for the common law experimental use exception. *See* Rebecca S. Eisenberg, Patents, *Product Exclusivity, and Information Dissemination: How Law Directs Biopharmaceutical Research and Development*, 72 FORDHAM L. REV. 477, 482-86 (2003) [hereinafter Eisenberg, *Patents, Product Exclusivity, and Information Dissemination*]; Gluck, *supra* note 7, at 6-7.

[102] 35 U.S.C. § 271(e). To offset delays in FDA approval, the act also allows patent term extensions of up to five years. 35 U.S.C. § 156.

preclinical research reasonably related to an FDA submission.[103] Nevertheless, the Hatch-Waxman Act falls far short of creating a noncommercial research exception from patent infringement.

C. Modifications to Patentable Subject Matter

A more drastic approach to eliminate access constraints on research tools is simply to remove them from patentable subject matter.[104] For example, courts could extend the traditional bar against patenting "products of nature"[105] to resources such as gene fragments and extracted, purified human embryonic stem cells.[106] Alternatively, they could extend the doctrinal prohibition against patenting natural laws, physical phenomena, and abstract ideas[107] to limit patents on research tools that are necessary to discover these elements.[108] These proposals, however, raise difficulties in light of expansive patentable subject matter doctrine. In the seminal case of *Diamond v. Chakrabarty*, the Supreme Court drew from the legislative history of the 1952 Patent Act in stating that "anything under the sun that is made by man" is eligible for patenting.[109] Although recent Supreme Court[110] and Federal Circuit[111] pronouncements signal a

[103] Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193 (2005).
[104] *See* 35 U.S.C. § 101 (defining patentable subject matter as "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof"); *see generally* Lee, *Inverting the Logic of Scientific Discovery*, *supra* note 1, at 92-103; Eileen M. Kane, *Patent Ineligibility: Maintaining a Scientific Public Domain*, 80 ST. JOHN'S L. REV. 519 (2006).
[105] *See, e.g.*, Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948) ("The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men."); Ex Parte Latimer, 889 Dec. Com. Pat. 123.
[106] Rai & Eisenberg, *supra* note 9, at 299. Of course, this would rarely affect "process" research tools, such as techniques for copying DNA.
[107] *See* Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).
[108] *See* Lee, *Inverting the Logic of Scientific Discovery*, *supra* note 1.
[109] 447 U.S. 303 (1980); *see also* Diamond v. Diehr, 450 U.S. 175, 192 (1981); State Street Bank & Trust Co. v. Signature Financial Group, Inc. 149 F.3d 1368 (Fed. Cir. 1998).

potential narrowing of patentable subject matter, the extent of future modifications is unpredictable. While Congress is currently considering patent reform,[112] curtailing patentable subject matter to enhance access to foundational research resources is not on the agenda.

Furthermore, summarily prohibiting patents on research tools would undermine private incentives to invent and market such technologies.[113] While certain publicly-developed research tools may warrant placement in the public domain, ex ante, broad brush legislative enactments are not well-suited for precisely identifying them.[114]

D. Additional Policy Levers for Tempering Patents on Research Tools

The requirements that a patented invention must be novel, useful, and nonobvious may also prevent undue patenting of research tools.[115] In particular, the utility requirement has in fact

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[110] *See* Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., __ U.S. __, 126 S. Ct. 2921, 2922 (2006) (per curiam) (Breyer, J., dissenting from the dismissal of certiorari) ("[S]ometimes *too much* patent protection can impede rather than 'promote the Progress of Science and useful Arts' . . . .").

[111] *See* In re Petrus A.C.M. Nuijten, 500 F.3d 1346 (Fed. Cir. 2007), *en banc reh'g denied*, 2008 WL 361044 (Fed. Cir. 2008) (denying a patent application claiming electronic signals); In re Stephen W. Comiskey, 499 F.3d 1365 (Fed. Cir. 2007) (denying a patent application claiming a method for arbitrating disputes); In re Bilski, 2008 WL 417680 (Fed. Cir. 2008) (casting doubt on the patentability of business methods). Academics have roundly criticized the current breadth of patentable subject matter. *See, e.g.*, Andrews et al., *supra* note 1, at 1396; Rochelle Cooper Dreyfuss, *Are Business Method Patents Bad for Business?*, 16 SANTA CLARA COMPUTER & HIGH TECH. L.J. 263 (2000); John R. Thomas, *The Patenting of the Liberal Professions*, 40 B.C. L. REV. 1139 (1999).

[112] *See* Patent Reform Act of 2006, S. 3818, 109th Cong. (2006); Patent Reform Act of 2005, H.R. 2795, 109th Cong. (2005); Steve Seidenberg, *Reinventing Patent Law*, ABA J., Feb. 2008, at 62-63.

[113] *See supra* note 100

[114] A narrower approach could exempt non-profit researchers from *remedies* arising from infringing such patented inventions. Analogously, the Patent Act exempts health care professionals from remedies arising from infringing patented medical techniques. 35 U.S.C. § 287(c); see Pallin v. Singer, 1995 WL 608365, 36 U.S.P.Q.2d 1050 (D. Vt. 1050 1995); Chris J. Katopis, *Patients v. Patents?: Policy Implications of Recent Patent Legislation*, 71 ST. JOHN'S L. REV. 329 (1997). However, there have been no congressional attempts to recreate this exception for noncommercial researchers, which in any event would be overinclusive.

[115] *See* 35 U.S.C. §§ 101-103. In this regard, public interest groups recently challenged the validity of human embryonic stem cell patents on nonobviousness grounds. *See* Andrew Pollack, *3 Patents on Stem Cells Are Revoked in Initial Review*, N.Y. TIMES, Apr. 3, 2007, at C2. *See generally* KSR Int'l Co. v. Teleflex Inc., __ U.S. __, 127 S. Ct. 1727, 1746 (2007).

curbed such patents.[116] In 2001 the Patent and Trademark Office issued guidelines requiring a demonstrated specific and substantial utility for all patented inventions.[117] These guidelines have made it more difficult to patent expressed sequence tags (ESTs) that encode proteins of no known biological activity.[118] However, the impact of these guidelines on the patenting of other research tools is unclear. Yet another mechanism for enhancing access to patented biomedical research tools is compulsory licensing,[119] whereby a government agency could issue licenses to a third party to practice a patented invention if the patentee did not disseminate it widely enough.[120] While compulsory licenses are available pursuant to 28 U.S.C. § 1498[121] and antitrust consent decrees, they are rarely granted in this country and are not promising avenues for enhancing access to patented research tools.[122]

Another potential approach involves the law of patent infringement remedies. In *eBay Inc. v. MercExchange, L.LC.*, the Supreme Court recently rejected the Federal Circuit's "general rule" of granting injunctions upon a finding of patent infringement.[123] Instead, it held that courts must apply a traditional four-factor equitable test to determine the appropriateness of an injunction.[124] As I have recently argued, this change provides courts with greater latitude to

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[116] Nelson, *supra* note 56, at 466; *see* Golden, *supra* note 12, at 182; *see* Brenner v. Manson, 383 U.S. 519, 534 (1966).
[117] Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001); MERGES & DUFFY, *supra* note 8, at 238-40; Golden, *supra* note 12, at 129.
[118] In re Fisher, 421 F.3d 1365 (Fed. Cir. 2005).
[119] While the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement allows compulsory licensing, such licensing is much more common in other countries. *See* Jaffe, *supra* note 11, at 536, 551.
[120] F.M. Scherer & Jayashree Watal, *Post-TRIPS Options for Access to Patented Medicines in Developing Countries*, J. INT'L ECON. L. 913, 914 (2002).
[121] Sean M. O'Connor, *Intellectual Property Rights and Stem Cell Research: Who Owns the Medical Breakthroughs?*, 39 NEW ENG. L. REV. 665, 709-11 (2005) (characterizing § 1498 as a "formalized takings provision"). The federal government's recent proposal to compulsorily license Cipro under § 1498 in the wake of anthrax attacks drove down the price of that patented drug by 50%. Colleen Chien, *Cheap Drugs at What Price To Innovation: Does the Compulsory Licensing of Pharmaceutical Hurt Innovation?*, 18 BERKELEY TECH. L.J. 853, 868 (2003).
[122] Chien, *supra* note 121.
[123] 547 U.S. 388, 391 (2006).
[124] 547 U.S. at 391. In order to obtain an injunction, "A plaintiff must demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for

protect "infrastructural" inventions with a liability rule rather than a property rule.[125] However, it is too early to tell if courts will fully embrace this proposal. In the short time following *eBay*, courts have largely applied liability rule protection only in the "patent troll" context, denying injunctions to firms that assert but do not practice patents.[126] Even if courts protected research tool patents with damages rather than injunctions, such an approach is best suited to cases where a patent on some single, keystone asset—such as human embryonic stem cells—is the cause of patent holdup. It is less equipped to address anticommons scenarios arising from the need to bundle multiple licenses.

E. Summary

While valuable, public law attempts to temper patents on research tools face various limitations and uncertainties. A robust experimental use exception to patent infringement, as well as limitations on patentable subject matter, would overreach and undermine private incentives to invent and develop research tools. Targeted approaches such as a statutory experimental use exception and strengthening the utility requirement are useful but narrow in scope. Authorities rarely grant compulsory licenses in this country, and it is too early to assess the impact of recent changes in remedies doctrine. The complex incentives at issue render this a particularly difficult policy challenge. An ideal property regime would link public support to

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that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction." *Id*.

[125] *See* Lee, *The Evolution of Intellectual Infrastructure*, *supra* note 26; s*ee* Guido Calabresi & A. Douglas Melamed, *Property Rules, Liability Rules, and Inalienability: One View of the Cathedral*, 85 HARV. L. REV. 1089, 1092 (1972); J.H. Reichman, *Legal Hybrids Between the Patent and Copyright Paradigms*, 94 COLUM. L. REV. 2432 (1994).

[126] Andrew Beckerman-Rodau, *The Aftermath of* eBay v. MercExchange, 126 S. Ct. 1837 (2006): *A Review of the Subsequent Judicial Decisions*, J. PAT. & TRADEMARK OFF. SOC'Y 607, 632, 657 (2007); Benjamin H. Diessel, Note, *Trolling for Trolls: The Pitfalls of the Emerging Market Competition Requirement for Permanent Injunctions in Patent Cases Post*-eBay, 106 MICH. L. REV. 305, 312-15 (2007).

access requirements for research tools, but still maintain exclusivity where necessary to motivate private investment in product development. Given the inadequacy of public law mechanisms to address this challenge,[127] public institutions that support basic science are turning to markets and contracts to construct a noncommercial research commons for biomedicine

Part III. Private Ordering by Public Institutions

Where the law fails to provide optimal resource management, interested parties often resort to private ordering.[128] In particular, the perceived excesses of intellectual property rights have long spurred market actors to mitigate them through private arrangements. As Professor Robert Merges has influentially described, collective rights organizations often emerge to address the "tangled, twisted mass" of intellectual property rights that impedes productivity in many patent and copyright industries.[129] For example, around the turn of the twentieth century, patent pools arose in the automobile and aircraft industries to alleviate patent holdup in those fields.[130] Similarly, collective copyright licensing organizations such as ASCAP and BMI allow industry players to "contract into" liability rules in an aggregate fashion, thus creating an easily-accessible pool of licenses.[131] In the biomedical realm, some have argued for private collective action to resolve anticommons problems.[132]

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[127] *See* Nelson, *supra* note 56, at 466 ("I am not optimistic about how much of the problem can be dealt with by patent law.").
[128] *See generally* ROBERT ELLICKSON, ORDER WITHOUT LAW (1991); ELINOR OSTROM, GOVERNING THE COMMONS (1990).
[129] Robert P. Merges, *Contracting into Liability Rules: Intellectual Property Rights and Collective Rights Organizations*, 84 CAL. L. REV. 1293, 1295 (1996) [hereinafter Merges, *Liability Rules*].
[130] *Id*. at1340-58.
[131] *Id*. at 1328-40.
[132] Karl Bergmann & Gregory D. Graff, *The Global Stem Cell Patent Landscape: Implications for Efficient Technology Transfer and Commercial Development*, 25 NATURE BIOTECH. 419, 422 (2007).

At the most drastic level, industry players have addressed increasing propertization through another type of private ordering: simply relegating materials to the public domain. For example, the recent trend by biotechnology companies to patent single nucleotide polymorphisms (SNPs), which are useful as genetic disease markers, raised concerns that such patents could block useful research.[133] In response, pharmaceutical companies partnered with the Wellcome Trust to create the SNP Consortium,[134] which identifies SNPs and places all resulting information in the public domain.[135] Similarly, in 1995, Merck partnered with Washington University in St. Louis to create the Merck Gene Index, a freely-accessible public database of gene sequences.[136] Merck's initiative prevents patenting of these essential resources and has substantially eased potential anticommons threats.[137]

Outside of the biomedical realm, the access-enhancing potential of private ordering is perhaps best illustrated by open source software.[138] The most prominent open source license is the General Public License ("GPL"), which allows downstream users to make and distribute verbatim and modified versions of source code[139] and requires users to grant a license to anyone who comes into possession of a copy.[140] The license is considered "viral" because it "infects" all downstream iterations of code originally governed by the GPL.[141] Commentators laud open source licensing as enabling collaborative "peer production" that may be nimbler, faster, and

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[133] Rai & Eisenberg, *supra* note 9, at 298.
[134] *See* Nicholas Wade, *10 Drug Makers Join in Drive to Find Diseases' Genetic Roots*, N.Y. TIMES, Apr. 15, 1999, at ; Michael Morgan, *The SNP Consortium*, *in* NATIONAL RESEARCH COUNCIL, PROCEEDINGS OF THE SYMPOSIUM ON THE ROLE OF SCIENTIFIC AND TECHNICAL DATA AND INFORMATION THE PUBLIC DOMAIN (2003).
[135] Rai & Eisenberg, *supra* note 9, at 298; Merges, *A New Dynamism in the Public Domain*, *supra* note 22, at 189-90.
[136] *See* Merges, *A New Dynamism in the Public Domain*, *supra* note 22, at 188.
[137] *Id*. at 188.
[138] *See generally* Jacobsen v. Katzer, No. 2008-1001 (Fed. Cir. 2008).
[139] GNU General Public License Version 3, at §§ 4, 5 (June 29, 2007), *available at* http://www.gnu.org/licenses/gpl.txt.
[140] Id. at § 5.
[141] *See generally* Greg R. Vetter, *"Infectious" Open Source Software: Spreading Incentives or Promoting Resistance?*, 36 RUTGERS L.J. 53 (2004) (discussing viral licensing in the context of GPL version 2).

more robust than traditional firm structures.[142] IBM, for example, has engaged in substantial "property pre-empting" investments by supporting open source software.[143] Crucially, while the GPL enforces norms of open access, it is fundamentally predicated on the right to exclude inherent in copyright.[144]

Similarly, Creative Commons licenses allow content providers to selectively claim individual sticks in the bundle of rights normally conferred by copyright, thus enhancing access to their works.[145] These licenses extend beyond software to include all audio, video, images, and text; the power of these licenses to enhance access to otherwise proprietary material is enormous.[146] As Professor Pamela Samuelson notes, "Open source, CC [("Creative Commons")], and similar licensed materials are best understood as a contractually constructed information commons."[147] Most relevant for present purposes, Professors J.H. Reichman and Paul Uhlir have argued for using contracts to "reconstruct" a public domain for data that is increasingly subject to private control.[148]

Of course, the intersection of private ordering and intellectual property rights is not always salutary. Private ordering has raised concerns that "private legislation" can subvert the policy objectives of federal intellectual property law.[149] For example, "shrinkwrap" licenses allow content owners to assert, through contract, a higher degree of control over information than

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[142] *See* Benkler, *Coase's Penguin*, *supra* note 38, at 376-77, 415–22, 436–38; Dan M. Kahan, *The Logic of Reciprocity: Trust, Collective Action, and Law*, 102 MICH. L. REV. 71, 93-98 (2003); *but see* Vetter, *supra* note 141 (questioning the GPL's impact on software creation and distribution).
[143] *See* Merges, *A New Dynamism in the Public Domain*, *supra* note 22, at 192-93. IBM's motives, however, are far from altruistic. See *id*.
[144] Vetter, *supra* note 141, at 84; Boyle, *supra* note 25, at 65.
[145] Creative Commons, at http://creativecommons.org/; Merges, *A New Dynamism in the Public Domain*, *supra* note 22, at 183-84.
[146] *But see* Molly Shaffer Van Houweling, *The New Servitudes*, 96 GEORGETOWN L.J. 885, 923-49 (2008) (arguing that such licenses may raise problems similar to those associated with personal property servitudes).
[147] Samuelson, *Enriching Discourse*, *supra* note 22, at 800.
[148] Reichman & Uhlir, *supra* note 21.
[149] *See generally* Charles R. McManis, *The Privatization (or "Shrink-Wrapping") of American Copyright Law*, 87 CAL. L. REV. 173 (1999); Apik Minassian, *The Death of Copyright: Enforceability of Shrinkwrap Licensing Agreements*, 45 UCLA L. REV. 569, 601-02 (1997).

permitted under patent and copyright law.[150] Content providers have used shrinkwrap licenses to limit reverse engineering of computer programs, override fair use exceptions to copyright protection, and restrict the use of noncopyrightable databases.[151]

In all of these contexts, private ordering allows market actors to alter the baseline intellectual property landscape to advance their institutional objectives. Oftentimes, the pursuit of self-interest by private actors enhances social welfare. Thus Merck's preemption of EST patents and IBM's investment in open source software address intellectual property holdup in ways that public regulation has not. However, such behavior is not always welfare-enhancing, as seen in the proliferation of shrinkwrap licenses. Private ordering is a powerful tool, and it is guided by and effectuates the norms of those wielding it. The unstated premise of most accounts of private ordering is that such behavior is the prerogative of *for-profit* entities: while public institutions may play coordinating roles, for-profit institutions drive private ordering. However, public institutions are market participants, too.[152] As such, they can also leverage their substantial market power to advance institutional objectives.

Taking a cue from open source licensing, this Article argues that public institutions are adopting a private ordering model to advance the norm of open science[153] in contractual relationships with patentees. Current debates on upstream-downstream dynamics in biomedical patenting focus on potential productivity losses arising from upstream patents.[154] Underappreciated in this debate is an important facet of upstream-downstream dynamics: the *normative* character of institutions exercising control over upstream patents. Scholars have

[150] *See, e.g.*, ProCD v. Zeidenberg, 86 F.3d 1447 (1996); J.H. Reichman & Jonathan A. Franklin, *Privately Legislated Intellectual Property Rights: Reconciling Freedom of Contract with Public Good Uses of Information*, 147 U. PA. L. REV. 875 (1999).
[151] Reichman & Franklin, *supra* note 150, at 939-51.
[152] *Cf.* Evelyn Alicia Lewis, *When Entrepreneurs of Commercial Nonprofits Divorce: Is It Anybody's Business?*, 73 N.C. L. REV. 1761, 1765-74 (1995) (exploring the significant market power of some non-profits).
[153] *See* Rai & Eisenberg, supra note 9, at 289.
[154] *See supra* Part I.A.

demonstrated that scientists often adhere to knowledge-sharing norms that contravene the private rent-seeking inherent in patents.[155] To varying extents, the same holds true of public institutions as well.

As a gross schematic (one that I complicate later), along the continuum spanning basic research, applied research, and development, institutions that fund and produce upstream biomedical research tools—those closest to basic scientific findings—are most likely to exhibit norms privileging widespread access to technology rather than exclusion and profit-maximization. These institutions' control of inputs critical for biomedical research—money, patent rights, and materials—provides a "hook" for influencing the behavior of parties further along the research and development chain. The next Part will explore how these institutions are using this leverage to engage in market-based patent regulation.

Part IV. The Contractual Creation of a Biomedical Research Commons

Given the limitations and uncertainties of public law mechanisms to shield noncommercial research from patent infringement, public institutions are increasingly filling this void through private law models. Because this behavior includes government agencies acting pursuant to legislatively-enacted statutes, the terms "private law" and "private ordering" require some explanation in this context. The essence of this approach is that public institutions are advancing patent policy not through broadly-applicable laws, decisions, and rules, but by tying access requirements to the provision of research support in individual contractual relationships.

[155] Eisenberg, *Proprietary Rights and the Norms of Science*, *supra* note 47, at 182; Rai, *Regulating Scientific Research*, *supra* note 17; Kahan, *supra* note 142, at 90-93; ROBERT K. MERTON, THE SOCIOLOGY OF SCIENCE 275 (Norman W. Storer ed., 1973); WARREN O. HAGSTROM, THE SCIENTIFIC COMMUNITY (1965); BERNARD BARBER, SCIENCE AND THE SOCIAL ORDER (1953); *but see* F. Scott Kieff, *Facilitating Scientific Research: Intellectual Property and the Norms of Science—A Response to Rai and Eisenberg*, 95 Nw. U. L. Rev. 691 (2001) (arguing that sharing norms may merely be "aspirational")[hereinafter Kieff, *Facilitating Scientific Research*].

Institutions are acting not in a strictly legislative capacity, but as market actors placing strings on their contributions to biomedical research. Rather than altering the general nature of patent rights, public institutions are creating *in personam* obligations that limit the patent rights of individual grantees and licensees.

This Part surveys the contractual creation of a biomedical research commons. Following the three-part model of consideration-based patent regulation, it examines various institutions': 1) support for research leading to patented research tools; 2) adherence to norms favoring wide access to these tools; and 3) use of informal and formal contractual mechanisms to impose context-specific access requirements for these technologies. Part IV.A considers the NIH's leveraging of funds and the Bayh-Dole Act to ensure that publicly-financed research tools are widely available for scientific inquiry. Part IV.B examines California's requirements that recipients of state human embryonic stem cell research funding must share patented discoveries liberally with non-profit research institutions. Part IV.C considers university licensing practices ensuring wide access to patented research tools. Part IV.D explores the substantial contributions of non-profit organizations to biomedical research and examines their requirements that resulting patented research tools must be made widely available. Part IV.E highlights the growing importance of disease advocacy groups in supporting biomedical research and explores their practices for ensuring wide dissemination of patented research tools.

In all of these instances, an institution's significant "upstream" contributions to the development of a patented invention establish formal and informal claims on how a "downstream" patentee may use it. Utilizing this leverage, public institutions can enhance access to patented research tools in order to promote scientific research. Although the

experimental use exception has withered as a public law creation, institutions are helping to create a more effective one through contract.

A. The Federal Government

The federal government provides enormous support for basic biomedical research and is conditioning these contributions on expectations that resulting patented research tools will be widely available for scientific inquiry.[156] While the Bayh-Dole Act prevents funding agencies from directly regulating grantee patenting practices, the NIH has invoked informal quid pro quos to promote open licensing and even discourage patenting of key research resources. Liberalizing the administrative requirements of the Bayh-Dole Act could help the NIH realize the full potential of consideration-based patent regulation.

1. Federal Support for Basic Biomedical Research

The federal government dominates basic biomedical research funding in this country.[157] In 2003, the NIH, the "primary focal point of federally sponsored biomedical research,"[158]

[156] Reichman & Uhlir, *supra* note 21, at 326 ("The role of government in supporting scientific progress in general, and its influence on the creation and maintenance of the research commons in particular, cannot be overstated.").
[157] See Golden, *supra* note12 , at 136; *see generally* Harvey Brooks, *National Science Policy and Technological Innovation*, *in* THE POSITIVE SUM STRATEGY: HARNESSING TECHNOLOGY FOR ECONOMIC GROWTH 119 (Ralph Landau & Nathan Rosenberg eds., 1986). The federal government also supports research and development through tax subsidies. I.R.C. § 174 (1994); *see generally* Peter S. Arno & Michael H. Davis, *Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally Funded Research*, 75 TUL. L. REV. 631, 638 (2001).
[158] William H. Frist, *Federal Funding for Biomedical Research: Commitment and Benefits*, 287 JAMA 1722, 1724 (2002).

provided $26.4 billion for biomedical research, or 28% of the national total.[159] Similarly, in FY 2004, the NIH's $28 billion budget comprised about one third of national biomedical research spending.[160] While funding less aggregate biomedical research than private industry, the federal government actually funds more *basic* research, as opposed to applied research and development, than all private sources combined.[161] In 2004, 55% of NIH funds for research and development went to basic research.[162] According to its Roadmap for Medical Research, "[M]uch of NIH funding supports the exploration of fundamental biological mechanisms that would otherwise not be pursued due to the lack of market incentives."[163] This basic research, moreover, produces many research tools critical to further inquiry.

In addition to direct funding, the NIH also supports research by allowing grantees to patent taxpayer-financed inventions pursuant to the Bayh-Dole Act.[164] Prior to the Bayh-Dole Act, federal agencies possessed no uniform policy regarding the ownership of patents arising from taxpayer-funded ventures.[165] Some agencies took title to inventions while other agencies granted title to outside contractors and only retained a license for their own use.[166] Concerns

[159] Hamilton Moses III et al., *Financial Anatomy of Biomedical Research*, 294 JAMA 1333, 1335 (2005). As of 2002, the next largest federal sources of biomedical research funds were the Department of Defense ($1.2 billion), the Department of Agriculture ($0.5 billion), and the Department of Energy ($0.4 billion). *Id.*
[160] Elias A. Zerhouni, *US Biomedical Research: Basic, Translational, and Clinical Science*, 204 JAMA 1352, 1352 (2005).
[161] *See* Golden, *supra* note 12, at 139; Ronald L. Meeks, National Science Foundation, InfoBrief: Federal Agencies Supported R&D Grown Over the Period of FY 1994-2004, NSF 07-302 (revised), June 2007, at 1.
[162] Moses III et al., *supra* note 159, at 1338 table 4.
[163] NIH, Report to Congress on Affordability of Inventions and Products, July 2004, at 3 [hereinafter NIH, *Affordability of Inventions and Products*]. Gregory D. Graff et al., *The Public-Private Structure of Intellectual Property Ownership in Agricultural Biotechnology*, 21 NATURE BIOTECH. 989, 989 (2003); *see* Zerhouni, *supra* note 160, at 1355.
[164] Pub. L. No. 96-517, Sec. 6(a), 94 Stat. 3015, 3019-27 (1980) (codified as amended at 35 U.S.C. §§ 200-211). *See generally*, Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1691-1709 (1996) [hereinafter Eisenberg, *Public Research and Private Development*]; Arno & Davis, *supra* note 157, at 646-67.
[165] For a history of the Bayh-Dole Act and related legislation, see Eisenberg, *Public Research and Private Development*, *supra* note 164, at 1671-95; Ashley J. Stevens, *The Enactment of Bayh-Dole*, 29 J. TECH. TRANSFER 93, 93 (2004.
[166] Eisenberg, *Public Research and Private Development*, *supra* note 164, at 1677; *see* S. Rep. No. 96-480, at 2 (1979) (identifying at least 24 different patent policies among federal agencies).

grew that government-owned patents were stifling innovation because firms would not invest in developing inventions into commercial goods without having exclusive rights.[167] In order to put government-funded inventions to good use, and amid concerns over lagging economic competitiveness relative to Europe and Japan,[168] Congress passed the Bayh-Dole Act in 1980. The Act allowed and encouraged small businesses and non-profit organizations—including universities—to patent the results of government-sponsored research, provided that they satisfy certain statutorily defined conditions.[169] In a related vein, also in 1980, Congress passed the Stevenson-Wydler Technology Innovation Act, which required federal laboratories to take a more active role in transferring technology to private industry.[170]

The Bayh-Dole Act enables potentially significant market subsidies for research and development.[171] The act has led to an explosion of university patenting and has generated enormous income for some government contractors.[172] The act has also enhanced the commercialization of taxpayer-financed inventions, and *The Economist* called it "[p]ossibly the most inspired piece of legislation to be enacted in America over the past half-century."[173] Of course, the act has also attracted criticism for providing a double windfall to federal grantees,

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[167] In the 1970s, NASA had a commercialization rate of less than 1% for inventions under its free use policy, but 18-20% for inventions where contractors controlled patents. Aaron S. Kesselheim & Jerry Avorn, *University-based Science and Biotechnology Products*, 293 JAMA 850, 851 (2005).
[168] Timothy L. Faley & Michael Sharer, *Technology Transfer and Innovation: Reexamining and Broadening the Perspective of the Transfer of Discoveries Resulting from Government-Sponsored Research*, 3 COMP. TECH. TRANSFER & SOC'Y 109, 113 (2005); Clifton Leaf, *The Law of Unintended Consequences, Fortune*, Sept. 19, 2005, at .
[169] 35 U.S.C. §202. In 1984, President Reagan extended the policy to large business contractors, and Congress enacted this extension the same year. *See* Eisenberg, *Public Research and Private Development, supra* note , at 1694; Memorandum to the Heads of Executive Departments and Agencies: Government Patent Policy, Pub. Papers 248 (Feb. 18, 1983); S. Rep. No. 98-662, at 2 (1984), reprinted in 1984 U.S.C.A.N.N. 5799, 5800; Trademark Clarification Act of 1984, § 501(13), 35 U.S.C. § 210(c).
[170] Pub. L. 96-480, 94 Stat. 2311 (1980) (codified as amended at 15 U.S.C. §§ 3701-3717).
[171] *See* Michael S. Mireles, Jr., *States as Innovation System Laboratories: California, Patents, and Stem Cell Technology*, 28 CARDOZO L. REV. 1133, 1147-49 (2006) [hereinafter Mireles, *States as Innovation System Laboratories*].
[172] *See infra* Part IV.C.
[173] *Innovation's Golden Goose*, The Economist, Dec. 14, 2002, at 365.

who receive both taxpayer funds as well as patents on resulting inventions.[174] Nevertheless, under the current quid pro quo of government contracting, grant recipients stand to benefit substantially from patenting taxpayer-financed inventions.

2. Normative and Policy Concerns in Federal Support for Basic Biomedical Research

While the NIH provides enormous financial support for biomedical research, it does not do so primarily to make money. The NIH defines its mission as "science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy life and reduce the burdens of illness and disability."[175] While one of the goals of the NIH is to enhance the nation's economic well-being and ensure a high return on public investment in research,[176] the agency does not seek to maximize short-term profits. Vannevar Bush, the original architect of U.S. research policy under President Franklin D. Roosevelt, envisioned the federal government taking an active role in creating a scientific "reservoir of knowledge."[177] This reservoir, the prototypical upstream resource, would then facilitate myriad downstream applications promoting scientific, economic, and military development. Similarly, the NIH funds research to create a knowledge base for life-enhancing applications, not for direct institutional monetary gain.[178] Access is critical to achieving these

[174] *See* Eisenberg, *Public Research and Private Development*, *supra* note 164, at 1666; H.R. Rep. No. 96-1307, pt. 1 at 29-32, reprinted in 1980 U.S.C.C.A.C. 6487, 6487-91 (statement of Rep. Jack Brooks); *see also* Mireles, *States as Innovation System Laboratories*, *supra* note 171, at 1149-52; William A. Sage, *Funding Fairness: Public Health Investment, Proprietary Rights and Access to Health Care Technology*, 82 VA. L. REV. 1737, 1741 (1996).
[175] About NIH, available at http://www.nih.gov/about/index.html#mission.
[176] About NIH, available at http://www.nih.gov/about/index.html#mission.; *see* Faley & Sharer, *supra* note 168, at 112; Narin et al., supra note 83, at 317.
[177] Vannevar Bush, Science: The Endless Frontier, available at http://www.nsf.gov/about/history/vbush1945.htm.; Faley & Sharer, *supra* note 91, at 111.
[178] *See* National Institutes of Health, Review Criteria for and Rating of Unsolicited Research Grant and Other Applications (June 27, 1997), at http://grants.nih.gov/grants/guide/notice-files/not97-010.html.

goals, and in both policy and regulations, the NIH expresses access norms that directly contravene the exclusivity associated with private rent seeking.[179]

Similarly, while the Bayh-Dole Act provides valuable consideration to federal grantees, funding agencies do not expect any direct financial return from this support. Instead, a strong norm of access to and utilization of taxpayer-funded inventions runs throughout the statute. According to the Act, "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."[180] Furthermore, the Act seeks "to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise *without unduly encumbering future research and discovery*."[181] Indeed, the possibility that taxpayer-financed patents could stymie research seems antithetical to the Bayh-Dole Act. To advance its policy objectives, the act ensures that the government "obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions."[182]

Several provisions of the Bayh-Dole Act define these government rights. First, under 35 U.S.C. § 202(a)(ii), a funding agency can restrict patenting by a grantee in "exceptional circumstances" when the agency determines that withholding title to the invention "will better promote the policy and goals" of the act.[183] Second, the federal government retains a paid-up license to practice, or have practiced on its behalf, any invention that a contractor patents

[179] As an example of these norms, in 1994 the NIH voluntarily withdrew patent applications on expressed sequence tags (ESTs) because of their research tool character. Steven M. Ferguson, *Licensing and Distribution of Research Tools: National Institutes of Health Perspective,* 41 J. CLIN. PHARMACOL. 110S, 111S (2001).
[180] 35 U.S.C. § 200.
[181] 35 U.S.C. § 200 (emphasis added).
[182] 35 U.S.C. § 200.
[183] 35 U.S.C. § 202(a)(ii).

pursuant to the act.[184] Third, the federal government retains so-called "march-in rights" to compulsorily license inventions covered by the act if any of four statutorily-defined criteria are met.[185] Thus, in exchange for providing patent rights to taxpayer-funded inventions, funding agencies like the NIH retain formal claims on those inventions. Significantly, these rights apply not only to the government contractor that patents the invention, such as a university, but to all downstream licensees of the "subject invention" as well.[186]

3. Leveraging Support and Norms to Compel Access to Patented Research Tools

The NIH is leveraging federal funds to help address the problem of patent holdup. In 1999, the NIH issued principles and guidelines for the patenting and licensing of NIH-funded research tools by federal grant recipients ("Principles and Guidelines").[187] These Principles and Guidelines specifically promote wide dissemination of NIH-funded research resources.[188] Notably, the Principles and Guidelines distinguish between "internal use by non-profit

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[184] 35 U.S.C. § 202(c)(4).

[185] 35 U.S.C. § 203. The Bayh-Dole Act permits the federal government to issue a nonexclusive, partially exclusive, or exclusive license to a third party if the relevant federal agency determines that:

> (1) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;
> (2) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;
> (3) action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or
> (4) action is necessary because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204.

Id.

[186] *See* 35 U.S.C. § 201(e); Jaffe, *supra* note 11, at 533 ("[T]he rules governing the patentability of federally supported research essentially control university patenting.").

[187] NIH, *Principles and Guidelines*, 64 Fed. Reg. 72,090; *see* Josephine Johnston & Angela A. Wasunna, *Patents, Biomedical Research, and Treatments: Examining Concerns, Canvassing Solutions*, HASTINGS CENTER REPORT, Jan.-Feb. 2007, at s11; Pressman et al., *supra* note 19, at 32.

[188] NIH, *Principles and Guidelines*, 64 Fed. Reg. at 72,092-93 ("Progress in science depends upon prompt access to the unique research resources that arise from biomedical research laboratories through government, academia, and industry."). For a partial list of NIH-funded research tools, see Ferguson, *supra* note 179, at 111s.

institutions" and "commercial development and sale or provision of services," which may warrant some degree of exclusivity.[189] The guidelines recommend transferring patented research tools to non-profits on terms no more onerous than the Uniform Biological Material Transfer Agreement (UBMTA),[190] a standardized process for sharing biological materials developed by the NIH.[191] Furthermore, they recommend transferring NIH-funded research tools to for-profit entities "with the fewest encumbrances possible."[192] Notably, these Principles and Guidelines reflect a shift away from viewing patents as simple rights to exclude and recast them as governance regimes of selective access and exclusivity.[193]

These Principles and Guidelines also seek to implement the Bayh-Dole Act's[194] goal of maximizing utilization of research tools.[195] For assets primarily useful as research tools, "inappropriate licensing practices are likely to thwart rather than promote utilization, commercialization and public availability of the invention."[196] For research tools not requiring additional development, the Principles and Guidelines recommend "publication, deposit in an appropriate databank, widespread non-exclusive licensing or any number of dissemination techniques."[197] While exclusive licenses may be appropriate for additional commercial development, they should ultimately aim for widespread dissemination of a resulting product.[198]

[189] *Id*. at 72,093.
[190] National Institutes of Health, Uniform Biological Material Transfer Agreement: Discussion of Comments Received; Publication of Final Format of the Agreement, 60 Fed. Reg. 12,771 (March 8, 1995) [hereinafter NIH, *UBMTA*].
[191] NIH, *Principles and Guidelines*, 64 Fed. Reg. at 72,094.
[192] *Id*. at 72,094
[193] *See* Smith, *supra* note 35.
[194] NIH, *Principles and Guidelines*, 64 Fed. Reg. at 72,092.
[195] Ferguson, *supra* note 179, at 111S.
[196] NIH, *Principles and Guidelines*, 64 Fed. Reg. at 72,093.
[197] *Id*. at 72,093.
[198] *Id*. at 72,093.

While not directly enforceable, the NIH's funding power ensures that these Principles and Guidelines have "real teeth."[199] The NIH explicitly considers compliance with the guidelines in awarding grants.[200] Although the NIH may not regulate the patenting practices of federal grantees,[201] the NIH has incorporated these guidelines in reviewing individual applications.[202] The possibility of denying funding is clearly present, and operates as a strong incentive to comply.[203] For example, anecdotal evidence suggests that the "problematic" patent policies of a private firm partnering with the Texas Institute for Genomic Medicine contributed to the NIH's denial of federal research funds.[204] While commentators caution that the NIH may be exceeding its authority under the Bayh-Dole Act in "enforcing" these guidelines,[205] the NIH suggests that widespread noncompliance may spur regulatory or statutory intervention.[206] Indeed, the threat of invoking government rights under the Bayh-Dole Act has in some cases spurred compliance with non-binding policy guidelines.[207]

Other NIH policies also encourage the widespread availability of taxpayer-funded research resources.[208] In 2005, the NIH issued guidelines for licensing genomic inventions.[209] According to these "Best Practices," "NIH considers the sharing of . . . unique research resources

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[199] Mauricio A. Flores, *Taking the Profit Out of Biomedical Research Tools*, 17 NATURE BIOTECH. 819, 820 (1999).
[200] Pressman et al., *supra* note 19, at 32.
[201] Rai & Eisenberg, *supra* note 9, at 308. Under the Bayh-Dole Act, only the Secretary of Commerce may promulgate general regulations for licensing federally owned inventions. 35 U.S.C. §208. The NIH may only make such determinations in the context of individual grants. *See* Arti K. Rai & Rebecca S. Eisenberg, The Public and the Private in Biopharmaceutical Research, at 172, available at http://www.law.duke.edu/pd/papers/raieisen.pdf
[202] Flores, *supra* note 199, at 820; David Malakoff, *NIH Roils Academe with Advice on Licensing DNA Patents*, 303 SCIENCE 1757, 58 (2004).
[203] Flores, supra note 23, at 820.
[204] D.G., *NIH Knocks Out Key Mouse House*, 312 SCIENCE 1863, 1863 (2006).
[205] Rai & Eisenberg, supra note 9, at 308-09.
[206] NIH, *Principles and Guidelines*, 64 Fed. Reg. at 72,090; Ferguson, *supra* note 179, at 112S; cf. National Institutes of Health, National Human Genome Research Institute, NHGRI Policy Regarding Intellectual Property of Human Genomic Sequence, Apr. 9, 1996, at http://www.genome.gov/10000926 [hereinafter NHGRI, *Policy Regarding Intellectual Property of Human Genomic Sequence*].
[207] *See infra* notes 222-229
[208] *See, e.g.*, NIH, NIH Policy on Sharing of Model Organisms for Biomedical Research, NOT-OD-04-042, May 7, 2004, available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html.
[209] NIH, Best Practices for the Licensing of Genomic Inventions: Final Notice, 70 Fed. Reg. 18413, 18,415 (April 11, 2005).

(also called research tools) an important means to enhance the value of NIH-sponsored research."[210] These guidelines parallel practices at the NIH's own Office of Technology Transfer and recommend nonexclusively licensing genomic inventions. Significantly, the guidelines recognize the appropriateness of exclusive licensing when necessary to facilitate post-invention commercialization.[211]

In addition to issuing guidelines, the NIH has actively negotiated enhanced access to specific taxpayer-financed research tools. In the late 1990s, the University of Wisconsin's patents on extracted and purified human embryonic stem cells[212] raised concerns that exclusive rights would inhibit scientific investigations relying on these basic research tools.[213] To address these concerns, in 2001 the Public Health Service (PHS)[214] entered into a Memorandum of Understanding (MOU) with the WiCell Research Institute, a University of Wisconsin affiliate holding licenses to the stem cell patents.[215] Under the MOU, WiCell agreed to provide a research license for Wisconsin Patent Rights at low cost to PHS-supported researchers. Referring to the Bayh-Dole Act, the MOU states that "PHS funded the primate research studies at the University of Wisconsin – Madison that led to certain discoveries claimed in Wisconsin Patent Rights and therefore the Government has certain use and other rights to the intellectual property comprising the Wisconsin Patent Rights granted by law and regulation."[216] The MOU

[210] NIH, NIH Grants Policy Statement 115 (2003).
[211] Pressman et al., *supra* note 19, at 32.
[212] U.S. Patent No. 5,843,780 (filed Jan. 18, 1996); U.S. Patent No. 6,200,806 (filed June 26, 1998); *see* Lee, *Inverting the Logic of Scientific Discovery*, *supra* note 1, at 89-92.
[213] *See generally* Hazuka, *supra* note 1. These concerns intensified upon President Bush's partial ban on federal funds for human embryonic stem cell research.
[214] The PHS is the umbrella agency housing the NIH.
[215] Memorandum of Understanding Between WiCell Research Institute, Inc. and Public Health Service, U.S. Department of Health and Human Services 5 (Sept. 5, 2001), *available at* http://ott.od.nih.gov/pdfs/WiCellMOUhuman.pdf [hereinafter *WiCell MOU*] .
[216] *Id*. Some of the research was funded by Geron, a private biotechnology company, which received several commercial licenses for the patented human embryonic stem cells.

not only benefits NIH-funded scientists, but also requires WiCell to provide licenses to all non-profit organizations on similar terms.[217]

A historical example predating the Bayh-Dole Act further reveals the NIH's potential power to compel wide access to taxpayer-funded, grantee-patented research tools. In 1983, Richard Axel and his colleagues at Columbia University patented foundational processes and products related to inserting genes in mammalian cells; these inventions constitute critical research tools.[218] The NIH partially funded Axel's research, but Columbia's patent application preceded the Bayh-Dole Act by several months.[219] Accordingly, pursuant to the pre-Bayh-Dole regime, the NIH assigned the patent to Columbia on condition that the university had to license it widely and nonexclusively[220] and that it would not charge "unreasonable" royalties.[221]

At the far end of the spectrum, the NIH has also cited the "exceptional circumstances" provision of the Bayh-Dole Act to discourage patenting of key research resources. For example, as part of a Request for Applications, the National Human Genome Research Institute ("NHGRI"), a branch of the NIH, required applicants to agree to rapidly release human genome data to public databases as a condition of receiving funds.[222] NHGRI explicitly discouraged grantees from patenting raw human genomic DNA sequences,[223] which it believed lacked the specific utility to warrant patentability.[224] NHGRI stated that if grantees did in fact patent DNA

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[217] *Id*.
[218] U.S. Patent No. 4,399,216; Ken Howard, *Biotechs Sue Columbia over Fourth Axel Patent*, 21 NATURE BIOTECH. 955, 955 (2003).
[219] Bernard Wysocki Jr., *Columbia's Pursuit of Patent Riches Angers Companies*, WALL ST. J., Dec. 21, 2004, at A1.
[220] *Id*.
[221] *Id*.
[222] *See* Gregory A. Petsko, *Who Owns the Data?*, 6 GENOME BIOLOGY 107.1, 107.1 (2005); Human Genome Project Information at http://www.ornl.gov/sci/techresources/Human_Genome/home.shtml; NHGRI, *Policy Regarding Intellectual Property of Human Genomic Sequence*, *supra* note 206.
[223] Eliot Marshall, *Genome Researchers Take the Pledge*, 272 SCIENCE 477, (1996) [hereinafter Marshall, *Genome Researchers Take the Pledge*].
[224] NHGRI, *Policy Regarding Intellectual Property of Human Genomic Sequence*, *supra* note 206.

sequences, it would consider invoking the exceptional circumstances provision of the Bayh-Dole Act[225] to prohibit such practices.[226]

The NIH explicitly invoked the exceptional circumstances provision in an initiative to sequence the mouse genome, develop new model transgenic animals, and characterize these animals' phenotypes.[227] The NIH stated it would rely on this provision to prevent project grantees from patenting their results.[228] This approach was aimed at ensuring that the results of NIH mutagenesis initiatives would be rapidly and freely accessible to the scientific community.[229]

While demonstrating the potential of the Bayh-Dole Act to liberalize access to government-funded research tools, these examples are far from commonplace. The Bayh-Dole Act establishes an elaborate administrative procedure for challenging determinations of exceptional circumstances, including a right of appeal to the Court of Federal Claims.[230] As Professors Arti Rai and Rebecca Eisenberg argue, relaxing these administrative burdens could enhance the effectiveness of the exceptional circumstances provision.[231] Similarly, while the Act's march-in rights provide another potential route for consideration-based patent regulation, the NIH has never used them. In theory, the NIH could invoke these rights to compulsorily license patented research tools that were being underutilized. However, since Bayh-Dole's enactment, the NIH has considered only a handful of petitions to exercise march-in rights,

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[225] *See infra* Part IV.A.2.b.
[226] NHGRI, *Policy Regarding Intellectual Property of Human Genomic Sequence*, *supra* note 206.
[227] *See generally* NIH, Trans-NIH Mouse Initiatives, at http://www.nih.gov/science/models/mouse/; Steven O. Moldin et al., *Trans-NIH Neuroscience Initiatives on Mouse Phenotyping and Mutagenesis*, 12 MAMMALIAN GENOME 575 (2001).
[228] Eliot Marshall, *A Deluge of Patents Creates Hassles for Research*, 288 SCIENCE 255, (2000); NIH, Mouse Mutagenesis and Phenotype: Developmental Defects, RFA: HD-99-007, March 31, 1999, available at http://grants.nih.gov/grants/guide/rfa-files/RFA-HD-99-007.html ("NIH expects to make a Determination of Exceptional Circumstances (DEC) to eliminate the potential for patents on mutant mice, embryos, and sperm.").
[229] Moldin, *supra* note 227, at 580.
[230] Rai & Eisenberg, *supra* note 9, at 293; see 35 U.S.C. § 203(2); *see also* 35 U.S.C. § 202(b)(4); 37 C.F.R. § 401.4.
[231] Rai & Eisenberg, *supra* note 9, at 310.

rejecting all of them.[232] Again, as Professors Rai and Eisenberg argue, a chief difficulty in exercising these rights is that they can only take effect after elaborate administrative proceedings and exhaustion of court appeals.[233] Reforming this process could enhance the NIH's use of march-in rights to compel wide licensing of federally-funded research tools.[234]

Turning to its own internal research, the NIH's Intramural Research Tool Distribution Policy requires NIH scientists to make their research results widely available to the scientific community. Furthermore, when the NIH transfers patented research tools to private parties for commercial development, it reserves the right to make the tool widely available to others for research purposes.[235] The NIH observes that the success of this internal program could also extend to all federally funded research.[236]

4. Analysis

Through leveraging its enormous support for biomedical research, the NIH is creating, through contracts, a kind of noncommercial research exception to patent infringement that public law initiatives have not established. This consideration-based patent regulation has been instrumental in widening access to key resources such as human embryonic stem cells and raw

[232] NIH, Determination in the Case of Petition of CellPro, Inc., (Aug. 1, 1997), *available at* http://www.nih.gov/icd/od/foia/cellpro/pdfs/foia_cellpro39.pdf; NIH, In the Case of Norvir (July 2, 2004), *available at* http://www.essentialinventions.org/legal/norvir/norvir-29jan04petition.pdf; NIH, In the Case of Xatalan, Manufactured by Pfizer, Inc., Sept. 17, 2004; *see* Barbara M. McGarey and Annette C. Levey, *Patents, Products, and Public Health: An Analysis of the CellPro March-In Petition*, 14 BERKELEY TECH. L. J. 1095 (1999); Mireles, *States as Innovation System Laboratories*, *supra* note 171, at 1156-57; O'Connor, *supra* note 121, at 700-03.
[233] Rai & Eisenberg, *supra* note 9, at 294; 35 U.S.C. § 203(2); 37 C.F.R. § 401.6.
[234] Rai & Eisenberg, *supra* note 9, at .
[235] Public Health Service, Patent License Agreement – *Exclusive* 5, available at http://ott.od.nih.gov/docs/PHS%20Patent%20License-Exclusive-model%20102005.DOC.

The NIH has even negotiated greater access to *privately-developed* research tools, such as DuPont's patented Cre-*loxP* and OncoMouse technologies. *See generally* Eliot Marshall, *Sharing Reagents: NIH, DuPont Declare Truce in Mouse War*, 281 SCIENCE 1261, (1998); Eliot Marshall, *NIH Cuts Deal on Use of OncoMouse*, 287 SCIENCE 567, 567 (2000).
[236] Ferguson, *supra* note 179, at 110S

genomic DNA. Given the NIH's dominant position in the political economy of basic biomedical research funding, the potential size of a contractually-created research commons is substantial.

Substantively, this leverage allows the NIH to act on norms that diverge sharply from that of the classic patentee or research financier. Rather than favoring exclusivity and profit maximization, the NIH has a "strong interest" in the availability of patented research tools.[237] The NIH has exploited its funding power to advance this objective in transactions with grant recipients. The Bayh-Dole Act also represents a vehicle for advancing access norms. Here, money and patent rights provide "normative portals" for the NIH to promote the goal of open science in an increasingly proprietary environment.

Procedurally, these efforts reflect consideration-based patent regulation rather than a traditional public law model for advancing patent policy. The NIH embeds expectations of access to research tools in quid pro quos with individual grantees; the NIH's Principles and Guidelines are only relevant to federal grant recipients, not to patentees in general. Sidestepping constrained judicial interpretations of an experimental use exception and difficult congressional attempts to amend the Patent Act, the NIH is using its funding power to informally "contract" for a noncommercial research exception to patent infringement. This approach properly aligns incentives: the NIH only demands access to a patented research tool where taxpayers have satisfied the incentive to invent it. Ultimately, the "NIH has decided to take matters into its own hands" to address patent holdup.[238]

Although the Bayh-Dole Act is a federal statute, it also reflects the "private law," quid pro quo model for creating a biomedical research commons. The government rights established by the Bayh-Dole Act do not apply to all patented inventions, but only arise in the context of a

[237] Ferguson, *supra* note 179, at 110S.
[238] Golden, *supra* note 12, at 176.

particular bargain whereby contractors patent taxpayer-funded inventions. While the NIH rarely exercises its Bayh-Dole rights, they provide an influential baseline for the NIH to negotiate informal access to patented research tools. In conjunction with the Principles and Guidelines, these rights have the potential to establish a flexible system by which the NIH can distinguish among various taxpayer-financed inventions, prohibiting patenting of a few while imposing a noncommercial research exception for the rest. As others have argued, reforms to the Bayh-Dole Act's elaborate administrative procedures could significantly enhance the NIH's ability to regulate the patenting and licensing of taxpayer-funded inventions.[239]

B. State Governments

In contrast to the federal government, the State of California is taking a much more aggressive approach to consideration-based patent regulation; it explicitly conditions research funds on the requirement of sharing resulting patented inventions liberally with noncommercial researchers. Notably, however, California's research commons is limited to that state.

1. California's Funding of Human Embryonic Stem Cell Research

While state governments have historically provided relatively little funding for basic research, the emergence of state human embryonic stem cell research initiatives promises to change this landscape considerably. In 2003, state governments accounted for only 5% of

[239] Rai & Eisenberg, *supra* note 9, at .

overall biomedical research funding.[240] However, the federal government's ban on funding research on human embryonic stem cells derived after August 9, 2001[241] has motivated several state initiatives to fill this void.[242] As of January 2008, California, Connecticut, Illinois, Indiana, Maryland, Massachusetts, New Jersey, Ohio, New York, Washington, Wisconsin, and Virginia have authorized funds for human embryonic stem cell research.[243] Notwithstanding recent discoveries that adult stem cells can be reprogrammed to behave like embryonic stem cells,[244] many researchers still feel that embryonic stem cells, which are the targets of these state initiatives, remain the "gold standard" for stem cell research.[245]

This Subpart focuses on California's stem cell initiative because: 1) it vastly exceeds the size of other state initiatives;[246] 2) it is relatively mature and likely to be a model for other state initiatives; and 3) the high concentration of biomedical research in California means that state funding could significantly impact this field. In 2004, California voters resoundingly passed Proposition 71, which authorized $3 billion in state bond funds for stem cell research over a ten-

[240] Moses III et al., *supra* note 159, at 1335. Significantly, these figures do not directly capture funds from tobacco settlements or California's stem cell initiative. *Id*. at 1334; *see* Mireles, *States as Innovation System Laboratories*, *supra* note 171, at 1135 n.3 (collecting state statutes related to funding research).
[241] President George W. Bush, President Discusses Stem Cell Research (Aug. 9, 2001), http://www.whitehouse.gov/news/releases/2001/08/20010809-2.html; NIH, NIH Statement on the President's Stem Cell Address (Aug. 9, 2001), at http://www.nih.gov/news/pr/aug2001/od-09.htm; NIH, Federal Policy, at http://stemcells.nih.gov/policy/.
[242] *See, e.g.*, Jennifer L. Enmon, Note, *Stem Cell Research: Is the Law Preventing Progress?*, 2002 UTAH L. REV. 621, 647 (2002). While President Bush noted that 60 suitable cell lines were already in existence, these early lines were susceptible to defects and contamination from mouse feeder cells. Liza Gross, *Stem Cell Promise, Interrupted: How Long Do US Researchers Have to Wait?*, 5 PLOS BIOLOGY 6, 7 (2007); Joanna K. Sax, *The States "Race" with the Federal Government for Stem Cell Research*, 15 ANNALS HEALTH L. 1, 18 (2006). As of March 2007, the NIH Human Embryonic Stem Cell Registry contained 21 cell lines. NIH, Frequently Asked Questions (FAQs), at http://stemcells.nih.gov/info/faqs.asp.
[243] *See* Joe Palca, *States Take Lead in Funding Stem-Cell Research*, NPR, Apr. 1, 2007, at http://www.npr.org/templates/story/story.php?storyId=9244363; see generally National Conference of State Legislatures, Stem Cell Research, at http://ncsl.org/programs/health/genetics/embfet.htm; Lori Gruen & Laura Grabel, *Concise Review: Scientific and Ethical Roadblocks to Human Embryonic Stem Cell Therapy*, 24 STEM CELLS 2162 (2006); Susan Okie, *Stem-Cell Research—Signposts and Roadblocks*, 353 N. ENGL. J. MED. 1 (2005).
[244] Nicholas Wade, *Biologists Make Skin Cells Work Like Stem Cells*, N.Y. TIMES, June 7, 2007, at .
[245] Colin Nickerson, *Caution Urged in New Method for Stem Cells*, BOST. GLOBE, Dec. 17, 2007, at . Reprogramming these cells involves retroviruses, which may cause cancer.
[246] See National Conference of State Legislatures, *supra* note 243.

year period.[247] To administer the grants, Proposition 71 established the California Institute for Regenerative Medicine ("CIRM"),[248] a state agency governed by a 29-member Independent Citizens Oversight Committee ("ICOC") comprised of representatives from academia, government, business, and disease advocacy groups.[249]

2. Access Norms and Policy Objectives in California's Funding of Human Embryonic Stem Cell Research

Not surprisingly, CIRM does not fund biomedical research with the primary aim of making money off of it. According to Proposition 71, the overriding purpose of CIRM is to fund stem cell research "to realize therapies, protocols, and/or substantial mitigation of, major diseases, injuries, and orphan diseases."[250] Proposition 71 identifies several additional objectives, including improving California's health care system, reducing health care costs, and generating revenue from sponsored research.[251] Most relevant for our purposes, Proposition 71 states:

> The ICOC shall establish standards that require that all grants and loan awards be subject to intellectual property agreements that balance the opportunity of the State of California to benefit from the patents, royalties, and licenses that result from basic research, therapy development, and clinical trials with the need to assure that essential medical research is not unreasonably hindered by the intellectual property agreements.[252]

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[247] The ballot initiative passed 59 percent to 41 percent. Ceci Connolly, *Calif. Stem Cell Initiative Could Backfire Nationally*, WASH. POST, Nov. 14, 2004, at A15. *See generally* RUSSELL KOROBKIN, STEM CELL CENTURY 126-52 (2008); O'Connor, *supra* note 121, at 674-79; Molly Silfen, Note, *How Will California's Funding of Stem Cell Research Impact Innovation? Recommendations for an Intellectual Property Policy*, 18 HARV. J.L. & TECH. 459, 468-71 (2005); Connie Bruck, *Hollywood Science: Should a Ballot Initiative Determine the Fate of Stem-Cell Research*, NEW YORKER, Oct. 18 2004, at . As of June 28, 2008, CIRM had committed over $554 million in grants. *See* http://www.cirm.ca.gov/info/grants.asp.

[248] California Secretary of State, Text of Proposed Laws – Proposition 71, in California Official Voter Information Guide 147, 147 (2004), http://www.cirm.ca.gov/pdf/prop71.pdf.

[249] *Id*.

[250] *Id*.

[251] *Id*.

[252] *Id*. at 149.

Unlike the NIH, CIRM takes a financial stake in funded inventions. Nevertheless, CIRM seeks to ensure that patented, state-funded research tools do not inhibit scientific inquiry. These objectives are illustrated in CIRM's intellectual property regulations, which distinguish between non-profit[253] and for-profit grantees.[254]

3. Leveraging State Funds to Enhance Access to Patented Research Tools

While CIRM has adopted a Bayh-Dole model allowing grantees to patent state-financed inventions,[255] it explicitly limits their rights to ensure that patents do not impede biomedical research. CIRM regulations require that non-profit grantees must provide any state-financed, patented inventions to other non-profit research institutions at reasonable cost. Unlike the NIH's Principles and Guidelines, these regulations are legally enforceable. Non-profit grantees are required to reserve a basic research exception when licensing CIRM-funded patented inventions to third parties.[256] Furthermore, non-profit grantees must agree to make all such inventions readily accessible to California research institutions for noncommercial purposes.[257] CIRM regulations further promote the availability of funded inventions by stating that non-profit "[g]rantee organizations shall negotiate non-exclusive licenses whenever possible."[258]

[253] 17 Cal. Code Reg. § 100300-100310.
[254] 17 Cal. Code Reg. § 100400-100410.
[255] CIRM, Non-Profit Policy, *supra* note 4, at 2; CIRM, For-Profit Policy, *supra* note 4, at 4, 29; see Mireles, *States as Innovation System Laboratories*, supra note 171, at 1181-86.
[256] 17 Cal. Code Regs. § 100306(a); CIRM, Non-Profit Policy, *supra* note 4, at 18; see Mireles, *States as Innovation System Laboratories*, supra note 171, at 1190, 1199-1200.
[257] 17 Cal. Code Regs. § 100306(a); CIRM, NON-PROFIT POLICY, *supra* note 4, at 18, 37.
[258] 17 Cal. Code Regs. § 100306(b).

In addition, CIRM also mandates that non-profit grantees must make "biomedical materials"[259] described in academic publications widely available. Non-profit grantees must share such materials on reasonable terms within 60 days of a request to use them for research purposes.[260] Finally, CIRM maintains march-in rights to compulsorily license any CIRM-funded invention based on certain codified criteria.[261] March-in rights are available, for example, "[t]o meet requirements of public use."[262] Notably, however, CIRM's march-in rights lack the cumbersome administrative review provisions of the Bayh-Dole Act.[263] Ultimately, in the quid pro quo of accepting state funds, grantees must also accept limitations on their patent rights.[264]

While CIRM maintains different policies for for-profit grantees, they also promote widely disseminating state-funded research tools. Notably, the requirement of making patented inventions available for noncommercial research does not apply to for-profit grantees. Furthermore, CIRM does not require for-profit grantees to license their inventions non-exclusively. However, CIRM regulations still favor nonexclusive licensing, stating, "A [for-profit] Grantee may negotiate an Exclusive License if exclusivity is reasonably believed by Grantee to be an economic incentive necessary to achieve commercial development and availability of the invention."[265]

As with non-profit grantees, for-profit grantees must share CIRM-funded biomedical resources described in a publication within 60 days of a request to use them for research

[259] 17 Cal Code Regs. § 100301(d). CIRM's definition of "biomedical materials" is largely coextensive with the NIH's definition of research tools.
[260] CIRM, NON-PROFIT POLICY, *supra* note 4, at 28-31; 17 Cal. Code. Reg. § 100304 ; see Mireles, *States as Innovation System Laboratories*, supra note 171, at 1188-89.
[261] CIRM, NON-PROFIT POLICY, *supra* note 4, at 2, 22; 17 Cal. Code. Reg. § 100310 (2007).
[262] 17 Cal. Code Regs. § 100310.
[263] *See* Mireles, *States as Innovation System Laboratories*, supra note 171, at 1191.
[264] CIRM has also issued non-binding policy statements discouraging patenting of certain research tools such as transgenic mice, receptors, cell lines, hypothetical proteins, random single nucleotide polymorphisms (SNPs), halotypes, and proteins that have only research functions. CIRM, NON-PROFIT POLICY, *supra* note 4, at 32, 35.
[265] 17 Cal. Code Regs. § 100405(c).

purposes.[266] However, such sharing is not required if "a sharing request is in direct conflict with the business of the Grantee."[267] Finally, CIRM maintains march-in rights for inventions developed by for-profit entities with state funds.[268] Again, CIRM may exercise these rights if, among other reasons, "the Grantee or its exclusive licensee has failed to satisfy requirements for public use."[269]

4. Analysis

Exceeding the efforts of the NIH, CIRM explicitly requires broad access to state-funded, grantee-patented research tools. Although patent law and policy is a traditionally federal domain, CIRM's regulations reveal that states may serve as important policy actors in consideration-based patent regulation. Notwithstanding CIRM's financial interest in sponsored research, CIRM's policies reveal a commitment to ensuring the wide availability of state-funded technologies for research purposes.

At a mechanistic level, although CIRM's regulations have the force of law, they are conceptually couched in a contractual quid pro quo. CIRM's regulations explicitly state, "By accepting a CIRM grant award, the grantee agrees to comply with the provisions of these regulations."[270] Clearly, California could not enact a noncommercial research exception to patent infringement for inventions in that state; federal patent law would preempt such a

[266] CIRM, NON-PROFIT POLICY, *supra* note 4, at 28-31; CIRM, FOR-PROFIT POLICY, *supra* note 4, at 38; 17 Cal. Code. Reg. § 100304 (2007); 17 Cal. Code Reg. § 100404 (2008); see Mireles, *States as Innovation System Laboratories*, supra note 171, at 1188-89.
[267] 17 Cal. Code Regs. § 100404(c)(2).
[268] 17 Cal. Code Regs. § 100410.
[269] 17 Cal. Code Regs. § 100410(b)(3).
[270] 17 Cal. Code Regs. § 100300 (applying to non-profit grantees); 17 Cal. Code Regs. § 100400 (applying virtually identical language to for-profit grantees).

statute.[271] However, as a market participant, CIRM is free to place conditions on its funds to achieve a similar result with its grantees.

CIRM's intellectual property policies reveal several of the promises of consideration-based patent regulation. In the absence of a robust experimental use exception to patent infringement, CIRM is creating one through contract. Unlike NIH policy guidance, CIRM's regulations are directly enforceable by law. The targeted, context specific nature of consideration-based patent regulation also offers advantages relative to broad-brushed approaches to simply eliminate patents on research tools. CIRM's regulations, for example, distinguish between noncommercial research use and commercial sale of patented assets, allowing context-specific exclusivity of the latter to encourage commercialization.

However, CIRM's regulations also reveal several limitations of consideration-based patent regulation. While such regulation relies on institutions privileging access over exclusivity, CIRM takes a financial stake in funded research, thus generating potential conflicts of interest. Furthermore, while CIRM strictly distinguishes between for-profit and non-profit grantees, there may be situations where even for-profit grantees should be compelled to make patented inventions available for noncommercial research purposes. CIRM's approach also illustrates the possibility of self-dealing inherent in a contractually-created research commons. While science is universal, jurisdiction is not. CIRM only requires non-profit grant recipients to provide patented research tools to institutions located in California. This preference may exacerbate a balkanization of science that has helped California draw resources and talent away from other states; such consolidation is anticompetitive and may undermine the interests of the

[271] *See generally*, Bonito Boats Inc. v. Thunder Craft Boats, Inc. 489 U.S. 141, 164-68 (1989); Compco Corp. v. Day-Brite Lighting Inc., 376 US. 234, 237 (1964); Sears, Roebuck & Co v. Stiffel Co., 376 U.S. 225, 228-31 (1964); Mark A. Lemley, *Beyond Preemption, The Law and Policy of Intellectual Property Licensing*, 87 CAL. L. REV. 111, 138-39 (1999); Keith Aoki, *Balancing Act: Reflections on Justice O'Connor's Intellectual Property Jurisprudence*, 44 HOUS. L. REV. 965, 976-80 (2007).

national scientific community as a whole.[272] Expanding the scope of reserved research rights to *all* non-profit institutions would enhance the effectiveness of this state-funded research commons.

C. Universities

Unlike funding agencies such as the NIH and CIRM, universities are particularly critical to contractually creating a biomedical research commons because they actually hold a substantial number of patents. Increasingly, universities are maintaining the wide availability of such resources for noncommercial research when transferring technology to the private sector. Expanding these practices promises significant gains.[273]

1. University Contributions to Basic Biomedical Research

Universities play a predominant role in conducting basic biomedical research.[274] In 2002, universities and colleges spent $19.6 billion on biomedical research.[275] Eighty percent of the NIH's $28 billion in annual expenditures for medical research goes to more than 325,000 researchers at over 3,000 universities, medical schools, and other research institutions.[276] Unlike commercial firms, which tend to focus on applied research and development, universities

[272] *See* O'Connor, *supra* note 121, at 679; Sax, *supra* note 149, at 30-31; *cf.* Rebecca S. Eisenberg & Arti K. Rai, *Harnessing and Sharing the Benefits of State-Sponsored Research: Intellectual Property Rights and Data Sharing in California's Stem Cell Initiative*, 21 BERKELEY TECH. L.J. 1187, 1198 (2006).
[273] Nelson, *supra* note 56 at 467.
[274] Amanda L. Brewster et al., *Facilitating Humanitarian Access to Pharmaceutical and Agricultural Innovation*, *in* HANDBOOK OF BEST PRACTICES, *supra* note 52, at 52.
[275] Moses III et al., *supra* note 159, at 1337. Federal expenditures accounted for 64% of the research support provided by universities. *Id.*
[276] NIH, NIH Budget, at http://www.nih.gov/about/budget.htm.

particularly focus on *basic* research.[277] As a result of the close nexus of basic biomedical research and tangible applications, moreover, university research has generated a significant number of research tools,[278] including recombinant DNA technology, extracted and purified human embryonic stem cells, and genetically-modified disease models.[279]

Universities are not only generating these discoveries, they are also patenting them. A number of factors have driven the explosion in university patenting over the past three decades,[280] including: the Bayh-Dole Act; expansive patentable subject matter doctrine; advances in molecular biology revealing a relatively clear path from "basic" discoveries to commercial products;[281] and market pressures on universities.[282] University technology transfer offices, a relatively recent phenomenon, have become ubiquitous. Between 1991 and 2000, universities exhibited an 85% increase in inventions disclosed, a 238% increase in new patent applications, a 161% increase in licensing arrangements, and a 520% increase in royalties.[283] By 2002, universities were awarded more than 3,000 patents a year, with licensing revenues exceeding $1.2 billion.[284] The number of patents held and the number of licenses arranged by universities more than doubled between 1991 and 2005.[285]

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[277] National Patterns of R&D Resources: 2006 Data Update, Sept. 2007, at 26.
[278] *Cf.* Lemley, *Are Universities Patent Trolls?*, *supra* note 21, at 614.
[279] *See* Annetine C. Gelijns & Samuel O. Thier, *Medical Innovation and Institutional Interdependence: Rethinking University-Industry Connections*, 287 JAMA 72, 74 (2007).
[280] *See generally* Walter W. Powell & Jason Owen-Smith, *Universities and the Market for Intellectual Property in the Life Sciences*, 17 J. POL'Y ANALYSIS & MANAGEMENT 253 (1998); Lita Nelsen, *The Rise of Intellectual Property Protection in the American University*, 279 SCIENCE (1998). Of course, university patenting did not begin with the Bayh-Dole Act. *See* Charles Weiner, *Patenting and Academic Research: Historical Case Studies*, 12 SCIENCE, TECH., & HUMAN VALUES 50 (1987).
[281] *See* notes - and accompanying text.
[282] *See generally* DEREK BOK, UNIVERSITIES IN THE MARKETPLACE: THE COMMERCIALIZATION OF HIGHER EDUCATION (2003).
[283] Jerry G. Thursby & Marie C. Thursby, *University Licensing and the Bayh-Dole Act*, 310 SCIENCE 1052, 1052 (2003).
[284] Association of University Technology Managers, AUTM Licensing Survey, FY 2002 Survey Summary, available at www.autm.net/events/File/Surveys/02_Abridged_Survey.pdf.
[285] Association of University Technology Managers, AUTM Licensing Survey: FY 2005 (2007).

University patenting is particularly prevalent in the biopharmaceutical field.[286] University research in genetics and molecular biology spawned the biotechnology industry;[287] in that sector alone, universities hold approximately 18% of all patents.[288] Considering just one institution, between 1980 and 1997, nearly 40% of all patents and 50% of all licenses at Columbia University involved biomedical research tools.[289] In general, university patents are more likely to cover building blocks critical to innovation, including research tools, rather than particular downstream applications of a technology.[290] Universities thus hold assets of immense value that private firms seek to exploit.[291] The resulting leverage allows universities to advance institutional norms favoring a robust research commons in licenses with downstream parties.

2. Challenges to University Norms and Enduring Commitments to Open Science

While universities are traditionally seen as bastions of open science,[292] recent increases in university patenting have raised anxieties that commercial interests may be eroding traditional norms.[293] As a general matter, the increasing commercialization of universities has raised

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[286] Powell & Owen-Smith, *supra* note 280, at 257; Gelijns & Thier, *supra* note 279, at 73; Jaffe, *supra* note 11, at 541; Eisenberg, *Patents, Product Exclusivity, and Information Dissemination*, *supra* note 101, at 479.
[287] Gelijns & Thier, *supra* note 279, at 73; *see* G. Steven McMillan et al., *An Analysis of the Critical Role of Public Science in Innovation: The Case of Biotechnology*, 29 RESEARCH POLICY 1, 5 (2000).
[288] David E. Adelman & Kathryn L. DeAngelis, *Patent Metrics: The Mismeasurement of Innovation in the Biotech Patent Debate*, 85 TEX. L. REV. 1677, 1687 & n.44 (2007).
[289] Gelijns & Thier, *supra* note 279, at 74.
[290] Lemley, *Patenting Nanotechnology*, *supra* note 47, at 616.
[291] Kesselheim & Avorn, *supra* note 167, at 851; *cf.* Narin et al., *supra* note 83, at 318. Of course, knowledge transfer between academic and private-sector institutions is often complex and bidirectional. Golden, *supra* note 12, at 119; Gelijns & Thier, *supra* note 279, at 76.
[292] *See* Lemley, *Patenting Nanotechnology*, supra note 47, at 610; Sally Smith Hughes, *Making Dollars out of DNA: The First Major Patent in Biotechnology and the Commercialization of Molecular Biology, 1974–1980*, 92 ISIS 541 (2001).
[293] *See generally* BOK, *supra* note 282; *see also* JENNIFER WASHBURN, UNIVERSITY, INC.: THE CORPORATE CORRUPTION OF HIGHER EDUCATION (2005); Gelijns & Thier, supra note 279, at 76; Catherine D. DeAngelis, *The Influence of Money on Medical Science*, 296 JAMA 996 (2006); Raymond S. Fersko & Hind Merabet, *Sponsored Research and the Public's Right to Know*, 63 DRUG DEVELOPMENT RESEARCH 103 (2005); Steven Brint, *Creating the Future: 'New Directions' in American Research Universities*, 43 MINERVA 23 (2005); Michael Gibbons,

concerns over: financial interests unduly influencing research agendas,[294] increased secrecy and publication delays,[295] manipulation of results,[296] decreases in academic productivity,[297] conflicts of interest between universities and their faculties,[298] weakening of academic freedom,[299] the erosion of public confidence in university science,[300] and even reduced dissemination of university research findings throughout the developing world.[301] Complicating the rise of university patenting has been the independent, though related, rise in university-industry partnerships.[302] These partnerships often allow industry partners to obtain patent rights arising from industry-sponsored, university-conducted research.[303]

Most salient for our purposes, university patenting may be eroding traditional academic norms of open science. University-generated knowledge that would have previously entered the public domain is now being subject to intellectual property constraints,[304] which may exacerbate

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Changing Patterns of University-Industry Relations, 38 MINERVA 1573 (2000); Melissa Healy, *From Fundings to Findings*, L.A. TIMES, Aug. 6, 2007, at .

[294] Eyal Press & Jennifer Washburn, *Kept University*, THE ATLANTIC MONTHLY, March 2000; Powell & Owen-Smith, *supra* note 280 at 270; Pierre Azouley et al., The Impact of Academic Patenting on the Rate, Quality, and Direction of (Public) Research, (NBER Working Paper No. 11917, 2006), available at http://www.nber.org/papers/w11917; Brett M. Frischmann, *Commercializing University Research Systems in Economic Perspective: A View From the Demand Side*, *in* 16 UNIVERSITY ENTREPRENEURSHIP AND TECHNOLOGY TRANSFER: PROCESS, DESIGN, AND INTELLECTUAL PROPERTY 155, 176-78.

[295] BOK, *supra* note 282, at 64-76; Press & Washburn, *supra* note 294; David Blumenthal et al., *Relationships Between Academic Institutions and Industry in the Life Sciences – An Industrial Survey*, 334 NEW ENG. J. M. 368 (1996); Margo A. Bagley, *Academic Discourse and Proprietary Rights: Putting Patents in Their Proper Place*, 47 B.C. L. REV. 217, 217 (2006); Jon F. Merz et al., *Diagnostic Testing Fails the Test*, 415 NATURE 577, 579 (2002).

[296] Press & Washburn, *supra* note 294.

[297] David Blumenthal et al., *Participation of Life-Science Faculty in Research Relationships in Industry*, 335 NEW ENG. J. M. 1734, 1738 (1996).

[298] David J. Triggle, *Patenting the Sun: Enclosing the Scientific Commons and Transforming the University – Ethical Concerns*, 63 DRUG DEVELOPMENT RESEARCH 139, 143-44 (2005).

[299] Risa L. Lieberwitz, *The Marketing of Higher Education: The Price of the University's Soul*, 89 CORNELL L. REV. 76, 793-98 (2004).

[300] Triggle, *supra* note 298, at 144-45.

[301] Triggle, *supra* note 298, at 145.

[302] *See, e.g.*, Press & Washburn, *supra* note 294, at ; Jennifer Washburn, *Big Oil Buys Berkeley: The BP-UC Berkeley Research Deal Pushes Academic Integrity Aside for Profit*, L.A. Times, Marc 24, 2007, at ; Kevin Buckley, New University-Industry Collaborations, at http://blog.biocommercialization.com/2008/01/24/new-university-industry-collaborations.aspx.

[303] *See, e.g.*, Eliot Marshall, *NIH Cuts Deal on Use of OncoMouse*, 287 SCIENCE 567 (2000).

[304] Triggle, *supra* note 298, at 143.

anticommons problems.[305] Additionally, Professor Mark Lemley has questioned whether universities behave like "patent trolls," entities that accumulate patents but do not manufacture goods, instead relying on licensing fees and the threat of litigation for revenue.[306] Indeed, several high-profile cases reveal universities' aggressive approach to enforcing their patents.[307]

While some argue that profit motives are distorting academic norms, it is worth noting that university patents rarely generate significant revenues.[308] As of 2003, university licenses produced over $1 billion a year in revenue.[309] Though significant, "Patent revenues account for a trivial fraction of overall university research budgets, while public research funding remains of critical importance."[310] In one survey, median net licensing income for research institutions was only $1.13 million per year.[311] Of all university patent licenses in 2000, only 43% earned royalties, and 0.56% earned more than $1 million.[312] Among U.S. institutions, the ratio of licensing income to privately-sponsored research was 5% or less in 2005.[313] There is a high degree of variability in revenues from university licensing, which exhibits a "winner-take-all" dynamic where a few institutions and a few inventions earn most of the money.[314] For example, the nine-campus University of California's net licensing income of $91 million far exceeds the average revenue for a university system.[315] Furthermore, five patented inventions account for

[305] Rai & Eisenberg, supra note 9, at 295-303; *see also* Graff et al., *supra* note 33, at 995.
[306] Lemley, *Are Universities Patent Trolls?*, *supra* note 21, at 619. Lemley concludes that characterization as a troll should be determined by behavior, not institutional identity.
[307] *See, e.g.*, Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559 (Fec. Cir. 1997); Eolas Technologies v. Microsoft, 399 F.3d 1325 (Fed. Cir. 2005).
[308] Dave A. Chokshi & Rahul Rajkumar, *Leveraging University Research to Advance Global Health*, 298 JAMA 1934, 1936 (2007); Gregory K. Sobolski et al., *Technology Licensing, Lessons From the U.S. Experience*, 294 JAMA 3137, 3137 (2005).
[309] Thursby & Thursby, *supra* note 283, at 1052.
[310] Eisenberg, *Public Research and Private Development*, *supra* note 164, at 1726.
[311] Sobolski et al, *supra* note 308, at 3137.
[312] Thursby & Thursby, *supra* note 283, at 1052.
[313] Sobolski et al, *supra* note 308, at 3137-40.
[314] Sobolski et al., *supra* note 308, at 3137; David Baltimore, *On Over-Weighting the Bottom Line*, 301 SCIENCE 1050, 1050 (2003); Leaf, *supra* note 168, at .
[315] Sobolski et al., *supra* note 308, at 3138.

about 95% of all licensing revenues at Columbia University.[316] Ultimately, financial success from university licensing is uneven, unpredictable, and unlikely.

Notwithstanding this new proprietary landscape, and perhaps partially due to the difficulty of translating patents into profits, traditional academic values of open science still persist.[317] At an individual and group level, the scientific community has long been characterized by norms emphasizing openly sharing knowledge and ideas.[318] These "public sector values" have been cultivated by the taxpayer-funded research system encompassing university and government laboratories.[319] University knowledge production is motivated by a host of non-financial rewards and is built on freely exchanging ideas and information.[320] While some caution that patents have eroded this communal culture,[321] others observe that informal sharing norms persist even within an increasingly proprietary environment.[322]

It appears that a similar phenomenon applies at the institutional level as well. In some ways, the traditional norms of open science have adapted themselves to the new patent-intensive environment in which universities currently operate.[323] At a broad level, universities are still committed to widely and promptly disseminating research results.[324] These principles also extend, at least in part, to intellectual property policies. While one must be skeptical of high-

[316] Gelijns & Thier, *supra* note 279, at 75.
[317] *See* Baltimore, *supra* note 314, at 1050; Nelsen, *supra* note 56, at ("[M]ost universities insist that dissemination of research results is key to their identity and mission and will not agree to keep the project results secret."). Of course, some view closer collaborations with private firms as intrinsically related to universities' traditional mission to disseminate knowledge. Faley & Sharer, *supra* note 168, at 114.
[318] *See supra* note .
[319] Golden, *supra* note 12, at 153.
[320] *See* Kahan, *supra* note 142, at 90-93.
[321] Eisenberg, *Proprietary Rights and the Norms of Science*, *supra* note 47, at 182; Rai, *Regulating Scientific Research*, *supra* note 17.
[322] Robert P. Merges, *Property Rights Theory and the Commons: The Case of Scientific Research*, SOC. PHIL. & POL'Y, Summer 1996, at 145, 150 [hereinafter Merges, *Property Rights Theory and the Commons*].
[323] Murray, *supra* note 76, at 42; *cf.* Merges, *Property Rights Theory and the Commons*, *supra* note 322, at 150.
[324] Thursby & Thursby, *supra* note 283, at 1052; Eisenberg, *Patents and Data-sharing in Public Science*, *supra* note 47, at 1013 (2006; Choski & Rajkumar, *supra* note , at 1936 (collecting university mission statements); *see also* Robert E. Litan et al., Commercializing University Inventions: A Better Way (Apr. 2007) (working paper, Nat'l Bureau of Econ. Research), available at http://www.kauffman.org.pdf/NBER_0407.pdf.

level rhetoric, the stated policies of virtually all universities espouse using intellectual property to advance social welfare with secondary regard for financial rewards.[325] For example, Harvard University's policy acknowledges the university's "primary commitment" to the public interest.[326] For its part, the Association of University Technology Managers (AUTM) observes that most of its members "would define success through the criterion of public benefit."[327] While the commercialization of universities is a real phenomenon, and academic institutions may have legitimate reasons for pursuing licensing income,[328] these norms suggest that universities can and do take a wider view of patenting than revenue maximization.[329]

3. University Licensing Policies Favoring Access to Patented Research Tools

Indeed, universities are leveraging their ownership of research tools patents to ensure, in contractual transactions with external parties, a robust research commons in biomedicine.[330]

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[325] *See, e.g.*, Brewster et al., *supra* note 274, at 49, 51(collecting policies of the top four universities in terms of patent activity).

[326] Harvard University, Statement of Policy In Regard to Intellectual Property, Feb. 4, 1998, available at http://otd.harvard.edu/resources/policies/patent/PatentPolicy.pdf; *see also* Yale University, Yale University Patent Policy, Feb. 1998, available at http://www.yale.edu/ocr/pfg/policies/patents.html ("The objective of the University is to assure the development of its technology in furtherance of its own educational mission and for the benefit of society in general."); UC Davis, Office of Research, Licensing and Confidentiality, available at http://www.innovationaccess.ucdavis.edu/home.cfm?id=ovc,23,1728,1718,1719,1725 ("Agreements with external parties shall support the ability of the University to make available for the public benefit in a diligent and timely manner any resulting innovations and works of authorship.").

[327] Association of University Technology Managers, U.S. Licensing Activity Survey: FY 2006, at13.

[328] Such income can offset tuition and operating expenses, but comes at the expense of academic and industry parties who must pay licensing fees. Lemley, *Are Universities Patent Trolls?*, *supra* note 21, at 620

[329] *See id*. at 611 ("University technology transfer ought to have as its goal maximizing the social impact of technology, not merely maximizing the university's licensing revenue.").

[330] Universities and research organizations have been particularly proactive in enhancing access to patented resources in agricultural biotechnology. Public Intellectual Property Resources for Agriculture (PIPRA), a consortium of over 40 universities and research institutions, bundles and licenses agriculture-related patents for low-cost exploitation in the developing world. Richard C. Atkinson et al., *Intellectual Property Rights: Public Sector Collaboration for Agricultural IP Management*, 301 SCIENCE 174 (2003). CAMBIA, an Australian research institute, has adopted an "open licensing" approach to disseminating biological materials. *See* Richard Jefferson, *Science as Social Enterprise*, INNOVATIONS, Vol. 1, No. 4, p. 13 (2006).

a. Reserved Research Exemptions for Licensed Inventions

Increasingly, universities are reserving research exceptions for themselves and other non-profit organizations as a condition of licensing patented technologies to outside parties.[331] A recent survey of university licensing revealed the presence of "a strong and expanding retained and transferable research-use right, even within exclusive, all fields of use licenses."[332] Typically, these provisions do not only reserve a research exemption for the licensing institution itself, but also provide for research licenses for all other non-profit research institutions as well.[333] According to Andrew Neighbour of UCLA, technology transfer offices "always insist on a research exception not only for themselves, but for other nonprofit institutions; adding the other nonprofits into the research exception has been a trend."[334]

For example, boilerplate language in an exclusive license from Harvard University states that "Harvard will retain the right, for itself and other not-for-profit research organizations, to practice the subject matter of the patent rights for internal research, teaching and other educational purposes."[335] Other universities take a slightly different approach, reserving research rights on behalf of non-profits but maintaining themselves as gatekeepers for those rights. Thus an exclusive license from the University of California reserves "the right of The Regents . . . to make and use the invention . . . and associated technology and allow other

[331] *See* Benkler, *Commons-Based Strategies*, *supra* note 21, at 1110-11; Brewster et al., *supra* note 274, at 56; Murray, *supra* note 76, at 39.
[332] Pressman et al., *supra* note 19, at 35.
[333] *See*, *e.g.*, *id*. at 35 (drawing examples from Harvard University, UCSD, UCLA, UCSF, and UC Berkeley).
[334] *Id*. at 35.
[335] Licensing Harvard Patent Rights: a Guideline to the Essentials of Harvard's License Agreements, *at* http://www.techtransfer.harvard.edu/resources/guidelines/license/; *see also* Stanford University, Exclusive Agreement 2, available at http://otl.stanford.edu/industry/resources/exclusive.pdf;

educational and nonprofit institutions to do so for education and research purposes."[336] Notably, these clauses directly respond to the Federal Circuit's narrow conception of the experimental use exception articulated in *Madey v. Duke University*.[337] Many of these clauses define the research exception by explicitly listing the types of activities that *Madey* held did *not* qualify for the common law experimental use exception. While these clauses enhance access to all university-generated inventions for research purposes, enhanced access to research tools is particularly important because of their centrality to the scientific enterprise.

A recent consortium of university technology transfer officers organized by Stanford University recommends that universities reserve the right to practice licensed inventions and to allow other non-profit and governmental organizations to do so as well.[338] The guidelines include this example provision, similar to Harvard's:

> *INSTITUTION reserves the rights, for itself and others, to*
> *(i) make and use, solely for NON-COMMERCIAL RESEARCH PURPOSES, the subject matter described and claimed in PATENT RIGHTS and covered by PROPERTY RIGHTS and*
> *(ii) provide to OTHERS the BIOLOGICAL MATERIALS; each solely for NON-COMMERCIAL RESEACH PURPOSES.*[339]

Again, the guidelines define "non-commercial research purposes" with explicit reference to *Madey*.[340] The Stanford consortium also notes that reserving a research exemption corresponds with the NIH's recommendations for best practices for licensing genomic inventions.[341]

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[336] Alan B. Bennett, *Reservation of Rights for Humanitarian Uses*, *in* HANDBOOK OF BEST PRACTICES, *supra* note 52, at 42. *See also* In the Public Interest: Nine Points to Consider in Licensing University Technology 10-12, *available at* news-service.stanford.edu/news/2007/march7/gifs/whitepaper.pdf [hereinafter, *In the Public Interest*]; *See also* Wisconsin Alumni Research Foundation, Standard Non-Exclusive License Agreement 1, 9, available at http://www.warf.org/uploads/media/20031002132027680_Std_non_exclusive_license_agrmt.pdf; Baylor College of Medicine, Exclusive License Agreement – Research Product 3, available at http://www.bcm.edu/blg/docs/lic_research.dot.

[337] Bennett, *supra* note 336, at 42; *In the Public Interest*, *supra* note 336, at 11.

[338] *In the Public Interest*, *supra* note 336, at 2.

[339] *Id*. at 10.

b. Exclusive Versus Nonexclusive Licensing

Universities are also promoting the wide availability of research tools by favoring nonexclusive licensing of such technologies (or even deciding not to patent them).[342] Several decades ago, Stanford University and the University of California nonexclusively licensed the Cohen-Boyer patents covering gene splicing, a fundamental research tool, for a relatively low rate of $10,000 per license.[343] This appears to be a win-win situation in which widespread licensing of gene splicing helped it become the single most profitable invention licensed by these two universities.[344]

The issue of exclusive or nonexclusive licensing of research tools is complicated by the fact that the same resource—such as patented human embryonic stem cells—may both facilitate academic research and represent a precursor to commercial products requiring further investment and development; in the latter situation, some degree of exclusivity may be necessary to provide private incentives to innovate.[345] While the majority of university licenses continue to be

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[340] *Id*. at 11.
[341] NIH, Best Practices for the Licensing of Genomic Inventions: Final Notice, 70 Fed. Reg. at 18,415 (April 11, 2005).
[342] *Cf*. Lemley, *Are Universities Patent Trolls?*, *supra* note 21, at 612; Lemley, *Patenting Nanotechnology*, *supra* note 47, at 627. While such licenses still "tax" downstream users, and are therefore questionable for publicly-funded inventions, they provide greater access than exclusive licenses. *See* Eisenberg, *Public Research and Private Development*, *supra* note 164.
[343] *See* Lee, *The Evolution of Intellectual Infrastructure*, *supra* note 26, at 93-94.
[344] David C. Mowery & Arvids A. Ziedonis, *Numbers, Quality, and Entry: How Has the Bayh-Dole Act Affected U.S. University Patenting and Licensing?*, 1 INNOVATION POLY' & ECON. 187, 194 (2001); Smith Hughes, *supra* note 293, at 542. Columbia University also nonexclusively licensed the Axel patents related to gene insertion in mammalian cells, but only did so upon direct compulsion by the NIH. See *supra* Part IV.A.
[345] Jaffe, *supra* note 11, at 552; *but see* Golden *supra* note 12.

exclusive,[346] universities are adopting policies drawing these distinctions and favoring nonexclusive licensing of research tools for noncommercial research purposes.[347]

Consistent with the policies of the NIH and many academic journals, the Stanford consortium recommends that

> [a]bsent the need for a significant investment—such as to optimize a technology for wide use—broad, non-exclusive licensing of tools such as genomic and proteomic inventions can help maximize the benefits derived from those technologies, in part by removing obstacles to further innovation.[348]

However, context-specific exclusivity may be appropriate for research tools that could benefit from additional "optimization." Thus, following these guidelines, a university should ensure that licenses for research reagents, kits, or devices are "exclusive for the sale, but not use" of such resources.[349] In this manner, members of the scientific community may use these patented technologies for research purposes,[350] but they may not *sell* them, thus maintaining the commercial incentives of exclusive licensees.

Evidence suggests that universities are already following these policies.[351] A survey of university technology transfer offices revealed a preference for nonexclusively licensing most DNA research tools.[352] Furthermore, respondents noted that the same patent could be licensed differently for research use versus commercial use.[353] On a related note, universities distinguish between different types of technologies in their licensing approaches. Universities are likely to patent and exclusively license DNA sequences that encode therapeutic proteins because of the

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[346] Lemley, *Are Universities Patent Trolls?*, *supra* note 21, at 617.
[347] *See* Lemley, *Patenting Nanotechnology*, *supra* note 47, at 628 (suggesting utilizing the Bayh-Dole Act to restrict exclusive licensing of basic building block patents by universities).
[348] *In the Public Interest*, *supra* note 336, at 3.
[349] *Id*. at 5.
[350] *Id*. at 5.
[351] *See* Golden, *supra* note 12, at 143 ("[G]overnment laboratories and universities have favored widespread granting of non-exclusive licenses, particularly for their more fundamental inventions.").
[352] Pressman et al., *supra* note 19, at 34-35.
[353] *Id*. at 35.

high risk and commercialization costs associated with developing these products.[354] However, universities are less likely to patent (and more likely to nonexclusively license) DNA sequences that are markers only, as the immediate utility of such inventions is unclear and the development costs associated with them are relatively small.[355]

4. Analysis

In a broad sense, university licensing practices illustrate the privatization of public policy in patent law. In the absence of an adequate doctrinal or statutory experimental use exception, universities are creating one through contract. Given the dominant role that universities play in technology transfer, the potential impact of broad-based adoption of these policies is substantial.

The viability of this effort depends on the strength of access norms in the face of potential profits arising from exclusivity. In *Madey v. Duke University*, the Federal Circuit characterized universities as commercial entities with business objectives that included raising revenues.[356] While this characterization is true to a certain extent, academic norms still persist. While it is beyond the scope of this Article to resolve the impact of patenting and commercial influences on university culture, it is fair to say that universities are a different sort of patentee than most commercial firms.[357] The traditional goal of universities has been to serve the public interest

[354] *Id*. at 33.
[355] *Id*. at 33-34.
[356] Madey v. Duke University, 307 F.3d 1351 (Fed. Cir. 2002).
[357] Even this is controversial for some. For example, Columbia University has attracted significant criticism for its attempts to extend the life of the Axel patents on techniques for inserting genes in cells. *See, e.g.*, Wysocki, Jr., *supra* note 219, at A1; Howard, *supra* note 218; *Ownership At Too High a Price*, 21 NATURE BIOTECH. 953, 953 (2003).

with education and research, not to maximize profits.[358] Indeed, the unique normative character of universities was one basis for justifying the Bayh-Dole Act:

> To the extent that opponents of private appropriation feared that vesting ownership in important discoveries in a single firm would inhibit the dissemination of new knowledge, they might be less troubled by university ownership of patents in view of the general inclination of universities toward widespread dissemination of new knowledge.[359]

This framing reflects the belief that "[t]he for-profit and not-for-profit sectors differ deeply in their missions, cultures, resources, and incentives, and these differences deserve some respect."[360] Of course, access norms may also be self-serving; universities reserving broad research exceptions ensure that patent holdup will not impede investigations by their own scientists.

Notably, the mechanism by which universities are articulating these norms and constructing a research commons is contracts. Universities are reserving research rights for themselves and other non-profit institutions in patent licenses. Furthermore, universities are enhancing the availability of patented research tools through nonexclusively licensing. Universities are actively "contracting around" *Madey v. Duke University* to build a commons of patented, university-generated inventions that are widely available for non-profit research.

Of course, university insistence on access conditions in licensing practices faces several challenges. First, the disconnect between university intellectual property policy and practice reflects in many ways a principal-agent problem. Technology transfer offices whose performance is measured by revenues have strong incentives to grant exclusive licenses.[361] If

[358] Baltimore, *supra* note 314, at 1050; *see In the Public Interest*, *supra* note 336, at 9 (identifying "the dual goals of nurturing future research and using the innovations of university research to provide the broadest possible benefit to the public").
[359] Eisenberg, *Public Research and Private Development*, *supra* note 164, at 1701.
[360] Gelijns & Thier, *supra* note 279, at 77.
[361] Lemley, *Are Universities Patent Trolls?*, *supra* note 21, at 616; *see* Faley & Sharer, *supra* note 168, at 125.

these offices are to act consistently with lofty mission statements, universities must consider changing their incentive structures and performance metrics. In general, public scrutiny, moral suasion, and recognition that licensing windfalls are unlikely can help universities take a broader view of their role in technology transfer.[362] Second, universities should ensure that reserved research exemptions automatically apply to *all* non-profit research organizations (not just themselves) so as to prevent the possibility of scientific "fiefdoms." Finally, as Professors Rai and Eisenberg have argued, university technology transfer offices (as opposed to the NIH) may lack the technical competence to optimally manage the licensing of patented biomedical inventions.[363] Distinguishing among various technologies, licensees, and uses is crucial for ideal exploitation of these inventions.[364] To address these concerns, universities may need to devote more resources to technology transfer offices that currently employ an average of four professionals.[365]

D. Non-Profit Funding Organizations

Non-profit organizations are also tying funds to requirements that grant recipients share patented research tools widely for noncommercial use.[366] In 2003, non-profit organizations

[362] *See* Lemley, *Are Universities Patent Trolls?*, *supra* note 21, at 627; Jaffe, *supra* note 11, at 552; Mark Lemley, quoted in Witnesses Say Universities Too Rigid In Licensing Patent Rights Under Bayh-Dole, July 18, 2007, available at http://www.law.stanford.edu/news/details/1043/.
[363] Rai & Eisenberg, *supra* note 9, at 305.
[364] Bennett, *supra* note 336, at 42; Thursby & Thursby, *supra* note 283, at 1052; Yale University, *supra* note 326; *see* Pressman et al., *supra* note 19, at 37.
[365] Lorelei Ritchie de Larena, *The Price of Progress: Are Universities Adding to the Cost?*, 43 HOUS. L. REV. 1373, 1387, 1412 (2007).
[366] Foundations established by nineteenth-century industrialists played a major role in funding early biomedical research, but were eclipsed by government funding following World War II. *See* Robert I. Field et al., *Toward a Policy Agenda on Medical Research Funding: Results of a Symposium*, 22 HEALTH AFFAIRS 224, 225, 227 (2003); P. Balaram, *Philanthropy and the Funding of Science*, 83 CURRENT SCIENCE 537, 537 (2002).

provided $2.5 billion to support biomedical research,[367] and they are expected to grow in importance as funding sources.[368] Furthermore, *what* they fund is oftentimes more important than *how much* they fund. Foundations fill gaps by funding research that is scientifically speculative, politically risky, or unpopular and where commercial value is low or not readily apparent.[369] This "gap filling" function extends to funding new and interdisciplinary research that may not receive NIH support.[370] For example, by its own description, the Howard Hughes Medical Institute (HHMI) prizes "bold thinking and scientific risk taking" in awarding grants.[371] Interestingly, the high tech boom of the 1990s produced a new generation of "venture philanthropists" who are particularly committed to strategic risk-taking.[372] By providing venture capital in new, cutting edge areas of biomedical research, non-profits exert greater influence over research than their absolute dollar contributions suggest.

This monetary support, moreover, often comes with strings attached. As a case study, this Subpart will focus on HHMI, a "major force in funding biomedical research"[373] that contributed $599 million to research in 2007.[374] As with other non-profits, HHMI does not support biomedical research to profit from it. HHMI's intellectual property policies state that it "conducts scientific research in the public interest," and that it has adopted its policies "to help ensure that inventions, discoveries, and other fruits of HHMI's research are made available for

[367] Moses III et al., *supra* note 159, at 1335. In 2006, the top five contributors to biomedical research in the United States were the Bill and Melinda Gates Foundation ($908 million), the Howard Hughes Medical Institute ($694 million), the Sowers Institution for Medical Research ($73 million), High Q and CHDI ($50 million), and the Ellison Medical Foundation ($36 million). Lucy Olding-Smee, *The Money Tree*, 447 SCIENCE 251, 251 (2007).
[368] Moses III et al., *supra* note 159, at 1338-39; Jeffrey Mervis, *U.S. Science Adviser Tells Researchers to Look Elsewhere*, 316 SCIENCE 817, 817 (2007).
[369] Moses III et al., *supra* note 159, at 1339; Field et al., *supra* note 366, at 227.
[370] Moses III et al., *supra* note 159, at 1338.
[371] Howard Hughes Medical Institute, 2007 Annual Report 2 (2007); *see also* Bill and Melinda Gates Foundation, Annual Report 2006, at 14 (2007) ("We try new ideas in the laboratory and in the field – sometimes taking risks that business and government can't.").
[372] Trisha Guru, *Biomedical Philanthropy, Silicon Valley Style*, 410 NATURE 140, 140-43 (2001).
[373] Balaram, *supra* note 366, at 538.
[374] HHMI, 2007 Annual Report 78.

the benefit of the public."[375] Consistent with other public institutions, HHMI embeds access-related policy objectives in funding arrangements with private grantees.

HHMI maintains several policies ensuring wide access to patented research tools arising from its funding. HHMI possesses a unique structure in that it sponsors investigators at "host institutions"—usually universities—as well as conducts intramural research at its Janelia Farm Research Campus. HHMI claims an ownership interest in any invention where at least one inventor is an HHMI employee.[376] Although grantees may patent their inventions, HHMI retains an institution-wide, paid-up, non-exclusive irrevocable license to use any HHMI-funded invention for noncommercial purposes.[377]

HHMI's policy on research tools is consistent with NIH guidelines,[378] and it "expects all HHMI research tools to be made available to the scientific research community on reasonable terms and in a manner that enhances their widespread availability."[379] HHMI is also a signatory to the NIH's Uniform Biological Materials Transfer Agreement,[380] and it encourages streamlined material transfers to non-profit organizations.[381] Given the reach of HHMI funding throughout the biomedical research world, the scope of these policies is substantial.

As with CIRM, HHMI also maintains policies specific to materials, data, and software described in academic publications.[382] Upon publication of HHMI-funded work, laboratory

[375] HHMI, Science Policies, Intellectual Property Policy (SC-600) 1, *available at* http://www.hhmi.org/about/research/sc600.pdf [hereinafter HHMI, *Intellectual Property Policy*].
[376] HHMI, Intellectual Property and HHMI Employees: A Guide for Host Institutions 3, *available at* http://www.hhmi.org/pdf/host-guide.pdf [hereinafter HHMI, *Intellectual Property Guide for Host Institutions*].
[377] HHMI, *Intellectual Property Guide for Host Institutions*, *supra* note , at 7; Howard Hughes Medical Institute, Research Tools (SC-310), at 1, *available at* http://www.hhmi.org/about/research/sc_310.pdf. [hereinafter HHMI, *Research Tools*].
[378] NIH, *Principles and Guidelines*, 64 Fed. Reg. at 72,092 n.1.
[379] HHMI, *Research Tools*, *supra* note 377, at 1.
[380] HHMI, Materials Transfers (SC-330), *available at* http://www.hhmi.org/about/research/sc330.pdf. [hereinafter HHMI, *Material Transfers*].
[381] HHMI, *Materials Transfers*, *supra* note 380, at 1.
[382] HHMI, Sharing of Publication-Related Materials, Data and Software (SC-300), May 15, 2007, *available at* http://www.hhmi.org/about/research/sc_300.pdf [hereinafter HHMI, *Sharing of Publication-Related Materials*]. As

heads are "expected" to make materials, data, databases, and software available for research use within 60 days of receiving a request.[383] If material described in a publication is or will be patented, grant recipients should make a license for noncommercial research use available to third parties.[384]

HHMI policies also apply to host institutions sponsoring HHMI investigators. In such situations, HHMI assigns its patent rights to the host institution—usually a university—and allows it to coordinate technology transfer decisions.[385] However, host institutions have an "obligation to include certain provisions for HHMI's benefit in each license."[386] This includes HHMI's irrevocable license to use any subject property for research purposes.[387] In addition, HHMI prohibits host institutions from licensing rights to *future* technology in a manner that exceeds what is necessary to commercialize an invention.[388] This underscores HHMI's commitment to preserving the widest zone of research uses for patented inventions while maintaining the profitability of commercial applications. Furthermore, consistent with its research tools policy, host institutions should make resources developed by HHMI investigators available to scientists at non-profit organizations and to for-profit companies for use in internal research on reasonable terms.[389] Where a host institution proposes to license an HHMI research

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with the NIH, HHMI also required grant recipients contributing to the Human Genome Project to place their data in a public database. Petsko, *supra* note 222, at 107.1.

[383] HHMI, *Sharing of Publication-Related Materials*, *supra* note 382, at 1-3.

[384] *Id*. at 2.

[385] HHMI, *Intellectual Property Policy*, *supra* note 375, at 3.

[386] HHMI, *Intellectual Property Guide for Host Institutions*, *supra* note 376, at 6.

[387] HHMI, *Intellectual Property Policy*, *supra* note 375, at 3.

[388] HHMI, *Intellectual Property Guide for Host Institutions*, *supra* note 376, at 6.

[389] HHMI, *Intellectual Property Guide for Host Institutions*, *supra* note 376, at 9; HHMI, *Research Tools*, *supra* note 377.

tool on an exclusive basis, HHMI requires a licensing plan showing how the tool will be made widely available to the scientific community.[390]

HHMI policies on sharing research tools and published materials also govern licensing of inventions developed at its Janelia Farm Research Campus.[391] This includes reserving a research use exception in all licenses with downstream partners as well as favoring nonexclusive licensing of research tools.

1. Analysis

While contracts governing non-profit funding arrangements do not usually fall under the rubric of patent law and policy, they can have an enormous impact on the accessibility of patented research tools. Although small in absolute amounts, the financial contributions of non-profit organizations to biomedical research are strategically important and increasing. Instead of passively providing money, organizations such as HHMI are leveraging resources to influence the behavior of their grant recipients. Again, the quid pro quo arrangement of contracts is the mechanism by which non-profits exert this influence. In accepting money, grantees must also accept claims by the funding organization over the disposition of patented inventions.

Non-profit funding agencies thus emerge as policy actors in creating a research commons for biomedicine. Experienced players such as HHMI are similar to the NIH in terms of technical competence and are well-equipped to draw meaningful distinctions between research use and commercial sale of patented assets. However, HHMI's efforts also exhibit certain limitations.

[390] HHMI, *Research Tools*, *supra* note 377, at 1. Additionally, HHMI retains march-in rights on all licensed inventions. However, HHMI will only exercise these march-in rights to meet public health or safety needs. HHMI, *Intellectual Property Guide for Host Institutions*, *supra* note 376.
[391] HHMI, *Intellectual Property Policy*, *supra* note 375, at 4.

HHMI only reserves a paid-up research license for itself and requires transfer of patented materials to outside non-profits on "reasonable terms," thus permitting a small degree of price discrimination. Widening the scope of reserved research rights to all non-profits would better advance the objective of open science.

E. Disease Advocacy Groups

A surprising example of the convergence of upstream contributions, norms of open science, and contracts limiting patent rights arises in the context of disease advocacy groups. Such groups often contribute money and labor to advance research,[392] but they sometimes offer a rather unique input as well: bodily tissues necessary to study rare diseases. Disease advocacy groups are taking an entrepreneurial approach to their support of biomedical research to ensure that patents arising from their contributions do not impede further inquiry.[393] Two case studies illustrate the role of disease advocacy groups in contractually creating a noncommercial biomedical research commons.

The development of a diagnostic test for Canavan disease, a gene-linked cerebral degenerative disorder,[394] demonstrates the vital support that tissue donors can provide to biomedical research.[395] In 1987, Daniel Greenberg, the father of two children suffering from

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[392] *See* Shannon F. Terry et al., *Advocacy Groups as Research Organizations: The PXE International Example*, 8 NATURE REVIEWS: GENETICS 157, 158-59 (2007).
[393] *See generally*, Carlos Novas, *The Political Economy of Hope: Patients' Organizations, Science, and Biovalue*, 1 BIOSOCIETIES 289, 293 (2006). AIDS activists provided the template for proactive participation of patient groups in biomedical research. Id. at 292. *See also* Cori Hayden, *Taking as Giving: Bioscience, Exchange, and the Politics of Benefit-sharing*, 37/5 SOCIAL STUDIES OF SCIENCE, 729, 738-39 (2007).
[394] National Institutes of Neurological Disorders and Stroke, What is Canavan Disease?, at http://www.ninds.nih.gov/disorders/canavan/canavan.htm.
[395] *See* Donna M. Gitter, *Ownership of Human Tissue: A Proposal for Federal Recognition of Human Research Participants' Property Rights in Their Biological Material*, 61 WASH. & LEE L. REV 257, 325-330 (2004); Radhika Rao, *Genes and Spleens: Property, Contract, or Privacy Rights in the Human Body*, J. LAW, MEDICINE & ETHICS,

Canavan disease, persuaded scientist Reuben Matalon to develop molecular probes to trace the disease to its source.[396] Greenberg provided Matalon with blood, brain, and urine samples from his own family. Along with various patients' organizations, Greenberg helped establish a registry of 160 Canavan-afflicted families.[397] Utilizing these tissue donations, in 1993 Matalon isolated the aspartoacylase gene associated with Canavan disease and developed a genetic test to screen for the condition.

As the Canavan episode illustrates, however, the norms of the disease advocacy community can diverge sharply from that of most patentees. The Canavan Foundation began offering free Canavan screening in 1996. Matalon's employer at the time of his discovery was Miami Children's Hospital (MCH), which, unbeknownst to the families and patients' organizations, applied for a patent on the Canavan gene in 1994, receiving it in 1997.[398] In 1998, MCH began licensing a Canavan screening test, but charged a royalty of $12.50 per test and limited the total number of tests that laboratories could perform.[399] Greenberg and the patients' organizations objected to these constraints. They brought suit in October 2000 against MCH, alleging a variety of claims, including misappropriation of trade secrets, based on Matalon's use of the children's blood and tissue.[400] While upstream contributors favored wide access to the patented gene, the downstream patentee favored exclusivity.

SYMPOSIUM, GENETICS AND GROUP RIGHTS, 371, 372-74 (2007); Sabrina Safrin, *Chain Reaction: How Property Begets Property*, 82 NOTRE DAME L. REV. 1917, 1933-34 (2007).

[396] Eliot Marshall, *Families Sue Hospital, Scientist for Control of Canavan Gene*, 290 SCIENCE 1041, 1062 (2000) [hereinafter Marshall, *Families Sue Hospital*].

[397] Novas, *supra* note 393, at 299; Marshall, *Families Sue Hospital*, *supra* note 396, at 1062; Canavan Foundation, Canavan Foundation Joins Lawsuit against Miami Children's Hospital, Oct. 30, 2000, at http://www.canavanfoundation.org/news/10-00_miamihostpital.php.

[398] Novas, *supra* note 393, at 299.

[399] MCH planned to lucratively license the test to a large commercial lab. Rao, *supra* note 395, at 373.

[400] Marshall, *Families Sue Hospital*, *supra* note 71, at 1062; Canavan Foundation Joins Lawsuit against Miami Children's Hospital, supra note 397

Ultimately, the disease advocates were able to leverage their contributions to carve a research exception out of MCH's patent rights. In *Greenberg v. Miami Children's Hospital*, Greenberg and the various non-profit groups argued that by virtue of their contributions, they had a right to control commercialization of the patent.[401] The donors believed that any resulting genetic tests would be readily affordable "and that [the] research would remain in the public domain."[402] The court dismissed all of the plaintiffs' claims except their claim for unjust enrichment.[403] That issue was never resolved on the merits, however, as the parties entered into a confidential settlement. Notably, the settlement provided for continued royalty-based testing by licensed laboratories, but royalty-free use by institutions, doctors, and scientists engaged in "pure" research.[404]

As the Canavan gene controversy illustrates, disease advocacy groups can provide vital inputs to basic biomedical research. Furthermore, members of the patient community often privilege developing cures and facilitating further scientific investigation rather than maintaining exclusivity and maximizing profits.[405] Ultimately, Greenberg and the disease advocacy groups were able to extract a research exception for MCH's patented gene, although they did so in a very costly and indirect manner: litigation.

Contrary to the Canavan disease groups, the advocacy group associated with pseudoxanthoma elasticum (PXE) has more directly leveraged upstream contributions of bodily

[401] 264 F. Supp. 2d 1064 (S.D. Fla. 2003); *see* Gitter, *supra* note 395, at 331-38; see Marshall, *Families Sue Hospital*, *supra* note 396, at 1062; Rao, *supra* note 395, at 373.
[402] Greenberg v. Miami Children's Hosp. Research Inst., Inc., 208 F. Supp. 2d 918, 921 (N.D. Ill. 2002). The court subsequently transferred the case to the Southern District of Florida.
[403] 264 F. Supp. at 1066.
[404] Canavan Foundation, Joint Press Release (Sept. 29, 2003), available at http://www.canavanfoundation.org/news/09-03_miami.php; Novas, *supra* note 393, at 301.
[405] *Cf.* Terry et al., *supra* note 392, at 158.

tissues to control the availability of patented discoveries arising from them.[406] In 1994, Patrick and Sharon Terry's two children were diagnosed with PXE, a rare genetic disorder that affects connective tissue.[407] Shortly thereafter, the Terrys "began to scheme about what we would do if we were managing research on this disease."[408] In 1995, the Terrys founded PXE International, which, among other functions,[409] established a blood and tissue registry to facilitate PXE research.

Responding in part to the Canavan disease episode, PXE International negotiated contracts with researchers whereby it would retain ownership rights in any patents arising from research based on access to its registry.[410] This arrangement allowed PXE International to share in any revenue, ensure affordable genetic tests, and influence future licensing. The registry has thus served as a "significant relay of power" through which PXE International has been able to coordinate and influence scientific activities.[411]

Ultimately, PXE International was able to leverage its research contributions to obtain patent rights in the PXE gene. The organization was instrumental in the 2000 discovery by University of Hawaii pathobiologist Charles Boyd of the transporter gene that causes PXE.[412] In an unusual move, Sharon Terry was listed as a co-inventor on the patent application for the gene, along with four university researchers.[413] As per standard practice, the University of Hawaii held

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[406] See Gitter, *supra* note 395, at 315-24; Paul Smaglik, *Tissue Donors Use Their Influence in Deal Over Gene Patent Terms*, 407 NATURE 821, 821 (2000); Safrin, *supra* note 395, at 1934-35; Gina Kolata, *Sharing of Profits is Debated As the Value of Tissue Rises*, N.Y. TIMES, May 15, 2000, at .

[407] Eliot Marshall, *Patient Advocate Named Co-Inventor On Patent for the PXE Disease Gene*, 305 SCIENCE 1857, 1225 (2004) [hereinafter Marshall, *Patient Advocate*].

[408] Shannon F. Terry, *Learning Genetics*, HEALTH AFFAIRS, Vol. 22, No. 5, 166, 169 (2003). According to Shannon Terry, "We didn't want to do the science without the ethics and the only way to make it all work was to have control of it ourselves." Arthur Allen, *Who Owns My Disease?*, MotherJones.com, Nov/Dec 2001 (quoting Shannon Terry).

[409] In the course of three years, the Terrys raised $500,000 for research. Allen, *supra* note 408, at .

[410] Gitter, *supra* note 395, at 317; Matt Fleischer, *Patent Thyself*, AMERICAN LAWYER, June 21, 2001, at 87.

[411] Novas, *supra* note 393, at 296.

[412] The gene is known alternatively as ABCC6 or MRP6.

[413] Marshall, *Patient Advocate*, *supra* note 407, at 1226. Although she conducted various laboratory procedures and helped write the account of the gene discovery, Terry is a non-scientist. *Id*.

the rights to Boyd's inventions. Initially, conflict arose between the university's interest in selectively licensing the gene and PXE International's commitment to broad and low-cost licensing.[414] Ultimately, however, the two parties reached an agreement whereby PXE International would make all licensing decisions and the parties would split the royalties deriving from any diagnostic test or marketable product.[415]

Significantly, through exercising control over the patented PXE gene, PXE International has ensured its accessibility for research purposes.[416] PXE International has licensed the gene to 19 laboratories and eight biotechnology companies.[417] Such widespread licensing is consistent with PXE International's aim to maximize "patient-centric opportunities."[418] In this case, PXE International has been able to exercise its ownership of the PXE gene to ensure its availability in a research commons.

1. Analysis

The experiences of groups associated with Canavan and PXE disease reveal how disease advocacy groups are actively engaged in private ordering to prevent patent holdup. These groups are leveraging their contribution of bodily materials to biomedical research to impose access requirements on resulting patented technologies. Although not normally seen as policy actors, these organizations are engaged in consideration-based patent regulation. While the contributions of advocacy groups to biomedical research are not new, the Terrys' experience

[414] Gitter, *supra* note 395, at 318.
[415] Gitter, *supra* note 395, at 318.
[416] Novas, *supra* note 393, at 297.
[417] Novas, *supra* note 393, at 297.
[418] A similar strategy has been used by the Alpha-1 Foundation, which represents Alpha-1 antitrypsin deficiency sufferers. Jasper Bovenberg, *Whose Tissue Is It Anyway*, 23 NATURE BIOTECH? 929, 931 (2005); Jon F. Merz et al., *Protecting Subjects' Interests in Genetic Research*, 70(4) AMERICAN JOURNAL OF HUMAN GENETICS 965, 966 (2002) [hereinafter Merz et al., *Protecting Subjects' Interests]*.

represents a powerful template for how such groups can enhance the availability of resulting discoveries.[419] This promises to be a growing trend.[420]

These episodes reflect disease advocacy groups' deep commitment to access norms.[421] Unlike downstream patentees such as MCH and the University of Hawaii, disease advocates generally aim for the wide availability of patented assets. According to Shannon Terry, her co-ownership of the PXE gene patent ensures that PXE International is now "driving the boat;"[422] she considers herself and her organization "stewards" of the gene.[423] Norms matter a great deal to how these organizations utilize patents. In the basic research context, they are utilizing patents in an inclusive fashion to enhance access to critical resources.

In a variety of ways, contracts are driving these efforts[424] First, in the most direct sense, PXE International's ownership of the PXE gene patent allows it to license the patent widely throughout the research community. Second, even aside from owning a patent itself, quid pro quos governing tissue donations allow advocacy groups to influence the disposition of patented genes. While the Canavan plaintiffs did not own the Canavan gene patent, they were ultimately able to translate their contributions of unique bodily materials to ensure a research exception for MCH's patented gene. More formally, PXE International explicitly conditions access to its tissue registry on receiving some say in how resulting intellectual property would be used. The explicit quid pro quo of these registries is that if a scientist wants access, she must agree to provide any resulting patented materials widely for research purposes.

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[419] Novas, *supra* note 393, at 297.
[420] Gitter, *supra* note 395, at 318. Cure Autism Now and the Juvenile Diabetes Research Foundation International have also pooled members' specimens to create biorepositories. *Id*. at 318-19. Shannon Terry is currently the President and CEO of the Genetic Alliance, a coalition of over 600 disease advocacy groups. PXE International, http://www.pxe.org/english/View.asp?x=1683.
[421] Novas, *supra* note 393, at 303.
[422] Marshall, *Patient Advocate*, *supra* note 407, at 1226.
[423] Terry, *supra* note 408, at 170.
[424] Cf. Gitter, *supra* note 395, at 315.

This approach portends many benefits for advancing research. It expands the contractually-created commons to biomedical resources affecting rare disease, which are unlikely to be the subject of NIH funding. From the perspective of institutional competence, motivated disease groups may be well-positioned to distinguish between various uses of patented research tools, exclusively licensing technology when necessary to facilitate additional development. The entrepreneurial engagement of disease advocacy groups may also serve interests of fairness. As commentators have noted, it may be unacceptable "to presume that patients, subjects, disease-associated advocacy groups, foundations, and government (and in turn, taxpayers) are all pure altruists, as policies and practices now do presume, especially when these stakeholders have contributed in a meaningful way to the research enterprise."[425] Providing tissue donors with some say in the availability of resulting patented inventions acknowledges their vital contributions to basic research.

Of course, these efforts face several challenges. As in other contexts, control over intellectual property may facilitate parochialism. While investigating the PXE gene may reveal insights into macular degeneration, hypertension, and cardiovascular disease,[426] it is conceivable that PXE International's interest in the gene may only extend to its namesake disease, thus leaving other conditions unexplored.[427] Furthermore, claims by previously "altruistic" tissue donors add another layer of negotiation to the costs of conducting research. Additionally, tissue donors negotiating quid pro quos raise unique biomedical ethical concerns beyond the scope of

[425] Merz et al., *Protecting Subjects' Interests*, *supra* note 418, at 969.
[426] Novas, *supra* note 393, at 297; Rao, *supra* note 395, at 378; *cf*. Gitter, *supra* note 395, at 323; Bovenberg, *supra* note 418, at 932.
[427] While Shannon Terry has stated that "we don't just represent people with PXE, we represent anybody who has anything," she nonetheless acknowledges that PXE International's focus is to help develop a low-cost PXE diagnostic test and treatment. Fleischer, *supra* note 410, at 100.

this Article.[428] This behavior substantially challenges the notion of the gift as the founding gesture of participation in biomedical research.[429] Such "compensation" may conflict with prohibitions against "undue inducement"[430] and may discourage truly altruistic donations by patients whose tissues are necessary to conduct research.[431]

Part V. Opportunities, Challenges, and Prescriptions

Across, government, academia, and the non-profit sector, upstream institutions are taking matters into their own hands to address potential patent holdup in biomedical research. These efforts do not represent exogenous regulation, but arise from within the political economy of the biomedical research sector. In many ways, these efforts respond directly to the perceived limitations of public law solutions, most notably the narrowing of the experimental use exception, and reflect the privatization of public policy in patent law. This Part critically assesses this trend, providing prescriptions for public institutions to better manage the contractual construction of a research commons. In so doing, it explores the promises and perils of consideration-based patent regulation more generally.

A. Opportunities and Advantages

[428] The Human Genome Organisation has cautiously endorsed benefit-sharing for participants in biomedical research. The Human Genome Organisation, Statement on Benefit-Sharing, Apr. 9, 2000, available at http://cellbank.nibio.go.jp/information/ethics/kiban01/downloadEN/HUGOStatement_on_Benefit_Sharing.htm.
[429] Hayden, *supra* note 393, at 740.
[430] *Id*. at 739; Bartha Knoppers, *Status, Sale, and Patenting of Human Genetic Material: An International Survey*, 22(1) NATURE GENETICS 23, 24 (1999).
[431] Fleischer, *supra* note 410, at 87.

The primary advantage of a contractual approach to exempting noncommercial research from patent infringement is that it is actually working. Existing public law initiatives to address this problem, such as the common law experimental use exception, are inadequate, and crafting a more effective centralized solution would be technically and politically difficult. On the contrary, tying access conditions to valuable consideration in individual contracts is an implementable approach that can provide certain access to at least a subset of patented research tools. While it cannot achieve the scope of public law initiatives, consideration-based patent regulation by individual institutions represents a supplementary working solution to patent holdup.

These efforts arise organically from the existing "normative hierarchy" of biomedical research, where institutions that dominate upstream research support generally seek to disseminate the fruits of that research widely. While the norms and motivations of the institutions profiled here are certainly not homogenous[432]—frictions, for example, have arisen between the NIH and universities—in policy and practice they distinguish themselves from traditional rent-seeking patentees. This trend does not involve profit-maximizing firms sacrificing revenues in order to "do the right thing."[433] Rather, it involves public institutions wielding their substantial market power to promote self-articulated norms.

Of particular importance, consideration-based patent regulation provides considerable freedom to operate for governmental entities. Legislatively reforming patent rights is cumbersome and likely to embroil vested political interests, and potential judicial innovations are constrained by existing doctrine. However, by placing conditions on funds, the NIH can

[432] Merz et al., *Protecting Subjects Interests'*, *supra* note 418.
[433] Interestingly, firms are increasingly heeding these requests. *See A Special Report on Corporate Social Responsibility*, The Economist, Jan. 19, 2008; Joel C. Dobris, *SRI—Shibboleth or Canard (Socially Responsible Investing, That Is)*, 42 REAL PROP. PROB. & TRUST J. 755, (2008).

encourage and arguably compel individual grantees to adopt open licensing practices. The greater freedom to operate is especially salient to state governments. If California enacted a general noncommercial research exception to patent infringement in that state, such a statute would surely run afoul of federal preemption doctrine.[434] However, by acting in a funding capacity rather than a "legislative" capacity, CIRM is free to impose just that restriction on its grantees.

Unlike traditional regulation, the *in personam* nature of this approach also allows for precise, highly contextualized policy interventions. Access and exclusivity both play important roles in optimally exploiting biomedical resources, which often requires distinguishing research use from commercial development and sale. As distinctions increase, information costs rise and patents begin to function less like simple rights to exclude and more like complex governance regimes.[435] General legislation may lack the granularity to address individual situations. Through maintaining thousands of grantor-grantee and licensor-licensee relationships, public institutions are negotiating, monitoring, and fine-tuning arrangements to ensure that patented research tools are widely available for noncommercial research while maintaining context-specific exclusivity to ensure commercial development. Along similar lines, tying access conditions to material support correctly aligns economic incentives. There is a recursive element here where expectations of access to patented research tools only arise where public support has helped satisfy the incentive to invent.

B. Challenges and Prescriptions

[434] *See supra* note .
[435] *See* Smith, *supra* note 35.

Of course, consideration-based patent regulation in general, and the contractual creation of a research commons in particular, must address several challenges. First, such efforts only establish a research commons within the funding and licensing sphere of certain public institutions. Not all institutions will voluntarily adopt these safeguards, thus resulting in a patchwork commons. Furthermore, the Bayh-Dole Act prevents the NIH from directly establishing a research exception for federally-funded biomedical inventions. As others have noted, streamlining the administrative requirements of the Bayh-Dole Act would strengthen the NIH's authority to direct patentee licensing practices.[436] Such reforms would also enhance the NIH's ability to compel recalcitrant public institutions—including universities—to adopt open licensing policies.

A more serious challenge is that placing onerous burdens on grant recipients and patent licensees may chill public-private sector partnerships and technological development. After all, the primary motivation behind the Bayh-Dole Act was to provide exclusive rights to the private sector to encourage commercializing taxpayer-funded inventions. Excessive strings on money, patent rights, or materials could stifle these exchanges.[437] However, carefully drafted *noncommercial research* exceptions can ensure exclusivity for sale of refined inventions to encourage investment in product development. For example, allowing patented human embryonic stem cells to be widely used for academic research, but allowing context-specific, exclusive licensing for commercial development leading to "value-added" products is an appropriate approach to take.[438] Several of these initiatives sharply distinguish non-profit from

[436] Rai & Eisenberg, *supra* note 9.
[437] *Cf*. Constance Holden, *Universities Find Too Many Strings Attached to Foundation's Offer*, 312 SCIENCE 1127 (2006).
[438] I emphasize "context specific" because an exclusive licensee may not be well situated to coordinate the development of *all* commercial applications of assets so "pluripotent" as human embryonic stem cells. *See* Rai & Eisenberg, *supra* note 9, at 309-10.

for-profit entities, only requiring that patented research tools be widely available to the latter. However, where public support has satisfied the incentive to invent and where no additional benefit to exclusivity exists, public institutions should consider insisting on wide access to research tools for *for-profit* entities as well.

A related challenge is institutional competence. In certain situations, the best course of action is to refrain from patenting a resource. In many others, distinctions are crucial for technologies that simultaneously represent fully-functional research tools as well as precursors to more refined commercial products. Some public entities, such as the NIH and non-profit funding agencies, may be better situated than others to draw these distinctions.[439] As entities like CIRM gain more experience in monitoring grants, their technical capacity will increase. Furthermore, collective organizations like the Stanford consortium and the Association of University Technology Managers can provide technical assistance to university technology transfer offices to help implement the provisions described here.

A consistent challenge of private-law mechanisms is the specter of parochialism. CIRM's contractually constructed research commons only applies in California. Furthermore, some university licenses only automatically grant research exceptions to *their own* scientists rather than to non-profit researchers in general. Additionally, it is conceivable that the stewards of the PXE gene may privilege research on that disease while shunning open use of the gene to study other conditions. These examples illustrate the potential for self-dealing inherent in institution-driven enforcement of public policy. To fully advance open science, public institutions should draft intellectual property policies and licenses to allow all noncommercial research uses of publicly-developed inventions.

[439] *See* Rai & Eisenberg, *supra* note 9.

A significant limitation on these efforts is that they depend on institutions acting upon "upstream" norms. This challenge has many facets. First, institutions may articulate norms to which they would rather not adhere, at least in certain contexts.[440] This criticism is particularly salient to universities, some of which espouse the ideals of open science while vigorously enforcing their patents.[441] Second, institutions often subscribe to conflicting norms. Thus, for example, while CIRM promotes open sharing of discoveries, it also takes a financial stake in the research it funds. Finally, implementing organizational norms is subject to principal-agent problems. This is illustrated in the disconnect between lofty intellectual property policies and the behavior of some university technology transfer offices. For such offices to act consistently with stated policies, university leadership may need to modify their incentive structures and performance metrics. In a broad sense, disciplined focus on organizational objectives, coordinated action (to eliminate free riders), and compulsion from other public institutions (such as the NIH) can help reinforce upstream norms.

Part VI. Implications for Patent Law, Institutions, and Theory

In addition to providing working solutions to patent holdup, the contractual creation of a research commons holds several broader implications for patent law.

Most notably, it illustrates a significant shift from property to contract as a means for implementing patent policy. Unlike traditional judicial, legislative, or administrative regulation, this model embeds policy objectives in contractual quid pro quos. Instead of altering the nature

[440] *Cf.* Oona Hathaway, *Do Human Rights Treaties Make a Difference?*, 111 YALE L. J. 1935 (2002) (arguing that countries sometimes enjoy the expressive benefits of ratifying human rights treaties without actually complying with them).
[441] *See, e.g.*, Howard, *supra* note 218.

of patent rights in general, these *in personam* contractual arrangements create individual access requirements for research technologies. This shift from property to contract, moreover, provides a new perspective on how patents achieve their policy objectives. At a primary level, patents promote technological progress through their property-like character; exclusive rights spur invention, disclosure, and commercialization, and promote efficient allocation of resources devoted to innovation.[442] However, at a secondary level, certain policy objectives are best advanced by selectively curbing these exclusive rights through contracts.

Furthermore, consideration-based patent regulation reveals that money, labor, materials, and licenses represent "normative portals" for injecting public values in the patent system. Patents, which have attracted criticism for facilitating economic monopolies, may be said to suffer from a normative monopoly in which preoccupation with exclusivity overshadows broader social ends. However, patented technologies—including foundational research tools—arise from myriad inputs that can come with normative strings attached.[443] This Article has focused on the norm of open science, but public institutions are also leveraging research support to promote access to essential medicines and commercialization of existing inventions.[444] Of course, the dynamics of these efforts may differ considerably from creating a research commons. For example, the NIH's short-lived experience with a "reasonable pricing" requirement for patented drugs arising from public-private partnerships illustrates that upstream demands may overreach and undermine incentives to innovate.[445]

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[442] See supra note .

[443] An alternative approach would allow strict patents on government-financed inventions, increase taxes on these patentees, and utilize these revenues to subsidize licenses for noncommercial researchers. While not resolving the merits of this approach, this Article points out that consideration-based patent regulation avoids the redundancy of taxpayers financing licenses for taxpayer-financed inventions.

[444] *See supra* note .

[445] *See* NIH, A Plan to Ensure Taxpayer's Interests are Protected *10; Thomas A. Hemphill, *Economic Considerations in Cooperative Research and Development Agreements (CRADA)*, 28 TECH. IN SOC'Y 321, 328-29 (2006); Sage, *supra* note 174, at 1742.

Consideration-based patent regulation also challenges prevailing characterizations of participants in the patent system, thus highlighting the importance of institutional norms. A fundamental premise of the patent system is that parties investing in technology seek to maximize profits. While this is a reasonable assumption for many players, it is can be grossly inaccurate for others. Public institutions contributing enormous amounts of money, labor, and materials to research and development leading to patented inventions do so with only secondary regard for profits.[446] Because of normative considerations, providing upstream institutions with property rights on research tools (or legal claims on those rights) may significantly enhance the availability of these technologies to the scientific community.

Further upsetting institutional stereotypes, the creation of a biomedical research commons casts public institutions as dynamic, entrepreneurial market actors. In recent years, must useful commentary has revealed a new "dynamism in the public domain."[447] In the typical narrative, for-profit firms utilize private ordering to resolve intellectual property holdup, and public institutions merely facilitate these efforts. However, consideration-based patent regulation reveals that public institutions, wielding enormous market power, can drive private ordering as well. In this regard, the patent system exhibits a self-correcting feature in which frustrations over patent holdup motivate "private" working solutions.[448] While Congress can significantly impact patent practice by amending the Patent Act, the NIH can also do so through the power of the purse.

Along these lines, this Article identifies a wider universe of "policy levers" beyond Congress, courts, and the PTO that are available to advance patent policy.[449] Self-recognition as

[446] *See* Strandburg, *Users as Innovators*, *supra* note 11.
[447] *See* Merges, *A New Dynamism in the Public Domain*, *supra* note 22.
[448] *See id*.
[449] *See* Burk & Lemley, *supra* note 37.

policy actors may spur public institutions to expand existing practices. For example, armed with this self-recognition, university technology transfer officials may be more likely to reserve broad research rights for patented research tools as well as to nonexclusively license them.[450] Intellectual property scholarship has highlighted the benefits of decentralized peer production, in which loosely coordinated parties act on communal norms to contribute to value-generating programs.[451] Open source software is a frequently cited example. Paralleling the benefits of decentralized production, these efforts represent decentralized patent *regulation* arising from numerous independent institutions acting upon similar norms.

Finally, consideration-based patent regulation allows for democratizing the rewards of innovation.[452] As Professor James Boyle has observed, intellectual property law consistently favors those who produce refined goods rather than the suppliers of the inputs that make them possible.[453] Furthermore, "[w]ithout legal recognition of the key contributions and rights of early stage researchers, the public credits and financial rewards based on their discoveries will inure exclusively to those who control the final step of production."[454] Taxpayers, universities, non-profit organizations, and tissue donors contribute significantly to biomedical research and should be able to expect something in return.[455] Consideration-based patent regulation provides a path by which contracts can preserve what intellectual property would otherwise take away. Conditioning the support of public institutions on assurances that resulting patents will not disrupt fundamental research is one way to acknowledge their vital upstream contributions.[456]

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[450] Lemley, *Are Universities Patent Trolls?*, *supra* note 21, at 611.
[451] *See generally* Benkler, *Coase's Penguin*, *supra* note 38.
[452] *See* Sunder, *supra* note 39.
[453] BOYLE, *supra* note 39.
[454] Kesselheim & Avorn, *supra* note 167, at 850.
[455] Merz et al., *Protecting Subjects' Interests*, *supra* note 418, at 969.
[456] However, actually asserting these claims, which were always theoretically available to upstream contributors, will increase transaction costs.

Conclusion

Ironically, while patents aim to promote progress, patents on the technological inputs to biomedical research can inhibit scientific inquiry and the development of life-enhancing applications. "Public law" mechanisms to address this challenge, such as the common law experimental use exception, have not provided a satisfactory solution. In the wake of these shortcomings, this Article argues that public institutions are fruitfully engaged in private ordering to prevent patent holdup. Operating within the political economy of the biomedical research sector, institutions are leveraging their enormous support for research as well as norms favoring wide access to technologies to contractually construct a biomedical research commons.

In particular, this Article argues that public institutions—including federal and state funding agencies, universities, non-profit organizations, and disease advocacy groups—are conditioning significant research support on requirements that grantees and licensees make patented inventions widely available for scientific investigation. Through informal and formal mechanisms, the NIH and CIRM are compelling grant recipients to openly share patented research tools arising from public funds. Universities are reserving noncommercial research exceptions when licensing research tools and favoring nonexclusive rather than exclusive licensing of such inventions. Non-profit funding organizations and disease advocacy groups are conditioning access to money and bodily tissues on requirements that recipients do not assert resulting patents to inhibit biomedical research. In all of these instances, public institutions are leveraging upstream research support to advance the norm of open science.

At a substantive level, this inquiry highlights the importance of institutional norms in the patent system. Within the "normative hierarchy" of biomedical research, institutions providing

the most critical support for upstream research are also generally committed to widely disseminating research tools. This confluence of access norms and enormous material support creates an opportunity ripe for pervasive, market-based patent regulation. At a procedural level, these efforts reflect a shift from property to contract as a mechanism for advancing patent policy. Rather than centralized regulation altering the general scope of patent rights, this approach advances public policy objectives through the faster, nimbler, and more palatable medium of individualized quid pro quos. Responding to the deficits of public law mechanisms, institutions are privatizing public policy in patent law. Conscientious drafting of contractual arrangements, enhanced technical competence, and consistent adherence to institutional norms can strengthen these efforts moving forward.

In addition to providing working solutions to patent holdup, consideration-based patent regulation holds several broader implications for patent law. Institutions are using contracts not only to promote open science, but also to enhance access to essential medicines and ensure commercialization of inventions. Furthermore, this development reveals that myriad actors beyond Congress, federal courts, and the PTO can fruitfully participate in advancing patent policy. Finally, consideration-based patent regulation provides upstream contributors with a greater role in determining how patented inventions are used, thus democratizing the management of innovation. Optimal exploitation of research technologies often requires both access and exclusivity; by asserting their values in the marketplace, upstream institutions are helping to strike a more fruitful balance between public and private norms in the development of new technologies.