

CONTRACTING TO PRESERVE OPEN SCIENCE: CONSIDERATION-BASED REGULATION IN PATENT LAW

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ABSTRACT

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, are limited in their effectiveness. 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, nonprofits, and disease advocacy groups are conditioning 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 toward “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*

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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.

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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) reflect a significant new development.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, nonprofit grantees must make patented inventions "readily accessible" to California institutions for noncommercial research purposes.⁵ In essence, CIRM is contractually creating a research commons within the State

¹ See *infra* Part I. See generally Lori Andrews et al., *When Patents Threaten Science*, 314 *SCIENCE* 1395, 1395–96 (2006); 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); Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 *SCIENCE* 698, 698–701 (1998); 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*]; Suzanne Scotchmer, *Standing on the Shoulders of Giants: Cumulative Research and the Patent Law*, 5 *J. ECON. PERSP.* 29, 39–30 (1991).

² See CAL. CODE REGS. tit. 17, §§ 100300–100310, 100400–100410 (2008).

³ See *infra* Part IV.B.

⁴ See CAL. CODE REGS. tit. 17, §§ 100300–100310 (codifying CIRM intellectual property policies for nonprofit organizations); *id.* §§ 100400–100410 (codifying CIRM intellectual property policies for for-profit organizations).

⁵ *Id.* § 100306(a). It is expected that a substantial majority of CIRM grantees will be nonprofit institutions, such as universities.

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 inhibit scientists from using critical technologies, public institutions are leveraging their significant support for biomedical research to "contract" for enhanced access to such technologies.

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 medicines⁷ and hinder commercialization of existing inventions.⁸

The standard retort to this critique is that access constraints are necessary to motivate investments in new technology. However, this retort does not hold in all contexts.⁹ It is particularly questionable within the political economy of biomedical research, where government, academic, and nonprofit institutions

⁶ The National Institutes of Health (NIH) describes 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." NIH, 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., MICHAEL E. GLUCK, KAISER FAMILY FOUND., FEDERAL POLICIES AFFECTING THE COST AND AVAILABILITY OF NEW PHARMACEUTICALS 6 (2002), available at <http://www.kff.org/rxdrugs/loader.cfm?url=/commonspot/security/getfile.cfm&pageId=14078>; 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); Anupam Chander & Madhavi Sunder, *The Romance of the Public Domain*, 92 CAL. L. REV. 1331, 1332 (2004); Amy Kapczynski et al., *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, 20 BERKELEY TECH. L.J. 1031, 1046–51 (2005); Evan Ackiron, 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 firms that assert patents but do not produce any goods or services, often referred to colloquially as "patent trolls"). But see ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, *PATENT LAW AND POLICY* 939–40 (4th ed. 2007) (noting that nonpracticing patent aggregators may play valuable roles 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) (arguing that the justification for strong patent rights loses significant force in the context of publicly sponsored research).

provide enormous support for research leading to patented inventions.¹⁰ Many patented research tools, for example, arise from taxpayer-funded investigations conducted at nonprofit universities. This support undermines the notion that patent exclusivity is necessary to provide incentives to invent.¹¹ Of course, exclusivity may still be required to encourage private firms to 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 that potentially address this challenge—such as a common law experimental use exception to patent infringement¹⁵—have only achieved partial success.

Looking beyond public law mechanisms, 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 make resulting patented inventions widely available for noncommercial research purposes. In essence, these institutions are building, through contract-like *quid pro quos*, a research commons for biomedicine.

This exchange of valuable consideration for widespread access to patented technologies illustrates a general phenomenon that I call “consideration-based

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

¹¹ Adam B. Jaffe, *The U.S. Patent System in Transition: Policy Innovation and the Innovation Process*, 29 RES. POL’Y 531, 552 (2000); Rai & Eisenberg, *supra* note 9, at 300; cf. Katherine J. Strandburg, *Users as Innovators: Implications for Patent Doctrine*, 79 U. COLO. L. REV. 467, 471 (2008) [hereinafter Strandburg, *Users as Innovators*] (noting that the benefits of self-use frequently motivate invention independent of profit expectations).

¹² F. Scott Kieff, *Property Rights and Property Rules for Commercializing Inventions*, 85 MINN. L. REV. 697, 703 (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, at 291.

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 WM. & MARY L. REV. 127, 129 (2000).

¹⁵ See *infra* Part II.B.

¹⁶ While several of these initiatives, such as reserved research exceptions by universities, increase access to wide classes of patented inventions for noncommercial research, this Article focuses on enhancing access to research tools because of their centrality to scientific inquiry. See *infra* Parts II, IV.C.

patent regulation.” Exclusive rights on research tools are problematic because these assets are foundational inputs to a wide range of downstream uses. However, these inputs 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 these tools for scientific inquiry. This contractually driven practice offers a swifter, nimbler, and more precise mechanism for influencing the behavior of patentees than traditional patent regulation.¹⁷ While this Article focuses on consideration-based patent regulation as a means to enhance access to patented research tools, public institutions are also using this mechanism to advance other access-related policy objectives as well.¹⁸

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, nonprofit organizations, and disease advocacy groups.¹⁹ While each of these entities has received individual scholarly attention,²⁰ this Article identifies and explores underappreciated commonalities arising from their diverse intellectual property strategies.²¹ Within this effort, the National Institutes of Health (NIH) is leveraging significant taxpayer funds to encourage and arguably compel grant recipients

¹⁷ Cf. Arti Kaur 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 *infra* notes 525–26 and accompanying text.

¹⁹ Cf. Kapczynski et al., *supra* note 7, at 1037. Where necessary, I will distinguish among these “public” institutions.

²⁰ See, e.g., *id.* at 1031 (addressing universities); Rai & Eisenberg, *supra* note 9, at 289 (focusing on the NIH).

²¹ Another set of institutions that falls within this paradigm is scientific journals. Many leading journals, including *Science* and *Nature*, explicitly require authors to make biomedical resources described in published articles widely available to the research community. See COMM. ON RESPONSIBILITIES OF AUTHORSHIP IN THE BIOLOGICAL SCI., NAT’L RESEARCH COUNCIL, SHARING PUBLICATION-RELATED DATA AND MATERIALS: RESPONSIBILITIES OF AUTHORSHIP IN THE LIFE SCIENCES 4 (2003); David Cyranoski, *Share and Share Alike?*, 420 NATURE 602 (2002); Eliot Marshall, *The UPSIDE of Good Behavior: Make Your Data Freely Available*, 299 SCIENCE 990 (2003) [hereinafter Marshall, *The UPSIDE of Good Behavior*]. Given that publications are the currency of career advancement among academic scientists, journals enjoy a significant degree of leverage to compel authors to share patented (and unpatented) research tools. See COMM. ON RESPONSIBILITIES OF AUTHORSHIP IN THE BIOLOGICAL SCI., *supra*, at 4 (“[T]he act of publishing is a *quid pro quo* in which authors receive credit and acknowledgment in exchange for disclosure of their scientific findings.”). Because of space constraints, this Article will not directly address journals as public institutions engaged in consideration-based patent regulation. However, many of the other public institutions profiled here, including CIRM and the Howard Hughes Medical Institute, explicitly encourage or require grantees to make biomedical resources described in academic publications widely available for noncommercial research purposes.

to share patented inventions with noncommercial scientists. CIRM explicitly requires such sharing within California. Universities are reserving nonprofit research exceptions and favoring nonexclusive rather than exclusive licenses when transferring foundational research technologies to industry. Nonprofit organizations and disease advocacy groups are explicitly and implicitly conditioning receipt of money, tissue samples, and other valuable consideration on assurances that patented inventions arising from these inputs will be widely available for research purposes. While these efforts are far from identical, they all illustrate a contractual approach to tempering patent rights, which can significantly broaden access to research technologies.²²

Before proceeding, some distinctions are in order. In some cases, biomedical research is best advanced by simply relegating foundational technologies to the public domain.²³ 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 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 when public support has satisfied the incentive to invent the underlying tool, exclusive rights may still be necessary to motivate additional private investment in product development.²⁴ Accordingly, in

²² 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., Yochai Benkler, *Commons-Based Strategies and the Problem of Patents*, 305 *SCIENCE* 1110, 1110–11 (2004) [hereinafter Benkler, *Commons-Based Strategies*]; Mark A. Lemley, *Are Universities Patent Trolls?*, 18 *FORDHAM INTELL. PROP. MEDIA & ENT. L.J.* 611 (2008) [hereinafter Lemley, *Are Universities Patent Trolls?*]; Rai & Eisenberg, *supra* note 9, at 289. Furthermore, unlike arguments for maintaining open access to *data* through contracts, this Article focuses on the very different challenge of enhancing access to patented biomedical inventions. See J.H. Reichman & Paul F. Uhler, *A Contractually Reconstructed Research Commons for Scientific Data in a Highly Protectionist Intellectual Property Environment*, 66 *LAW & CONTEMP. PROBS.* 315 (2003).

²³ Cf. Lee, *Inverting the Logic of Scientific Discovery*, *supra* note 1, at 82 (arguing for broad access to certain knowledge-producing technologies, including research tools). 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*]. Although not the central focus of this Article, the erosion of the public domain itself raises significant concerns. See, e.g., James Boyle, *The Second Enclosure Movement and the Construction of the Public Domain*, 66 *LAW & CONTEMP. PROBS.* 33 (2003) (arguing against the private “enclosure” of information previously available in the public domain); Jessica Litman, *The Public Domain*, 39 *EMORY L.J.* 965 (1990) (arguing that authorship necessarily involves reshaping the prior works of others); Pamela Samuelson, *Enriching Discourse on Public Domains*, 55 *DUKE L.J.* 783 (2006) [hereinafter Samuelson, *Enriching Discourse*] (considering the benefits of accepting the existence of multiple public domains); cf. Leslie A. Kurtz, *Copyright: The Scenes a Faire Doctrine*, 41 *FLA. L. REV.* 79, 83–84 (1989) (discussing why *scenes a faire* should reside in the public domain as uncopyrightable subject matter).

²⁴ This was the rationale behind the Bayh–Dole Act, which allows federal grantees to patent taxpayer-financed inventions precisely to encourage their development into marketable products. Kieff, *Property Rights*

certain circumstances, such assets should be widely available for high-value uses such as noncommercial research²⁵ while subject to exclusive rights for commercialization and sale.²⁶ Unlike broad-brush public law approaches, contractual approaches are well-suited to draw these distinctions.²⁷ Consistent with these principles, rather than relegating publicly supported research tools to the public domain or allowing patentees to assert strict exclusive rights in all circumstances, public institutions are creating a limited, noncommercial research exception to patent infringement for these resources.

This Article reveals a new dimension to “private ordering” that has long sought to resolve intellectual property holdup.²⁸ It shows that such behavior is not the exclusive domain of for-profit entities; governments, universities, and nonprofits are dominant players in innovation markets, and they actively engage 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 privileging access to resulting technologies rather than strict exclusivity, and (3) implement these norms through “contractual” mechanisms with downstream parties. The opportunities raised by consideration-based

and Property Rules, *supra* note 12, at 746 n.209; Rai & Eisenberg, *supra* note 9, at 299. *But see* Golden, *supra* note 12, at 166 (arguing that patents on university discoveries may be unnecessary if firms can extract value from patenting manufacturing processes or refined goods).

²⁵ Noncommercial research includes investigations conducted by nonprofit institutions as well as “internal” investigations at for-profit firms that are not directly commercialized. *See infra* notes 201–05 and accompanying text.

²⁶ While this Article attempts to distinguish between noncommercial research use and commercial sale, other distinctions are also relevant for optimally licensing patented research tools. *See* NIH, Principles and Guidelines, *supra* note 6, at 72,094 (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).

²⁷ For reasons related to those described here, 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. *See generally* 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 & COLLABORATION, July 3, 2006, <http://www.pubmedcentral.nih.gov/picrender.fcgi?artid=1523369&blobtype=pdf>. Furthermore, other mechanisms are available to liberalize access to privately developed tools that achieve “infrastructural” status. *See* Peter Lee, *The Evolution of Intellectual Infrastructure*, 83 WASH. L. REV. 39, 102–20 (2008) [hereinafter Lee, *The Evolution of Intellectual Infrastructure*].

²⁸ *See, e.g.*, Merges, *A New Dynamism in the Public Domain*, *supra* note 23, at 183 (arguing that investments by private market actors can help resolve intellectual property holdup without the need for legal intervention); *see also* Robin Feldman & Kris Nelson, *Open Source, Open Access, and Open Transfer: Market Approaches to Research Bottlenecks*, 7 NW. J. TECH. & INTELL. PROP. 14 (2008) (noting several market approaches to mitigating the effects of patent thickets).

regulation suggest caution before attempting centralized patent reform to resolve research holdup, as contractual arrangements by institutional players within the biomedical sector may more effectively address this challenge.²⁹ With this recognition, policy objectives shift from ensuring correct ex ante definitions of patent rights to lowering transaction costs to encourage efficient ex post negotiations over those rights.

These efforts are notable both substantively and procedurally. At a substantive level, they reveal the vast importance of institutional norms in the patent system.³⁰ While patent theory presumes that actors in the patent system are profit-maximizing entities,³¹ this presumption can be grossly inaccurate. Consideration-based patent regulation both reveals and exploits the upstream–downstream “normative structure” of the biomedical field.³² Subject to qualification,³³ public institutions that provide significant “upstream” support for investigations leading to research tools are also generally committed to widely disseminating them.³⁴ Alternatively, “downstream” entities that develop commercial products, such as pharmaceutical and biotechnology firms, tend to favor exclusivity and profit maximization.³⁵ The confluence of significant upstream support and norms favoring access creates a situation ripe with possibility.³⁶ Normative considerations thus provide a powerful reason

²⁹ In addition to addressing the tangible problem of alleviating patent holdup in biomedical research, this regulatory model also reveals an underappreciated, *contractual* mechanism by which parties may create and manage a commons. See Michael J. Madison et al., *Constructing Commons in the Cultural Environment* 10 (U. of Pittsburgh Law Sch. Legal Stud. Res. Paper Series, Working Paper No. 2008-26, 2008), <http://ssrn.com/abstract=1265793> (discussing the challenges of understanding the construction of cultural commons arrangements).

³⁰ Cf. Cass R. Sunstein, *Social Norms and Social Roles*, 96 COLUM. L. REV. 903, 929 (1996) (describing “norm entrepreneurs” who help facilitate large-scale social change); Harold Hongju Koh, *The 1998 Frankel Lecture: Bringing International Law Home*, 35 HOUS. L. REV. 623, 647 (1998) (extending this concept to describe “transnational norm entrepreneurs”).

³¹ See Giles S. Rich, *The Relation Between Patent Practices and the Anti-Monopoly Laws*, 24 J. PAT. OFF. SOC'Y 159, 164 (1942).

³² 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 enormous amount of basic research that facilitates private sector development.

³³ See *infra* Part IV.

³⁴ Cf. Golden, *supra* note 12, at 110 (“[O]ver-emphasis on patent protection risks displacing a system of public sector values that appears to have served science and society well.”).

³⁵ *Id.* at 106, 131, 133.

³⁶ *Id.* at 109 (“[Legal commentators] have largely ignored the details of the multi-billion dollar system of investment, mostly public and mostly university-based, that provides most of the researchers and basic research that drives modern biotechnology.”).

for why the initial allocation of patent rights on research tools (or contractual claims on those rights) matters a great deal.³⁷

At a procedural level, consideration-based patent regulation reflects an important shift from broad-based, legislatively defined property rights to individual contracts as a means for advancing patent policy. Intellectual property encourages innovation by granting inventors a right to exclude, but sometimes public policy requires tempering exclusive rights through contracts. I use the term “contract” broadly to include both informal *quid pro quos* as well as explicit contracts, such as funding agreements and licenses. This contractual 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 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 permitting selective exclusion and access.³⁸ These governance regimes, and the high information costs they entail, are better managed through *in personam* contractual relationships than *in rem* property rules.³⁹

A contractually created biomedical research commons may significantly increase access to patented research tools, and this Article offers several prescriptions for enhancing the creation and effectiveness of such a commons. Contrary to prevailing technology transfer policy, public institutions should engage in incentives-based patenting analyses that will likely lead to less patenting of certain research tools and more sharing of protected resources with commercial entities. This Article proposes that the NIH play a catalytic role in standardizing terms and coordinating the efforts of disparate public institutions, thereby helping to create a single, coherent research commons. Greater technical assistance from the NIH and organizations such as the

³⁷ 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 do 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 et al., *supra* note 27, at *2 (examining the development of PCR in a private corporate setting).

³⁸ See Henry E. Smith, *Exclusion Versus Governance: Two Strategies for Delineating Property Rights*, 31 J. LEGAL STUD. S453 (2002).

³⁹ 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).

Association of University Technology Managers (AUTM) can help encourage public institutions to adopt “open science”⁴⁰ best practices. More concretely, streamlining the procedural and substantive standards of the Bayh–Dole Act would strengthen the NIH’s ability to widen access to taxpayer-financed research tools. Narrowly drafted exceptions for *noncommercial* research can maintain private incentives to develop inventions into marketable products and thus ensure the robustness of public–private partnerships. Furthermore, public institutions should adopt policies allowing *all* nonprofit institutions to access publicly supported research tools, thus preempting the emergence of scientific “fiefdoms.”

In addition to providing working solutions to patent holdup, the contractual creation of a biomedical research commons has several broader implications for patent law. At a macroscopic level, it reflects the privatization of public policy. This trend is embodied in a shift from property to contract and from broad, across-the-board legal pronouncements to individualized quid pro quos as mechanisms to advance patent policy. This model recasts government bodies from stodgy rulemaking institutions to nimble market actors utilizing the power of the purse to effectuate public objectives. This model also vastly widens the range of “policy levers”⁴¹ available to advance patent policy to include the intellectual property practices of funding agencies, universities, nonprofit foundations, and disease advocacy groups. In addition, the contractual creation of a biomedical research commons also reveals the vast importance of industry structure in determining the impact of patents on innovation; consideration-based patent regulation has particular traction in the biomedical sector because of the dominance of public support in that field. Furthermore, public institutions may employ contractual strategies to advance a variety of objectives beyond maintaining a robust research commons, such as enhancing access to essential medicines and preempting the threat of “patent trolls.”⁴² Significantly, this regulatory model provides “upstream” contributors with a greater role in managing the fruits of innovation, historically the exclusive province of downstream patentees and licensees.⁴³

⁴⁰ See Rai & Eisenberg, *supra* note 9, at 289.

⁴¹ Cf. Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1579 (2003).

⁴² See *infra* notes 525–26 and accompanying text.

⁴³ See JAMES BOYLE, SHAMANS, SOFTWARE, AND SPLEENS 119–43 (1996) (arguing that the benefits of intellectual property regimes usually inure to those who control the final steps of production); Madhavi Sunder, *IP²*, 59 STAN. L. REV. 257, 284 (2006) (advocating culturally and socially sensitive approaches to intellectual property to complement the dominant incentives paradigm).

Part I examines access constraints inherent in the patent system and explains 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 contractual 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 institutions to biomedical research, their normative commitments to open science, and contractual practices that limit the exclusive rights of downstream patentees to advance this policy interest. Part V turns more directly from the descriptive to the normative, assessing the opportunities and challenges posed by consideration-based patent regulation as well as offering prescriptions for effectively implementing it. Part VI explores the significant implications of this phenomenon for patent law, institutions, and theory.

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.⁴⁴ As is well-recognized, the technical knowledge inherent in an invention is a public good, which is nonrival⁴⁵ (multiple parties can use it without diminishing its availability) and nonexcludable⁴⁶ (absent legal intervention, it is difficult if not impossible to exclude others from appropriating it).⁴⁷ Public goods such as new inventions are subject to undersupply in the absence of exclusive rights because noninnovating firms could simply free-ride on the research and development of others. Patents allow inventors to exclude free riders, thus enabling an

⁴⁴ FREDERIC M. SCHERER, *INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE* 442 (2d ed. 1980); 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.

⁴⁵ See 6 THE WRITINGS OF THOMAS JEFFERSON 180–81 (H.A. Washington ed., Taylor & Maury 1854) (describing ideas as “expansible over all space, without lessening their density in any point”).

⁴⁶ While firms may protect valuable information as a trade secret, it may be difficult to maintain the secrecy of information and still exploit it without legal intervention, such as enforceable nondisclosure agreements.

⁴⁷ See generally Kenneth J. Arrow, *Economics of Welfare and the Allocation of Resources for Invention*, in *THE RATE AND DIRECTION OF INVENTIVE ACTIVITY* 614–16 (Nat’l Bureau of Econ. Research ed., 1962) (noting the difficulties of preventing outside parties from appropriating information).

adequate return on investment.⁴⁸ The necessary tradeoff is that exclusive rights may constrain access to patented inventions.⁴⁹

While access constraints on patented end-user goods may be problematic,⁵⁰ access constraints on the technological *inputs* to research and development are particularly troublesome.⁵¹ In the biomedical realm, patents on upstream “research tools”⁵² may inhibit downstream productive activity. A significant challenge of legislative and judicial attempts to enhance access to research tools is that no clear definition of that term exists.⁵³ For the purposes of this Article, I define a “research tool” as a broadly enabling tool for discovery that is useful to many scientists as an input to experimentation.⁵⁴ Examples of patented tools include extracted and purified human embryonic stem cells; short DNA sequences useful for finding specific genes, 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

⁴⁸ 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 Economic Theories of Patents—The Not-Quite-Holy-Grail*, 71 NOTRE DAME L. REV. 267 (1996) (same); Kitch, *supra* note 44, at 266–71 (elaborating prospect theory). But see Mark A. Lemley, *Ex Ante Versus Ex Post Justifications for Intellectual Property*, 71 U. CHI. L. REV. 129 (2004) (critiquing ex post justifications for intellectual property, including prospect theory).

⁴⁹ Cf. Carol M. Rose, *The Moral Subject of Property*, 48 WM. & MARY L. REV. 1897, 1900–03 (2007) (characterizing private property as a “second-best” approach to resource management).

⁵⁰ For example, patents on pharmaceuticals contribute to higher prices and decreased availability. See *supra* note 7 and accompanying text.

⁵¹ See Rebecca S. Eisenberg, *Patents and Data-Sharing in Public Science*, 15 INDUS. & CORP. CHANGE 1013, 1016 (2006) [hereinafter Eisenberg, *Patents and Data-Sharing in Public Science*]; Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177, 225 (1987) [hereinafter Eisenberg, *Proprietary Rights and the Norms of Science*]; cf. Mark A. Lemley, *Patenting Nanotechnology*, 58 STAN. L. REV. 601, 619–20 (2005) [hereinafter Lemley, *Patenting Nanotechnology*].

⁵² See *supra* note 6 and accompanying text.

⁵³ These definitional difficulties are somewhat 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, 192–93 (2005) (indicating that renegotiation may inject the flexibility needed to promote ex post contract performance).

⁵⁴ Cf. NIH, *Principles and Guidelines*, *supra* note 6, at 72,094 (acknowledging that the definition of “research tools” is necessarily expansive, and defining a research tool as a “tool for discovery” and a “broad, enabling invention” useful to many scientists).

one organism to another, known generally as recombinant DNA technology.⁵⁵ Status as a research tool is context-specific; a genetic diagnostic test functions as a medical product when used to diagnose a patient but represents a research tool when used to study a disease mechanism.⁵⁶ Furthermore, a research tool may be fully functional in its 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.⁵⁷ Crucially, many research tools arise not from applied, commercial research, but quite directly from basic biomedical investigations.

Many developments have coalesced to significantly increase the patenting of research tools.⁵⁸ First, courts have taken an expansive view of patentable subject matter,⁵⁹ such that in some cases the direct fruits of basic research can be patented.⁶⁰ Second, advances in molecular biology have revealed a relatively clear path from “basic” discoveries to commercial products, thus promoting their patenting.⁶¹ 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.⁶² Finally, there is much money to be made. Biomedical patents are essential to the pharmaceutical and biotechnology industries,⁶³ and profit expectations have motivated patenting up and down the research and development chain.⁶⁴

⁵⁵ For additional examples, see John P. Walsh et al., *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, in PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285, 296 (Wesley M. Cohen & Stephen A. Merrill eds., 2003) [hereinafter Walsh et al., *Research Tool Patents and Licensing*].

⁵⁶ Charles Clift, *Patenting and Licensing Research Tools*, in 1 INTELLECTUAL PROPERTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATION: A HANDBOOK OF BEST PRACTICES 82 (A. Krattinger et al. eds., 2007).

⁵⁷ See also Katherine J. Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81, 88–89 [hereinafter Strandburg, *What Does the Public Get?*] (distinguishing between experimenting *on* research tools and experimenting *with* research tools).

⁵⁸ See Rai & Eisenberg, *supra* note 9, at 291–95.

⁵⁹ See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) (holding that a human-made microorganism comprises patentable subject matter); *infra* notes 116–18 and accompanying text.

⁶⁰ Richard R. Nelson, *The Market Economy, and the Scientific Commons*, 33 RES. POL'Y 455, 462 (2004).

⁶¹ Eisenberg, *Patents and Data-Sharing in Public Science*, *supra* note 51, at 1014.

⁶² See *infra* Part IV.A, C.

⁶³ See Golden, *supra* note 12, at 106.

⁶⁴ Further exacerbating the problem of patents on cutting-edge biomedical research tools, these patents tend to be quite broad. See Burk & Lemley, *supra* note 41, at 1656; Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 TEX. L. REV. 989, 1072–73 (1997); Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 848–49 (1990); Patrick L.

Patents on research tools can hinder scientific inquiry in a variety of ways.⁶⁵ First, a patent on a critical, “keystone” asset can single-handedly hold up research.⁶⁶ As I have argued elsewhere, patents on technological “infrastructure,”⁶⁷ such as extracted and purified human embryonic stem cells, can impede wide arrays of scientific inquiry.⁶⁸ Second, the need to bundle multiple licenses for various patented assets can generate transaction costs that render such investigations prohibitively expensive.⁶⁹ This may produce a “tragedy of the anticommons,” wherein a proliferation of upstream exclusive rights leads to wasteful underexploitation of resources, represented here by foregone research.⁷⁰ For example, if a scientist needs to bundle licenses for many patented ESTs, aggregate costs may render an intended course of research unduly expensive.⁷¹ Third, similar to but distinct from the anticommons scenario is the challenge of patent thickets, where multiple overlapping patents cover a single technology.⁷² 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

Taylor, *Research Sharing, Ethics and Public Benefit*, 25 NATURE BIOTECH. 398, 399 (2007); Rai & Eisenberg, *supra* note 9, at 296.

⁶⁵ See Richard C. Levin et al., *Appropriating the Returns from Industrial Research and Development*, 3 BROOKINGS PAPERS ON ECON. ACTIVITY 783, 788 (1987).

⁶⁶ See Merges & Nelson, *supra* note 64, at 882 (discussing the Selden patent, which was used to control development of the automobile). See generally Scotchmer, *supra* note 1.

⁶⁷ See Brett M. Frischmann, *An Economic Theory of Infrastructure and Commons Management*, 89 MINN. L. REV. 917, 956 (2005) (applying economic theory to show that infrastructure enables myriad downstream activities, and arguing that infrastructure should be managed in an openly accessible manner).

⁶⁸ Lee, *The Evolution of Intellectual Infrastructure*, *supra* note 27, at 40; Lee, *Inverting the Logic of Scientific Discovery*, *supra* note 1, at 90.

⁶⁹ For a discussion of the challenges of negotiating technology licenses, see Lee, *The Evolution of Intellectual Infrastructure*, *supra* note 27, at 97–99.

⁷⁰ Heller & Eisenberg, *supra* note 1, at 698. See generally NAT’L RESEARCH COUNCIL, INTELLECTUAL PROPERTY RIGHTS AND RESEARCH TOOLS IN MOLECULAR BIOLOGY (1997); Michael A. Heller, *The Tragedy of the Anticommons: Property in the Transition from Marx to Markets*, 111 HARV. L. REV. 621 (1998) (showing that overlapping property rights may lead to underutilization of resources).

⁷¹ See Heller & Eisenberg, *supra* note 1, at 701.

⁷² See generally Burk & Lemley, *supra* note 41, at 1627; Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, in 1 INNOVATION POLICY AND THE ECONOMY 119 (Adam B. Jaffe et al. eds., 2001).

completely abandoned a project.⁷³ An earlier survey found “almost no evidence” that the presence of multiple upstream rights holders led to the complete cessation of projects.⁷⁴ Similarly, royalty stacking from multiple licenses did not represent a significant or pervasive threat to research.⁷⁵ Commentators observe a de facto experimental use exception whereby patentees “rationally forbear” from suing university scientists.⁷⁶ Private firms wish to avoid the negative publicity and ill-will that arises from suing universities, especially because 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.⁷⁷ In fact, many commercial patentees may explicitly seek to free-ride on such research, which may generate new licensing opportunities for their patents. For their part, nonprofit researchers are often oblivious to whether they are using patented inputs in their experiments,⁷⁸ and universities have incentives not to monitor such practices closely.⁷⁹

While rare, the potential for hindering noncommercial research is nonetheless significant.⁸⁰ For example, restrictive licensing of critical tools

⁷³ John P. Walsh et al., *Patents, Material Transfers and Access to Research Inputs in Biomedical Research 2* (Final Report to the Nat'l Acad. of Sci. Comm. Intellectual Prop. Rights in Genomic and Protein-Related Investments, 2005), <http://www2.druid.dk/conferences/viewpaper.php?id=776&cf=8> [hereinafter Walsh et al., *Patents, Material Transfers and Access to Research Inputs*]. The authors conclude that “friction” arising from material transfer agreements for *physical* property poses a much greater impediment to basic science. *Id.*

⁷⁴ Walsh et al., *Research Tool Patents and Licensing*, *supra* note 55, at 298.

⁷⁵ *Id.* at 299.

⁷⁶ Rai & Eisenberg, *supra* note 9, at 296; see Leon Rosenberg, *Perspectives from Different Sectors: Major Pharmaceutical Company*, in *INTELLECTUAL PROPERTY RIGHTS AND THE DISSEMINATION OF RESEARCH TOOLS IN MOLECULAR BIOLOGY* 61, 63 (National Academy Press 1997), available at <http://books.nap.edu/html/property>; Walsh et al., *Research Tool Patents and Licensing*, *supra* note 55, 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). The de facto experimental use exception also reflects a kind of private ordering, where a norm has developed of researchers ignoring patents and patentees refraining from suing them.

⁷⁷ 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*, *supra* note 73, at 30.

⁷⁸ John P. Walsh et al., *View from the Bench: Patents and Material Transfers*, 309 SCIENCE 2002, 2002 (2005).

⁷⁹ Doing so may expose them to enhanced damages for willful infringement. Eisenberg, *Patents and Data-Sharing in Public Science*, *supra* note 51, at 1019.

⁸⁰ Enhanced complexity of the patent landscape, increased awareness of patenting, and more aggressive enforcement of patents all suggest that patenting may play a greater inhibitory role in biomedical research

including the OncoMouse⁸¹ and polymerase chain reaction (PCR)⁸² 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.”⁸³ Additionally, evidence suggests that industry’s willingness to forbear enforcing patents against universities is waning.⁸⁴ Furthermore, proprietary claims can chill noncommercial research in ways other than through licensing fees and threatened 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 and declined to use 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.⁸⁵ Additionally, private ordering by the NIH and Merck has helped preempt patents on ESTs, thus averting a potential tragedy of the anticommons.⁸⁶ Given that biomedical research generates immense spillovers benefitting society at large,⁸⁷ even slight disruptions can have significant effects. Such research occupies “Pasteur’s Quadrant”: while it strives for deep understanding, it is also intrinsically oriented toward practical applications.⁸⁸

going forward. NAT’L RESEARCH COUNCIL, REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH, 125–26 (Stephen A. Merrill & Anne-Marie Mazza eds., 2006).

⁸¹ Eliot Marshall, *NIH Cuts Deal on Use of OncoMouse*, 287 SCIENCE 567 (2000) [hereinafter Marshall, *NIH Cuts Deal on Use of OncoMouse*]; Fiona Murray, *The Oncomouse That Roared: Resistance & Accommodation to Patenting in Academic Science*, AM. J. SOC. (forthcoming 2009), available at http://fmurray.scripts.mit.edu/docs/THE_ONCOMOUSE_THAT_ROARED_FINAL.pdf. Ultimately, the NIH negotiated with DuPont to ease these restrictions. See *infra* Part IV.A.

⁸² See *Cetus to Exact Royalties from PCR Sales; Probe Absolves Convicted Rapist*, BIOTECH. NEWSWATCH, Sept. 5, 1988, at 7.

⁸³ Walsh et al., *Research Tool Patents and Licensing*, *supra* note 55, at 302.

⁸⁴ Nelson, *supra* note 60, at 467; see also NAT’L RESEARCH COUNCIL, *supra* note 80.

⁸⁵ See *infra* Part IV.A.1.

⁸⁶ See Heller & Eisenberg, *supra* note 1, at 699.

⁸⁷ See Brett M. Frischmann & Mark A. Lemley, *Spillovers*, 107 COLUM. L. REV. 257, 257 (2007); Paula E. Stephan, *The Economics of Science*, 34 J. ECON. LIT. 1199, 1227–28 (1996).

⁸⁸ See generally DONALD E. STOKES, PASTEUR’S QUADRANT: BASIC SCIENCE AND TECHNOLOGICAL INNOVATION (1997); Francis Narin et al., *The Increasing Linkage Between U.S. Technology and Public Science*, 26 RES. POL’Y 317, 317 (2000); Nelson, *supra* note 60, at 455–57.

Much hangs in the balance, and accordingly many have decried the privatization of the scientific research commons.⁸⁹

II. THE CHALLENGES OF REGULATING ACCESS TO BIOMEDICAL RESEARCH TOOLS

A. *Open Access, Exclusion, and Governance*

While many observers argue for wide access to biomedical research tools, constructing an appropriate commons faces several complications. From the demand side,⁹⁰ the “infrastructural” ability of these resources to enable myriad downstream uses weighs in favor of allowing unfettered access to them.⁹¹ In general, society is better off when scientists have ready access to gene fragments, disease models, and basic laboratory procedures. This suggests that perhaps research tools should be exempt from patenting and freely available in the public domain.

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.⁹² While many scientists—including private sector scientists—routinely develop research tools simply for their own use,⁹³ patent exclusivity still provides additional incentives for firms to support this development. To borrow from real property, this consideration suggests applying the classic “exclusionary” conception of property rights: provide patentees with strong exclusive rights to allow them to internalize the value of their investments, thus maintaining robust incentives to invent.⁹⁴ Patentees

⁸⁹ See, e.g., Andrews et al., *supra* note 1, at 1396; Nelson, *supra* note 60, at 455.

⁹⁰ In economic terms, demand-side considerations relate to resource consumption while supply-side considerations relate to resource production.

⁹¹ See Frischmann, *supra* note 67, at 119; Frischmann & Lemley, *supra* note 87, at 282.

⁹² See Fore et al., *supra* note 27, at *12; Lee, *The Evolution of Intellectual Infrastructure*, *supra* note 27, at 110.

⁹³ Strandburg, *Users as Innovators*, *supra* note 11, at 469.

⁹⁴ Cf. Harold Demsetz, *Toward a Theory of Property Rights*, 57 AM. ECON. REV. 347 (1967). Although Demsetz addressed rivalrous property rather than nonrivalrous intellectual property, his arguments about exclusive rights helping to internalize externalities are salient to patent law.

would then be free to license or refuse to license their inventions as they see fit.⁹⁵

This concern for maintaining private incentives to invent is questionable, however, given that public sources—including taxpayer funding and nonprofit universities—produce a substantial proportion of research tools. Because public support has already satisfied the incentive to invent, the deadweight loss that arises from exclusive rights may not be socially justified. This suggests an intermediate policy response: while patents on privately developed inventions seem appropriate, perhaps *publicly supported* research tools should be openly available to all.

However, this proposal implicates the second supply-side complication. While open access may be appropriate for some publicly supported research tools, it is not appropriate for all of them. Many of these tools are “dual status” inventions: they both facilitate scientific research in their present state as well as represent precursors to value-added commercial products.⁹⁶ 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.⁹⁷ This was the rationale behind the Bayh–Dole Act, which provides exclusive rights to taxpayer-financed inventions precisely to motivate private investment in commercialization.

Ultimately, an optimal property regime for publicly supported research tools falls somewhere between open access and strict exclusive rights. To further the analogy to real property, the ideal paradigm is a governance regime of selective access and exclusivity.⁹⁸ Such a regime would (1) differentiate between publicly supported research tools that warrant exclusive rights to spur investment in “optimization” and those that do not; and (2) for the former, ensure that such tools are widely available for high-value activities, such as academic research, while maintaining requisite exclusivity to encourage

⁹⁵ See Smith, *supra* note 38, at S454–55 (“In exclusion, decisions about resource use are delegated to an owner who, as gatekeeper, is responsible for deciding on and monitoring specific activities with respect to the resource.”).

⁹⁶ Such products include therapies or even more highly refined research tools.

⁹⁷ Kieff, *Property Rights and Property Rules*, *supra* note 12, at 708–09.

⁹⁸ See Smith, *supra* note 38, at S455 (associating governance rules with common property regimes, in which a governed resource is selectively accessible for particular users and uses).

private development. Such a regime would rely heavily on context-specific distinctions that generate high information costs and would demand a significant degree of hands-on “intelligence” to manage.

B. The Limitations of Public Law Mechanisms

Establishing optimal access to patented biomedical research tools poses a difficult public policy challenge; unsurprisingly this challenge has elicited a number of actual and proposed “public law” responses.⁹⁹ 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 rights and obligations between individual parties.¹⁰⁰ 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,¹⁰¹ but none provides ideal access to research tools. Because of space constraints, I will focus on several prominent devices before briefly surveying others. As we will see, the gaps left by public law mechanisms define a valuable role for private law approaches to play a supplementary role.

1. 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.¹⁰²

⁹⁹ 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).

¹⁰⁰ 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 & Smith, *supra* note 39, at 777.

¹⁰¹ 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).

¹⁰² The doctrine has attracted voluminous academic commentary, much of it positive. See, e.g., 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); Rochelle Dreyfuss, *Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense Arrived?*, 46 ARIZ. L. REV. 457 (2004); Eisenberg, *Patents and the Progress of Science*, *supra* note 48; Janice M. Mueller, *No “Dilettante Affair”*: *Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1 (2001); Nelson, *supra* note 60, at 466; Strandburg, *What Does the Public Get?*, *supra* note 57. However, the doctrine has attracted negative commentary as well. See, e.g., 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.

Traditionally, the doctrine distinguished “philosophical,” noncommercial uses of patented inventions from commercial ones, exempting the former from infringement.¹⁰³ While theoretically this exception might have safeguarded university research from patent infringement, recent court decisions have largely foreclosed that possibility.¹⁰⁴

Most prominently, in *Madey v. Duke University*, the Federal Circuit construed the experimental use exception extremely narrowly.¹⁰⁵ 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.”¹⁰⁶ 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.¹⁰⁷

MICH. J.L. REFORM 141, 201–05, 211–16 (2004) [hereinafter Mireles, *Patents, Licensing, Research Tools*]; Elizabeth A. Rowe, *The Experimental Use Exception to Patent Infringement: Do Universities Deserve Special Treatment?*, 57 HASTINGS L.J. 921 (2006).

¹⁰³ *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (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.”); *see Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 862–63 (Fed. Cir. 1984); *Poppenhusen v. Falke*, 19 F. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861) (No. 11,279); *Sawin v. Guild*, 21 F. Cas. 554, 555 (C.C.D. Mass. 1813) (No. 12,391); 3 WILLIAM C. ROBINSON, *THE LAW OF PATENTS FOR USEFUL INVENTIONS* § 898, at 56 (Boston, Little, Brown, & Co. 1890).

¹⁰⁴ *See, e.g., Embrex, Inc. v. Serv. Eng’g Corp.*, 216 F.3d 1343, 1349 (Fed. Cir. 2000) (rejecting an experimental use defense by the commercial competitor of a patentee); *Roche Prods.*, 733 F.2d at 863 (holding that using a patented ingredient to perform necessary tests for FDA approval did not fall within the experimental use exception); *Deuterium Corp. v. United States*, 19 Cl. Ct. 624, 633 (Cl. Ct. 1990) (holding that government use of a patented method for removing hydrogen sulfide from a geothermal stream was not experimental); *Pitcairn v. United States*, 547 F.2d 1106, 1125–26 (Cl. Ct. 1976) (holding that government experiments involving patented aircraft technology constituted infringement). *See generally* Armstrong, *supra* note 102.

¹⁰⁵ 307 F.3d 1351 (Fed. Cir. 2002).

¹⁰⁶ *Id.* 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.

¹⁰⁷ *See Strandburg, What Does the Public Get?*, *supra* note 57, 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.”); *see 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 Ass’n of Am. Med.

Even if courts recognized a robust experimental use exception, it may be overly inclusive. As discussed, a general noncommercial research exception would discourage private companies from committing resources to invent and develop research tools primarily used by nonprofit scientists.¹⁰⁸

2. *The Statutory Experimental Use Exception*

While Congress has enacted a *statutory* experimental use exception, it is relatively narrow in scope. In 1984, Congress passed the Hatch–Waxman Act, which expedited the process by which firms may introduce generic versions of patented drugs.¹⁰⁹ 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.”¹¹⁰ 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 information submissions to the Food and Drug Administration (FDA) or other regulatory bodies, a relatively narrow range of uses. 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.

Cs. et al., as Amici Curiae Supporting Petitioner at 14, *Duke Univ. v. Madey*, 539 U.S. 958 (2003) (No. 02-1007); Suz Redfean, *The Madey Decision and Academic Research: Has the Sky Fallen?*, 1 *PRECLINICA* 230, 231 (2003). The United States appears to be the exception in this regard, as many patent-intensive countries, including most of western Europe, Canada, Japan, and Korea, recognize either a statutory or common law experimental use exception to patent infringement for “experimenting on” protected inventions. Strandburg, *What Does the Public Get?*, *supra* note 57, at 99 n.88. 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).

¹⁰⁸ *See* *Integra Lifesciences I Ltd. v. Merck KGaA*, 331 F.3d 860, 878 (Fed. Cir. 2003) (Newman, J., dissenting), *vacated*, 545 U.S. 193 (2005); *FED. TRADE COMM’N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY* 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.

¹⁰⁹ 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, Co.*, 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.

¹¹⁰ 35 U.S.C. § 271(e) (2006). To offset delays in FDA approval, the Act also allows patent term extensions of up to five years. *Id.* § 156.

Recently, the Supreme Court liberally construed the safe harbor, holding that it applies to the use of patented materials in *preclinical* research reasonably related to an FDA submission.¹¹¹ Nevertheless, the Hatch–Waxman Act falls far short of creating a noncommercial research exception from patent infringement.¹¹²

3. *Modifications to Patentable Subject Matter*

A more drastic approach to eliminating access constraints on research tools is simply to remove them from patentable subject matter.¹¹³ For example, courts could extend the traditional bar against patenting “products of nature”¹¹⁴ to resources such as gene fragments and extracted, purified human embryonic stem cells.¹¹⁵ Alternatively, they could extend the doctrinal prohibition against patenting natural laws, physical phenomena, and abstract ideas¹¹⁶ to limit patents on research tools that are necessary to discover these elements.¹¹⁷ These proposals, however, raise difficulties in light of expansive doctrinal notions of patentable subject matter. In the seminal case of *Diamond v. Chakrabarty*, the Supreme Court drew from the legislative history of the 1952 Patent Act in suggesting that “anything under the sun that is made by man” is eligible for patenting.¹¹⁸ Although recent Supreme Court¹¹⁹ and Federal

¹¹¹ Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193, 193 (2005).

¹¹² Congress has enacted several specialized intellectual property statutes that expressly establish a more comprehensive safe harbor for experimental use of protected material. See, e.g., 7 U.S.C. § 2544 (2006) (exempting use of a protected variety for plant breeding or other research from infringement under the Plant Variety Protection Act); 17 U.S.C. § 906(a)(1) (2006) (exempting reproduction of mask work for teaching, analyzing, or evaluating that mask work from infringement under the Semiconductor Chip Protection Act of 1984); *id.* § 1309(g) (exempting teaching and research uses of protected designs from infringement under the Vessel Hull Design Protection Act). See generally JOHN R. THOMAS, SCIENTIFIC RESEARCH AND THE EXPERIMENTAL USE PRIVILEGE IN PATENT LAW 17–19 (2004) (tracing the history of the common law and statutory experimental use exceptions and presenting options for developing an experimental use privilege).

¹¹³ 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).

¹¹⁴ 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*, 1889 Dec. Comm’r Pat. 123.

¹¹⁵ Rai & Eisenberg, *supra* note 9, at 299. Of course, this would rarely affect “process” research tools, such as techniques for copying DNA.

¹¹⁶ See *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

¹¹⁷ See Lee, *Inverting the Logic of Scientific Discovery*, *supra* note 1.

¹¹⁸ 447 U.S. 303 (1980); see also *Diamond v. Diehr*, 450 U.S. 175, 192 (1981).

Circuit¹²⁰ pronouncements signal a narrowing of patentable subject matter, the extent of future modifications is unpredictable. While Congress is currently considering patent reform,¹²¹ 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.¹²² 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.¹²³

4. Additional Policy Levers for Limiting Patents on Research Tools

The requirements that a patented invention must be novel, useful, and nonobvious may also prevent undue patenting of research tools.¹²⁴ In particular, the utility requirement has in fact curbed such patents.¹²⁵ In 2001,

¹¹⁹ See *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 126 (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’” (quoting U.S. CONST. art. 1, § 8, cl. 8)).

¹²⁰ See *In re Bilski*, 264 Fed. App’x 896, 897 (Fed. Cir. 2008) (casting doubt on the patentability of business methods); *In re Petrus A.C.M. Nuijten*, 500 F.3d 1346, 1357 (Fed. Cir. 2007), *en banc reh’g denied*, 2008 WL 361044 (Fed. Cir. 2008) (denying a patent application claiming electronic signals); *In re Comiskey*, 499 F.3d 1365 (Fed. Cir. 2007) (denying a patent application claiming a method for arbitrating disputes), *withdrawn and vacated in part*, 554 F.3d 967, 970 (Fed. Cir. 2009) (*en banc*) (remanding to district court “to consider the [35 U.S.C. § 101] issue in the first instance”). 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).

¹²¹ See Patent Reform Act of 2007, H.R. 1908, 110th Cong. (2007); Patent Reform Act of 2007, S. 1145, 110th Cong. (2007); Steve Seidenberg, *Reinventing Patent Law*, A.B.A. J., Feb. 2008, at 62–63.

¹²² See FED. TRADE COMM’N, *supra* note 108, at 36.

¹²³ A narrower approach could exempt nonprofit 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) (2006); see *Pallin v. Singer*, 36 U.S.P.Q.2d (BNA) 1050 (D. Vt. 1995). See generally Chris J. Katopis, *Patients v. Patents?: Policy Implications of Recent Patent Legislation*, 71 ST. JOHN’S L. REV. 329 (1997) (discussing the *Pallin* case and Congress’s legislative response). However, there have been no congressional attempts to recreate this exception for noncommercial researchers, which in any event would be overinclusive.

¹²⁴ 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.*, 550 U.S. 398 (2007). However, many commentators feel that the Federal Circuit’s nonobviousness jurisprudence regarding biotechnology inventions has made them unduly easy to patent. See *In re Deuel*, 51 F.3d 1552, 1558–59 (Fed. Cir. 1995).

¹²⁵ Nelson, *supra* note 60, at 466; see *Brenner v. Manson*, 383 U.S. 519, 534 (1966); Golden, *supra* note 12, at 182.

the Patent and Trademark Office issued guidelines requiring a demonstrated specific and substantial utility for all patented inventions.¹²⁶ These guidelines have made it more difficult to patent ESTs correlating to genes that encode proteins of no known biological activity.¹²⁷ However, the impact of these guidelines on the patenting of other research tools is unclear. Additionally, the “written description” requirement, which limits a patent’s scope of protection to that which the patent actually describes,¹²⁸ has also constrained broad claims to certain DNA sequences.¹²⁹

Yet another mechanism for enhancing access to patented biomedical research tools is compulsory licensing,¹³⁰ 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.¹³¹ While compulsory licenses are available pursuant to 28 U.S.C. § 1498¹³² and antitrust consent decrees, they are rarely granted in this country and are not promising avenues for enhancing access to patented research tools.¹³³

Another potential approach involves the law of patent infringement remedies. In *eBay Inc. v. MercExchange, L.L.C.*, the Supreme Court recently rejected the Federal Circuit’s “general rule” of granting injunctions upon a finding of patent infringement.¹³⁴ Instead, it held that courts must apply a traditional four-factor equitable test to determine the appropriateness of an

¹²⁶ Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001); see MERGES & DUFFY, *supra* note 8, at 238–40; Golden, *supra* note 12, at 129.

¹²⁷ See generally *In re Fisher*, 421 F.3d 1365 (Fed. Cir. 2005).

¹²⁸ 35 U.S.C. § 112, ¶ 1.

¹²⁹ *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1562 (Fed. Cir. 1997) (holding that a description of rat insulin cDNA as well as methods for deriving other cDNAs did not adequately describe human, mammalian, and vertebrate insulin cDNA).

¹³⁰ 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.

¹³¹ F.M. Scherer & Jayashree Watal, *Post-TRIPS Options for Access to Patented Medicines in Developing Nations*, 5 J. INT’L ECON. L. 913, 914 (2002).

¹³² See 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 proposal to compulsorily license Cipro under § 1498 in the wake of recent 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 Pharmaceuticals Hurt Innovation?*, 18 BERKELEY TECH. L.J. 853, 868 (2003).

¹³³ See Chien, *supra* note 132, at 872.

¹³⁴ 547 U.S. 388, 391 (2006).

injunction.¹³⁵ As I have recently argued, this change provides courts with greater latitude to protect “infrastructural” inventions with a liability rule rather than a property rule.¹³⁶ However, the availability of ex post liability rule protection may not provide complete ex ante assurance that a scientist may use a patented research tool and avoid an injunction. Furthermore, 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.¹³⁷ Even if courts protected research tool patents with damages rather than injunctions, such an approach is best suited for 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.

5. Summary

While valuable, public law attempts to mitigate 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 be overinclusive and undermine private incentives to invent and develop research tools. Targeted approaches such as a statutory experimental use exception and shoring up the utility and written description requirements are useful but narrow in scope. Authorities rarely grant compulsory licenses in this country, and the availability of ex post liability rules may not provide sufficient ex ante certainty to noncommercial researchers. The complex incentives at issue render this a particularly difficult policy challenge. An ideal property regime would link public support to enhanced access for research

¹³⁵ *Id.* at 391. 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 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.

¹³⁶ See Lee, *The Evolution of Intellectual Infrastructure*, *supra* note 27, at 45; see also 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, 2447 (1994).

¹³⁷ See Andrew Beckerman-Rodau, *The Aftermath of eBay v. MercExchange*, 126 S. Ct. 1837 (2006): *A Review of the Subsequent Judicial Decisions*, 89 J. PAT. & TRADEMARK OFF. SOC'Y 607, 631, 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).

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,¹³⁸ public institutions that support basic science are turning to markets and contracts to craft more tailored approaches.

III. PRIVATE ORDERING BY PUBLIC INSTITUTIONS

Where the law fails to provide for optimal resource management, interested parties often resort to private ordering.¹³⁹ 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 have emerged to address the “tangled, twisted mass” of intellectual property rights that impedes productivity in many patent and copyright industries.¹⁴⁰ 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.¹⁴¹ 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.¹⁴² In the biomedical realm, some have argued for private collective action to resolve anticommons problems.¹⁴³

At the most drastic level, industry players have addressed increasing proprietization through another type of private ordering: simply relegating materials to the public domain. For example, the recent trend by biotechnology companies to patent SNPs, which are useful as genetic disease markers, raised concerns that such patents could block useful research.¹⁴⁴ In response, pharmaceutical companies partnered with the Wellcome Trust to create the SNP Consortium,¹⁴⁵ which identifies SNPs and places all resulting

¹³⁸ See Nelson, *supra* note 60, at 466 (“I am not optimistic about how much of the problem can be dealt with by patent law.”).

¹³⁹ See generally ROBERT ELLICKSON, *ORDER WITHOUT LAW: HOW NEIGHBORS SETTLE DISPUTES* (1991); ELINOR OSTROM, *GOVERNING THE COMMONS* (1990).

¹⁴⁰ 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*].

¹⁴¹ *Id.* at 1340–58.

¹⁴² *Id.* at 1328–40.

¹⁴³ Karl Bergman & Gregory D. Graff, *The Global Stem Cell Patent Landscape: Implications for Efficient Technology Transfer and Commercial Development*, 25 NATURE BIOTECH. 419, 422 (2007).

¹⁴⁴ Rai & Eisenberg, *supra* note 9, at 298.

¹⁴⁵ See Michael Morgan, *New Paradigms in Industry: The Single Nucleotide Polymorphism Consortium*, in *THE ROLE OF SCIENTIFIC AND TECHNICAL DATA AND INFORMATION IN THE PUBLIC DOMAIN: PROCEEDINGS*

information in the public domain.¹⁴⁶ 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.¹⁴⁷ Merck's initiative prevents patenting of these essential resources and has substantially eased potential anticommons threats.¹⁴⁸

Outside of the biomedical realm, the access-enhancing potential of private ordering is perhaps best illustrated by open source software.¹⁴⁹ 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 code¹⁵⁰ and requires users to grant a license to anyone who comes into possession of a copy.¹⁵¹ The license is considered "viral" because it "infects" all downstream iterations of code originally governed by the GPL.¹⁵² Commentators laud open source licensing as enabling collaborative "peer production" that may be nimbler, faster, and more robust than traditional firm structures.¹⁵³ IBM, for example, has engaged in substantial "property preempting" investments by supporting open source software.¹⁵⁴ Crucially, while the GPL enforces norms of open access, it is fundamentally predicated on the right to exclude inherent in copyright.¹⁵⁵

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.¹⁵⁶ These licenses extend beyond software to include all audio, video, images, and text; the power of

OF A SYMPOSIUM 194–97 (Julie M. Esanu & Paul F. Uhlir eds., 2003); Nicholas Wade, *10 Drug Makers Join in Drive to Find Diseases' Genetic Roots*, N.Y. TIMES, Apr. 15, 1999, at A27.

¹⁴⁶ Merges, *A New Dynamism in the Public Domain*, *supra* note 23, at 189–90; Rai & Eisenberg, *supra* note 9, at 298.

¹⁴⁷ See Merges, *A New Dynamism in the Public Domain*, *supra* note 23, at 188.

¹⁴⁸ *Id.*

¹⁴⁹ See generally *Jacobsen v. Katzer*, 553 F.3d 1373 (Fed. Cir. 2008).

¹⁵⁰ GNU General Public License Version 3, §§ 4–5 (June 29, 2007), <http://www.gnu.org/licenses/gpl.txt>.

¹⁵¹ *Id.* § 5.

¹⁵² See 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).

¹⁵³ See Yochai Benkler, *Coase's Penguin, or, Linux and The Nature of the Firm*, 112 YALE L.J. 369, 376–77, 415–22, 436–38 (2002) [hereinafter Benkler, *Coase's Penguin*]; 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 152, at 59 (questioning the GPL's impact on software creation and distribution).

¹⁵⁴ See Merges, *A New Dynamism in the Public Domain*, *supra* note 23, at 192–93. IBM's motives, however, are far from altruistic. See *id.*

¹⁵⁵ Boyle, *supra* note 23, at 65; Vetter, *supra* note 152, at 84.

¹⁵⁶ Creative Commons, <http://creativecommons.org/> (last visited Nov. 16, 2008); see Merges, *A New Dynamism in the Public Domain*, *supra* note 23, at 183–84.

these licenses to enhance access to otherwise proprietary material is enormous.¹⁵⁷ As Professor Pamela Samuelson notes, “Open source, CC [Creative Commons], and similar licensed materials are best understood as contractually constructed information commons.”¹⁵⁸ Most relevant for present purposes, Professor J.H. Reichman and Paul Uhlir have advocated using contracts to “reconstruct” a public domain for data that is increasingly subject to private control.¹⁵⁹

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.¹⁶⁰ For example, “shrinkwrap” licenses allow content owners to assert, through contract, a higher degree of control over information than permitted under patent and copyright law.¹⁶¹ 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.¹⁶²

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 are the drivers of private ordering. However, public institutions are market participants,

¹⁵⁷ But see Molly Shaffer Van Houweling, *The New Servitudes*, 96 GEO. L.J. 885, 923–49 (2008) (arguing that such licenses may raise problems similar to those associated with personal property servitudes).

¹⁵⁸ Samuelson, *Enriching Discourse*, *supra* note 23, at 800.

¹⁵⁹ Reichman & Uhlir, *supra* note 22, at 325.

¹⁶⁰ See generally Charles R. McManis, *The Privatization (or “Shrink-Wrapping”) of American Copyright Law*, 87 CAL. L. REV. 173 (1999); Apik Minassian, Comment, *The Death of Copyright: Enforceability of Shrinkwrap Licensing Agreements*, 45 UCLA L. REV. 569, 601–02 (1997).

¹⁶¹ See, e.g., *ProCD, Inc. v. Zeidenberg*, 86 F.3d 1447, 1454 (7th Cir. 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, 877–78 (1999).

¹⁶² Reichman & Franklin, *supra* note 161, at 939–51.

too.¹⁶³ 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 in contractual relationships with patentees. Current debates on upstream–downstream dynamics in biomedical patenting focus on potential productivity losses arising from upstream patents.¹⁶⁴ Underappreciated in this debate is an important facet of upstream–downstream dynamics: the *normative* character of institutions exercising control over upstream patents. Scholars have demonstrated that scientists often adhere to knowledge-sharing norms that contravene the private rent-seeking model inherent in patents.¹⁶⁵ 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 these resources 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 explores how these institutions are using this leverage to engage in market-based patent regulation.

IV. THE CONTRACTUAL CREATION OF A BIOMEDICAL RESEARCH COMMONS

Given the limitations 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

¹⁶³ Cf. Evelyn Alicia Lewis, *When Entrepreneurs of Commercial Nonprofits Divorce: Is It Anybody's Business? A Perspective on Individual Property Rights in Nonprofits*, 73 N.C. L. REV. 1761, 1765–74 (1995) (exploring the significant market power of some nonprofits).

¹⁶⁴ See *supra* Part I.A.

¹⁶⁵ See ROBERT K. MERTON, *THE SOCIOLOGY OF SCIENCE* 275 (Norman W. Storer ed., 1973); Eisenberg, *Proprietary Rights and the Norms of Science*, *supra* note 51, at 182; Kahan, *supra* note 153, at 90–93; Rai, *Regulating Scientific Research*, *supra* note 17, at 80. But see F. Scott Kieff, *Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science—A Response to Rai and Eisenberg*, 95 NW. U. L. REV. 691, 697 (2001) [hereinafter Kieff, *Facilitating Scientific Research*] (arguing that sharing norms may merely be “aspirational”). See generally BERNARD BARBER, *SCIENCE AND THE SOCIAL ORDER* (1952); WARREN O. HAGSTROM, *THE SCIENTIFIC COMMUNITY* (1965).

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. 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 exclusive 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 the ways that various institutions (1) support research leading to patented research tools, (2) adhere to norms favoring wide access to these tools, and (3) use informal and formal contractual mechanisms to impose context-specific access requirements on these technologies. Section A considers the NIH’s leveraging of funds and rights retained under the Bayh–Dole Act to ensure that publicly financed research tools are widely available for scientific inquiry. Section B examines California’s requirements that recipients of state human embryonic stem cell research funding must share patented discoveries liberally with nonprofit research institutions. Section C considers university licensing practices ensuring wide access to patented research tools. Section D explores the substantial contributions of nonprofit organizations to biomedical research and examines their requirements that resulting patented research tools must be widely available for noncommercial research purposes. Section 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. Rather than the horizontal reciprocity represented by competing firms creating a patent pool, the efforts here represent vertical reciprocity: downstream patentees and licensees agree to share patented resources widely for noncommercial research purposes as a condition of receiving upstream support. Although the experimental use exception has withered as a public law creation, public 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 it is conditioning its contributions on expectations that grantees will make resulting patented research tools widely available for scientific inquiry.¹⁶⁶ 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. Streamlining 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.¹⁶⁷ In 2003, the NIH, the “primary focal point of federally sponsored biomedical research,”¹⁶⁸ provided \$26.4 billion for biomedical research, or 28% of the national total.¹⁶⁹ Similarly, in FY 2004, the NIH’s \$28 billion budget comprised about one-third of national biomedical research spending.¹⁷⁰ 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.¹⁷¹ In 2004, 55% of NIH funds for research and development went

¹⁶⁶ Reichman & Uhlir, *supra* note 22, 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.”).

¹⁶⁷ See Golden, *supra* note 12, 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 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) (describing the federal government’s use of tax deductions and credits to promote research and development by pharmaceutical companies).

¹⁶⁸ William H. Frist, *Federal Funding for Biomedical Research: Commitment and Benefits*, 287 JAMA 1722, 1724 (2002).

¹⁶⁹ 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.*

¹⁷⁰ Elias A. Zerhouni, *US Biomedical Research: Basic, Translational, and Clinical Sciences*, 294 JAMA 1352, 1352 (2005).

¹⁷¹ See RONALD L. MEEKS, NAT’L SCI. FOUND., INFOBRIEF: FEDERAL AGENCIES SUPPORTED R&D GROWTH OVER THE PERIOD FY 1994–2004, at 1 (revised June 2007), available at <http://www.nsf.gov/statistics/infbrief/nsf07302/nsf07302.pdf>; Golden, *supra* note 12, at 139.

to basic research.¹⁷² According to its Roadmap for Medical Research, “much of NIH funding supports the exploration of fundamental biological mechanisms that would otherwise not be pursued due to the lack of market incentives.”¹⁷³ This basic research, moreover, produces many research tools critical to further inquiry.

In addition to direct funding, the NIH also indirectly supports research by allowing grantees to patent taxpayer-financed inventions pursuant to the Bayh–Dole Act.¹⁷⁴ Prior to the Bayh–Dole Act, federal agencies possessed no uniform policy regarding the ownership of patents arising from taxpayer-funded ventures.¹⁷⁵ Some agencies took title to inventions while other agencies granted title to outside contractors and only retained a license for their own use.¹⁷⁶ Concerns grew that government-owned patents were stifling innovation because firms would not invest in developing inventions into commercial goods without possessing exclusive rights.¹⁷⁷ To put government-funded inventions to good use, and amid concerns over lagging economic competitiveness relative to Europe and Japan,¹⁷⁸ Congress passed the Bayh–Dole Act in 1980. The Act allowed and encouraged small businesses and nonprofit organizations—including universities—to patent the results of government-sponsored research, provided that they satisfy certain statutorily defined conditions.¹⁷⁹ In a related vein, also in 1980, Congress passed the

¹⁷² Moses et al., *supra* note 169, at 1338 tbl.4.

¹⁷³ NIH, DEP’T OF HEALTH & HUMAN SERVICES, REPORT TO CONGRESS ON AFFORDABILITY OF INVENTIONS AND PRODUCTS 3 (2004), available at <http://ott.od.nih.gov/NewPages/211856ottrept.pdf>; see Gregory D. Graff et al., *The Public-Private Structure of Intellectual Property Ownership in Agricultural Biotechnology*, 21 NATURE BIOTECH. 989, 989 (2003); Zerhouni, *supra* note 170, at 1355.

¹⁷⁴ Pub. L. No. 96-517, § 6(a), 94 Stat. 3015, 3019–27 (1980) (codified as amended at 35 U.S.C. §§ 200–211 (2006)). See generally Arno & Davis, *supra* note 167, at 646–67; 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*].

¹⁷⁵ For a history of the Bayh–Dole Act and related legislation, see Eisenberg, *Public Research and Private Development*, *supra* note 174, at 1671–95; Ashley J. Stevens, *The Enactment of Bayh-Dole*, 29 J. TECH. TRANSFER 93, 93 (2004).

¹⁷⁶ Eisenberg, *Public Research and Private Development*, *supra* note 174, at 1677; see S. REP. NO. 96-480, at 2 (1979) (identifying at least twenty-four different patent policies among federal agencies).

¹⁷⁷ 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).

¹⁷⁸ 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 COMPUTER TECH. TRANSFER & SOC’Y 109, 113 (2005); Clifton Leaf, *The Law of Unintended Consequences*, FORTUNE, Sept. 19, 2005, at 250.

¹⁷⁹ 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 Memorandum to the Heads of Executive Departments and

Stevenson–Wydler Technology Innovation Act, which required federal laboratories to take a more active role in transferring technology to private industry.¹⁸⁰

The Bayh–Dole Act enables potentially significant market subsidies for research and development.¹⁸¹ The Act has led to an explosion of university patenting and has generated enormous income for some government grantees.¹⁸² 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.”¹⁸³ Of course, the Act has also attracted criticism for providing a double windfall to federal grantees, who receive both taxpayer funds as well as patents on resulting inventions.¹⁸⁴ 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 support for biomedical research, it does not do so primarily for financial gain. 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.”¹⁸⁵ While the NIH generally aims to enhance the nation’s economic well-being and ensure a high return on public investment in research,¹⁸⁶ the agency does not seek to maximize short-term profits. Vannevar Bush, the original architect of U.S. research policy

Agencies: Government Patent Policy, 2 PUB. PAPERS 248 (Feb. 18, 1983); Trademark Clarification Act of 1984, § 501(13), 35 U.S.C. § 210(c); S. REP. NO. 98-662, at 2 (1984), *reprinted in* 1984 U.S.C.C.A.N. 5799, 5800; *see also* Eisenberg, *Public Research and Private Development*, *supra* note 174, at 1694.

¹⁸⁰ Pub. L. 96-480, 94 Stat. 2311 (1980) (codified as amended at 15 U.S.C. §§ 3701–3717 (2006)).

¹⁸¹ *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*].

¹⁸² *See infra* Part IV.C.

¹⁸³ *Innovation’s Golden Goose*, *ECONOMIST*, Dec. 14, 2002, at 3.

¹⁸⁴ *See* Eisenberg, *Public Research and Private Development*, *supra* note 174, at 1666. *See generally* H.R. REP. NO. 96-1307, pt. 1, at 29–32, *reprinted in* 1980 U.S.C.C.A.N. 6487, 6487–91 (statement of Rep. Jack Brooks); Mireles, *States as Innovation System Laboratories*, *supra* note 181, 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).

¹⁸⁵ NIH, About NIH, <http://www.nih.gov/about/index.html#mission> (last visited Nov. 16, 2008).

¹⁸⁶ *Id.*; *see* Faley & Sharer, *supra* note 178, at 112; Narin et al., *supra* note 88, at 317.

under President Franklin D. Roosevelt, envisioned the federal government taking an active role in creating a scientific “reservoir of knowledge.”¹⁸⁷ 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 monetary gain.¹⁸⁸ Access is critical to achieving this goal, and in both policy and practice, the NIH expresses access norms that directly contravene the exclusivity associated with private rent-seeking.¹⁸⁹

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.”¹⁹⁰ 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.*”¹⁹¹ Indeed, the possibility that taxpayer-financed patents could stymie research seems antithetical to the Bayh–Dole Act. Further illustrating its commitment to maximize technological development rather than profits, the Act requires that nonprofit grantees invest any surplus royalties or income earned on Bayh–Dole inventions in scientific research or education.¹⁹² 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.”¹⁹³

¹⁸⁷ See generally VANNEVAR BUSH, *SCIENCE: THE ENDLESS FRONTIER* (1945); Faley & Sharer, *supra* note 178, at 111.

¹⁸⁸ See NIH, *Review Criteria for and Rating of Unsolicited Research Grant and Other Applications*, NIH GUIDE FOR GRANTS & CONT., June 27, 1997, <http://grants.nih.gov/grants/guide/notice-files/not97-010.html>.

¹⁸⁹ As an example of these norms, in 1994, the NIH voluntarily withdrew patent applications on ESTs because of their research tool character. Steven M. Ferguson, *Licensing and Distribution of Research Tools: National Institutes of Health Perspective*, 41 J. CLINICAL PHARMACOLOGY 110S, 111S (2001).

¹⁹⁰ 35 U.S.C. § 200 (2006).

¹⁹¹ *Id.* (emphasis added).

¹⁹² *Id.* § 202(c)(7)(c).

¹⁹³ *Id.* § 200.

Several provisions of the Bayh–Dole Act define these government rights. First, pursuant to 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 objectives” of the Act.¹⁹⁴ Second, the federal government retains a paid-up license to practice, or have practiced on its behalf, any invention that a contractor patents pursuant to the Act.¹⁹⁵ 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.¹⁹⁶ 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 grantee that patents the invention, such as a university, but also to all downstream licensees of the “subject invention” as well.¹⁹⁷ The Act limits the ability of nonprofits (but not small businesses) to assign away their patent rights, thus ensuring that the government’s rights retained under the Act will always apply to subject inventions.¹⁹⁸

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 resources by federal grant recipients

¹⁹⁴ *Id.* § 202(a)(ii).

¹⁹⁵ *Id.* § 202(c)(4).

¹⁹⁶ *Id.* § 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.

¹⁹⁷ *See id.* § 201(e); Jaffe, *supra* note 11, at 533 (“[T]he rules governing the patentability of federally supported research essentially control university patenting.”).

¹⁹⁸ 35 U.S.C. § 202(c)(7)(A).

(“Principles and Guidelines”).¹⁹⁹ The Principles and Guidelines specifically recommend wide dissemination of NIH-funded research tools patented by grantees.²⁰⁰ Notably, the Principles and Guidelines distinguish between “internal use by nonprofit institutions” and “commercial development and sale or provision of services,” which may warrant some degree of exclusivity.²⁰¹ The Principles and Guidelines recommend that NIH grantees transfer patented research tools to nonprofits on terms no more onerous than the Uniform Biological Material Transfer Agreement (UBMTA),²⁰² a standardized process for sharing biological materials developed by the NIH.²⁰³ Furthermore, they recommend transferring NIH-funded research tools to for-profit entities utilizing research tools for internal research purposes “with the fewest encumbrances possible.”²⁰⁴ Notably, the Principles and Guidelines reflect a shift away from viewing patents as simple rights to exclude toward recasting them as governance regimes of selective access and exclusivity.²⁰⁵

The Principles and Guidelines also seek to implement the Bayh–Dole Act’s²⁰⁶ goal of maximizing utilization of research tools.²⁰⁷ 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.”²⁰⁸ For research tools not requiring additional development, the Principles and Guidelines recommend “publication, deposit in an appropriate databank, widespread non-exclusive licensing or any other

¹⁹⁹ NIH, Principles and Guidelines, *supra* note 6; see Josephine Johnston & Angela A. Wasunna, *Patents, Biomedical Research, and Treatments: Examining Concerns, Canvassing Solutions*, HASTINGS CENTER REP., Jan.–Feb. 2007, at S11 (“[T]he NIH issued guidelines stating that the recipients of NIH funds are expected to ensure that unique research resources are made available to the scientific research community.”); Lori Pressman et al., *The Licensing of DNA Patents by U.S. Academic Institutions: An Empirical Survey*, 24 NATURE BIOTECH. 31, 32 (2006).

²⁰⁰ See Ferguson, *supra* note 189, at 111S (listing several NIH-funded research tools); NIH, Principles and Guidelines, *supra* note 6, at 72,092 (“Progress in science depends upon prompt access to the unique research resources that arise from biomedical research laboratories through government, academia, and industry.”).

²⁰¹ NIH, Principles and Guidelines, *supra* note 6, at 72,093.

²⁰² NIH, Uniform Biological Material Transfer Agreement: Discussion of Public Comments Received; Publication of the Final Format of the Agreement, 60 Fed. Reg. 12,771 (Mar. 8, 1995).

²⁰³ NIH, Principles and Guidelines, *supra* note 6, at 72,094.

²⁰⁴ *Id.*

²⁰⁵ See *id.* (“Recipients [of NIH funds] should ensure that their intellectual property strategy for resources fitting [the research tool criteria] enhances rather than restricts the ultimate availability of the resource.”). See generally Smith, *supra* note 38.

²⁰⁶ NIH, Principles and Guidelines, *supra* note 6, at 72,092.

²⁰⁷ Ferguson, *supra* note 189, at 111S.

²⁰⁸ NIH, Principles and Guidelines, *supra* note 6, at 72,093.

number of dissemination techniques.”²⁰⁹ While exclusive licenses may be appropriate to encourage commercial development, they should ultimately aim for widespread dissemination of the resulting product.²¹⁰

The NIH’s funding power ensures that these Principles and Guidelines have “real teeth.”²¹¹ The NIH explicitly considers compliance with the guidelines in awarding grants²¹² and has successfully promoted their voluntary adoption.²¹³ Although the NIH may not directly regulate the patenting practices of federal grantees,²¹⁴ the NIH has incorporated these guidelines in reviewing individual applications.²¹⁵ The possibility of denying funding is clearly present and operates as a strong incentive to comply.²¹⁶ 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 for that institute.²¹⁷ While commentators caution that the NIH may be exceeding its authority under the Bayh–Dole Act in “enforcing” these guidelines,²¹⁸ the NIH suggests that widespread noncompliance may spur regulatory or statutory intervention.²¹⁹ Indeed, the threat of invoking government rights under the Bayh–Dole Act has in some cases spurred compliance with nonbinding policy guidelines.²²⁰

²⁰⁹ *Id.*

²¹⁰ *See id.* (“Where private sector involvement is desirable . . . licenses should be crafted to fit the circumstances, with the goal of ensuring widespread and appropriate distribution of the final tool product.”).

²¹¹ Mauricio A. Flores, *Taking the Profit out of Biomedical Research Tools*, 17 NATURE BIOTECH. 819, 820 (1999).

²¹² Pressman et al., *supra* note 199, at 32.

²¹³ Sara Boettiger & Alan B. Bennett, *Bayh-Dole: If We Knew Then What We Know Now*, 24 NATURE BIOTECH. 320, 321 (2006).

²¹⁴ *See* Rai & Eisenberg, *supra* note 9, at 308 (noting that the “NIH has no authority under the Bayh-Dole Act to issue broadly applicable substantive regulations concerning the licensing of inventions”). Under the Bayh–Dole Act, only the Secretary of Commerce may promulgate general regulations for licensing federally owned inventions. 35 U.S.C. § 208 (2006). The NIH may only make such determinations in the context of individual grants. *See* Rai & Eisenberg, *supra* note 9, at 308–09.

²¹⁵ Flores, *supra* note 211, at 820; *see* David Malakoff, *NIH Roils Academe with Advice on Licensing DNA Patents*, 303 SCIENCE 1757, 1758 (2004) (observing that the NIH “guidelines could harden into regulations accompanying grants”).

²¹⁶ Flores, *supra* note 211, at 820.

²¹⁷ D.G., *NIH Knocks Out Key Mouse House*, 312 SCIENCE 1863, 1863 (2006).

²¹⁸ *See, e.g.*, Rai & Eisenberg, *supra* note 9, at 308–09.

²¹⁹ Ferguson, *supra* note 189, at 112S; NIH, Principles and Guidelines, *supra* note 6, at 72,090; *cf.* National Human Genome Research Institute, NIH, NHGRI Policy Regarding Intellectual Property of Human Genomic Sequence (Apr. 9, 1996), <http://www.genome.gov/10000926> [hereinafter NHGRI, Policy Regarding Intellectual Property of Human Genomic Sequence].

²²⁰ *See infra* notes 236–43.

Other NIH policies also encourage the widespread availability of taxpayer-funded research resources.²²¹ In 2005, the NIH issued guidelines for licensing genomic inventions.²²² According to these “Best Practices,” “NIH considers the sharing of . . . unique research resources (also called research tools) an important means to enhance the value of NIH-sponsored research.”²²³ These guidelines parallel practices at the NIH’s own Office of Technology Transfer and recommend that grantees nonexclusively license genomic inventions. Significantly, the guidelines recognize the appropriateness of exclusive licensing when necessary to facilitate post-invention commercialization.²²⁴

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 cells²²⁵ raised concerns that exclusive rights would inhibit scientific investigations relying on these basic research tools.²²⁶ To address these concerns, in 2001 the Public Health Service (PHS)²²⁷ entered into a Memorandum of Understanding (MOU) with the WiCell Research Institute, a University of Wisconsin affiliate holding licenses to the stem cell patents.²²⁸ Under the MOU, WiCell agreed to provide a research license for Wisconsin Patent Rights at low cost to PHS-supported researchers.²²⁹ Referring to the Bayh–Dole Act, the MOU states that “PHS funded 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

²²¹ See, e.g., NIH, *NIH Policy on Sharing of Model Organisms for Biomedical Research*, NIH GUIDE FOR GRANTS & CONT., May 7, 2004, <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html>.

²²² NIH, Best Practices for the Licensing of Genomic Inventions: Final Notice, 70 Fed. Reg. 18,413–15 (Apr. 11, 2005).

²²³ NIH, NIH GRANTS POLICY STATEMENT 115 (rev. ed. 2003), available at http://grants1.nih.gov/grants/policy/nihgps_2003/nihgps_2003.pdf.

²²⁴ Pressman et al., *supra* note 199, at 32.

²²⁵ U.S. Patent No. 5,843,780 (filed Jan. 18, 1996); U.S. Patent No. 6,200,806 (filed June 26, 1998). See generally Lee, *Inverting the Logic of Scientific Discovery*, *supra* note 1, at 89–92.

²²⁶ See generally Hazuka, *supra* note 1. These concerns intensified upon former President Bush’s partial ban on federal funds for human embryonic stem cell research.

²²⁷ The PHS is the umbrella agency housing the NIH.

²²⁸ Memorandum of Understanding Between WiCell Research Institute, Inc. and Public Health Service, U.S. Department of Health and Human Services 5 (Sept. 5, 2001), <http://ott.od.nih.gov/pdfs/WiCellMOUhuman.pdf> [hereinafter WiCell MOU].

²²⁹ *Id.*

granted by law and regulation.”²³⁰ The MOU not only benefits NIH-funded scientists, but also requires WiCell to provide licenses to all nonprofit organizations on similar terms.²³¹

A historical example predating the Bayh–Dole Act further illustrates 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.²³² The NIH partially funded Axel’s research, but Columbia’s patent application preceded the Bayh–Dole Act by several months.²³³ Accordingly, pursuant to the pre-Bayh–Dole regime, the NIH compelled Columbia to license the patent widely and nonexclusively²³⁴ and prohibited it from charging “unreasonable” royalties.²³⁵

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.²³⁶ NHGRI explicitly discouraged grantees from patenting raw human genomic DNA sequences,²³⁷ which it believed lacked the specific utility to warrant patentability.²³⁸ NHGRI stated

²³⁰ *Id.* at 1. Some of the research was funded by Geron, a private biotechnology company that received several commercial licenses for the patented human embryonic stem cells. Debra Robertson, *NIH Sacrifices Commercial Rights in WiCell Deal*, 19 NATURE BIOTECH. 1001, 1001 (2001).

²³¹ WiCell MOU, *supra* note 228, at 5.

²³² U.S. Patent No. 4,399,216 (filed Feb. 25, 1980); Ken Howard, *Biotechs Sue Columbia over Fourth Axel Patent*, 21 NATURE BIOTECH. 955, 955 (2003).

²³³ Bernard Wysocki Jr., *College Try: Columbia’s Pursuit of Patent Riches Angers Companies; As University Seeks to Extend a \$600 Million Bonanza, Biotechs Refuse to Pay Up; Debate over Academic Values*, WALL ST. J., Dec. 21, 2004, at A1.

²³⁴ *Id.*

²³⁵ *Id.* The NIH has even negotiated greater access to *privately* developed research tools, such as DuPont’s patented Cre-*loxP* and OncoMouse technologies. See Marshall, *NIH Cuts Deal on Use of OncoMouse*, *supra* note 81, at 567; Eliot Marshall, *Sharing Reagents: NIH, DuPont Declare Truce in Mouse War*, 281 SCIENCE 1261 (1998).

²³⁶ See Gregory A. Petsko, *Who Owns the Data?*, 6 GENOME BIOLOGY 107.1, 107.1 (2005); Human Genome Project Information, http://www.ornl.gov/sci/techresources/Human_Genome/home.shtml (last visited Nov. 16, 2008); NHGRI, Policy Regarding Intellectual Property of Human Genomic Sequence, *supra* note 219.

²³⁷ Eliot Marshall, *Genome Researchers Take the Pledge*, 272 SCIENCE 477, 477 (1996) [hereinafter Marshall, *Genome Researchers Take the Pledge*].

²³⁸ NHGRI, Policy Regarding Intellectual Property of Human Genomic Sequence, *supra* note 219.

that if grantees did in fact patent DNA sequences, it would consider invoking the exceptional circumstances provision of the Bayh–Dole Act²³⁹ to prohibit such activity.²⁴⁰

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.²⁴¹ The NIH stated it would rely on this provision to prevent project grantees from patenting their results.²⁴² This approach was aimed at ensuring that the results of NIH mutagenesis initiatives would be rapidly and freely accessible to the scientific community.²⁴³

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.²⁴⁴ As Professors Arti Rai and Rebecca Eisenberg argue, relaxing the substantive and procedural requirements of the exceptional circumstances provision would enhance its effectiveness.²⁴⁵ 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 subject to underutilization. However, since Bayh–Dole's enactment, the NIH has considered only a handful of petitions to exercise march-in rights, and it has rejected all of them.²⁴⁶ Again, as

²³⁹ See *supra* Part IV.A.2.

²⁴⁰ NHGRI, Policy Regarding Intellectual Property of Human Genomic Sequence, *supra* note 219.

²⁴¹ See Steven O. Moldin et al., *Trans-NIH Neuroscience Initiatives on Mouse Phenotyping and Mutagenesis*, 12 MAMMALIAN GENOME 575 (2001); NIH, Trans-NIH Mouse Initiatives, <http://www.nih.gov/science/models/mouse/> (last visited Nov. 16, 2008).

²⁴² Eliot Marshall, *Property Claims: A Deluge of Patents Creates Hassles for Research*, 288 SCIENCE 255, 255 (2000); NIH, Mouse Mutagenesis and Phenotype: Developmental Defects (Mar. 31, 1999), <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.").

²⁴³ Moldin et al., *supra* note 241, at 580.

²⁴⁴ Rai & Eisenberg, *supra* note 9, at 293; see 35 U.S.C. § 203(2) (2006); *id.* § 202(b)(4); 37 C.F.R. § 401.4.

²⁴⁵ Rai & Eisenberg, *supra* note 9, at 310.

²⁴⁶ Petition of CellPro, Inc. (NIH Aug. 1, 1997) (determination), <http://www.nih.gov/news/pr/aug97/nihb-01.htm>; Case of NORVIR (NIH July 29, 2004) (determination), <http://www.ott.nih.gov/policy/March-in-norvir.pdf>; Case of Xalatan (NIH Sept. 17, 2004) (determination), <http://ott.od.nih.gov/policy/March-in-xalatan.pdf>; see Barbara M. McGarey & Annette C. Levey, *Patents, Products, and Public Health: An Analysis*

Professors Rai and Eisenberg argue, a significant difficulty in exercising these rights is that they can only take effect after elaborate administrative proceedings and exhaustion of rights of appeal.²⁴⁷ Reforming this process would enhance the NIH's ability to use march-in rights to compel wide licensing of federally funded research tools.²⁴⁸

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.²⁴⁹ The NIH observes that the success of this internal program could also extend to all federally funded research.²⁵⁰

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 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 maintaining the wide availability of patented research tools.²⁵¹ The objectives and provisions of the Bayh-Dole Act also reflect a deep commitment to access norms. Here, money and patent rights provide

of the *CellPro March-In Petition*, 14 BERKELEY TECH. L.J. 1095 (1999); Mireles, *States as Innovation System Laboratories*, *supra* note 181, at 1156–57; O'Connor, *supra* note 132, at 700–03.

²⁴⁷ Rai & Eisenberg, *supra* note 9, at 294; *see also* 35 U.S.C. § 203(2); 37 C.F.R. § 401.6.

²⁴⁸ *See* Rai & Eisenberg, *supra* note 9, at 294, 308 (acknowledging problems with cumbersome procedures and discussing NIH's failed attempt to reform procedures due to lack of legal authority).

²⁴⁹ Public Health Service, Patent License Agreement—Exclusive 5 (2008), <http://ott.od.nih.gov/docs/PHS%20Patent%20License-Exclusive-model%20102005.DOC>.

²⁵⁰ Ferguson, *supra* note 189, at 110S.

²⁵¹ *Id.*

“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 Principles and Guidelines are only relevant to federal grant recipients, not to patentees in general. Sidestepping the narrow common law experimental use exception and difficult legislative 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.²⁵²

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; they only apply in the context of a particular bargain whereby contractors patent taxpayer-funded inventions. While the NIH rarely exercises its Bayh–Dole rights, these rights hang like a sword of Damocles over federal funding arrangements, thus providing the NIH with significant leverage to negotiate access to grantee-patented research tools.²⁵³ In conjunction with the Principles and Guidelines, these rights help establish a flexible system in 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 may significantly enhance the NIH’s ability to regulate the patenting and licensing of taxpayer-funded inventions.²⁵⁴

²⁵² Golden, *supra* note 12, at 176.

²⁵³ See Minutes of the Intellectual Property Task Force of the California Institute for Regenerative Medicine 78–79 (Oct. 25, 2005), <http://www.cirm.ca.gov/transcripts/pdf/2005/10-25-05.pdf> [hereinafter Oct. 25, 2005 IP Task Force Minutes] (statement of Pamela Samuelson, Professor, School of Information Management and Systems and School of Law, U.C. Berkeley).

²⁵⁴ Rai & Eisenberg, *supra* note 9, at 294, 308 (noting the substantive and procedural difficulties of exercising rights under the Bayh–Dole Act). Others have gone further and suggested modifying the Bayh–Dole framework to specifically allow a research exception for all inventions financed under the Act. Boettiger & Bennett, *supra* note 213, at 321.

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 that grantees must share any resulting patented inventions 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 overall biomedical research funding.²⁵⁵ However, the federal government's ban on funding research on human embryonic stem cells derived after August 9, 2001,²⁵⁶ (which has only recently been lifted) motivated several state initiatives to fill this void.²⁵⁷ 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.²⁵⁸ Notwithstanding recent discoveries that adult stem cells can be reprogrammed to behave like embryonic stem cells,²⁵⁹ many researchers still feel that embryonic stem cells,

²⁵⁵ Moses et al., *supra* note 169, 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 181, at 1135 n.3 (collecting state statutes related to funding research).

²⁵⁶ President George W. Bush, Remarks by the President on Stem Cell Research (Aug. 9, 2001), http://www.dtrends.com/Government/stemcell_bush.pdf; Press Release, NIH, Statement on the President's Stem Cell Address (Aug. 9, 2001), <http://www.nih.gov/news/pr/aug2001/od-09.htm>; NIH, Federal Policy, <http://stemcells.nih.gov/policy> (last visited Jan. 16, 2009).

²⁵⁷ See, e.g., Jennifer L. Enmon, Note, *Stem Cell Research: Is the Law Preventing Progress?*, 2002 UTAH L. REV. 621, 647. While President Bush noted that sixty suitable cell lines were already in existence, some of 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 twenty-one cell lines. NIH, Frequently Asked Questions (FAQs), <http://stemcells.nih.gov/info/faqs.asp> (follow the first hyperlink listed under "Human Embryonic Stem Cell Line Availability and the Registry") (last visited Jan. 28, 2009).

²⁵⁸ See Joe Palca, *States Take Lead in Funding Stem-Cell Research*, NPR, Mar. 30, 2007, <http://www.npr.org/templates/story/story.php?storyId=9244363>. See generally 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 NEW ENG. J. MED. 1 (2005); Nat'l Conference of State Legislatures, *Stem Cell Research*, <http://ncsl.org/programs/health/genetics/embfet.htm> (last visited Nov. 16, 2008).

²⁵⁹ Nicholas Wade, *Biologists Make Skin Cells Work Like Stem Cells*, N.Y. TIMES, June 7, 2007, at A2.

which are the targets of these state initiatives, remain the “gold standard” for stem cell research.²⁶⁰

This subsection focuses on California’s stem cell initiative because (1) it vastly exceeds the size of other state initiatives,²⁶¹ (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. Although President Obama recently lifted certain restrictions on federal funding for human embryonic stem cell research,²⁶² the California initiative, which has already disbursed millions in grants,²⁶³ remains an important source of both funds and policy guidance for this research. In 2004, California voters resoundingly passed Proposition 71, which authorized \$3 billion in state bond funds for stem cell research over a ten-year period.²⁶⁴ To administer the grants, Proposition 71 established the California Institute for Regenerative Medicine (CIRM),²⁶⁵ a state agency governed by a twenty-nine-member Independent Citizens Oversight Committee (ICOC) comprised of representatives from academia, government, business, and disease advocacy groups.²⁶⁶

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,

²⁶⁰ Colin Nickerson, *Caution Urged in New Method for Stem Cells*, BOSTON GLOBE, Dec. 17, 2007, at A1. Reprogramming these cells involves retroviruses, which may cause cancer.

²⁶¹ See Nat’l Conference of State Legislatures, *supra* note 258.

²⁶² See Sheryl Gay Stolberg, *Obama Lifts Bush’s Strict Limits on Stem Cell Research*, N.Y. TIMES, Mar. 9, 2009, <http://www.nytimes.com/2009/03/10/us/politics/10stem.html>.

²⁶³ See CIRM, *Approved CIRM Grants*, <http://www.cirm.ca.gov/info/grants.asp> (last visited Nov. 16, 2008).

²⁶⁴ The ballot initiative passed 59% to 41%. 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 132, 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 62. As of June 28, 2008, CIRM had committed over \$554 million in grants. See CIRM, *supra* note 263.

²⁶⁵ CALIFORNIA SECRETARY OF STATE, *Text of Proposed Laws: Proposition 71*, in OFFICIAL VOTER INFORMATION GUIDE: CALIFORNIA GENERAL ELECTION 147, 147 (2004), available at <http://www.cirm.ca.gov/pdf/prop71.pdf>.

²⁶⁶ *Id.*

protocols, and/or . . . substantial mitigation of, major diseases, injuries, and orphan diseases.”²⁶⁷ Proposition 71 identifies several additional objectives, including improving California’s health care system, reducing health care costs, and generating revenue from sponsored research.²⁶⁸ 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.²⁶⁹

Unlike the NIH, CIRM takes a financial stake in funded inventions. While several scientific advisors recommended against aggressive revenue sharing requirements,²⁷⁰ Proposition 71 included this measure largely as a concession to political interests demanding some return on investment for public money. Nevertheless, CIRM also seeks to ensure that patented, state-funded research tools are widely available for scientific inquiry. These objectives are illustrated in CIRM’s intellectual property regulations, which distinguish between nonprofit²⁷¹ and for-profit grantees.²⁷²

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

Following many of the recommendations of the California Council on Science and Technology,²⁷³ CIRM adopted a Bayh–Dole model allowing grantees to patent state-financed inventions.²⁷⁴ However, CIRM explicitly

²⁶⁷ *Id.*

²⁶⁸ *Id.*

²⁶⁹ *Id.* at 149.

²⁷⁰ *See, e.g.*, CAL. COUNCIL ON SCI. & TECH. INTELLECTUAL PROP. STUDY GROUP, POLICY FRAMEWORK FOR INTELLECTUAL PROPERTY DERIVED FROM STATE-FUNDED RESEARCH 11 (2006) [hereinafter CCST]; Oct. 25, 2005 IP Task Force Minutes, *supra* note 253, at 23 (statement of Steve Rockwood, Co-Chair, California Council on Science and Technology, Intellectual Property Study Group) (“I think if you focus on how many nickels and dimes go back to the state treasury, you will miss the point.”); Minutes of the Intellectual Property Task Force of the California Institute for Regenerative Medicine 87 (Nov. 22, 2005), <http://www.cirm.ca.gov/transcripts/pdf/2005/11-22-05.pdf> [hereinafter Nov. 22, 2005 IP Task Force Minutes] (statement of Rebeca Eisenberg, Professor of Law, University of Michigan) (“Recoupment is a tax on product development.”).

²⁷¹ CAL. CODE REGS. tit. 17, §§ 100300–100310 (2008).

²⁷² *Id.* §§ 100400–100410.

²⁷³ *See* Mireles, *supra* note 181, at 1181–86.

²⁷⁴ CAL. CODE REGS. tit. 17, §§ 100306, 100406; *see* Mireles, *States as Innovation System Laboratories*, *supra* note 181, at 1181–86.

limits these rights to ensure that patents do not impede biomedical research.²⁷⁵ CIRM regulations require that nonprofit grantees provide any state-financed, patented inventions to other nonprofit research institutions at reasonable cost.²⁷⁶ Unlike the NIH's Principles and Guidelines, these regulations are legally enforceable. Nonprofit grantees are required to reserve a basic research exception when licensing CIRM-funded patented inventions to third parties.²⁷⁷ Furthermore, nonprofit grantees must agree to make all such inventions readily accessible to California research institutions for noncommercial purposes.²⁷⁸ CIRM regulations further promote the availability of funded inventions by stating that nonprofit "[g]rantee organizations shall negotiate non-exclusive licenses . . . whenever possible."²⁷⁹

In addition, CIRM also mandates that nonprofit grantees must make "biomedical materials"²⁸⁰ described in academic publications widely available. Nonprofit grantees must share such materials on reasonable terms within sixty days of a request to use them for research purposes.²⁸¹ Finally, CIRM maintains march-in rights to compulsorily license any CIRM-funded invention based on certain codified criteria.²⁸² March-in rights are available, for example, "[t]o meet requirements of public use."²⁸³ Notably, however, CIRM's march-in rights lack the cumbersome administrative review provisions of the Bayh-Dole Act.²⁸⁴ Ultimately, in the quid pro quo of accepting state funds, grantees must also accept limitations on their patent rights.²⁸⁵

²⁷⁵ In particular, the California Council on Science and Technology's working group commissioned to report to CIRM was particularly interested in maintaining the wide availability of patented research tools. Oct. 25, 2005 IP Task Force Minutes, *supra* note 253, at 24 (statement of Rockwood).

²⁷⁶ The vast majority of CIRM grantees will be nonprofit institutions, such as universities.

²⁷⁷ CAL. CODE REGS. tit. 17, § 100306(a); *see* Mireles, *States as Innovation System Laboratories*, *supra* note 181, at 1190, 1199–1200.

²⁷⁸ CAL. CODE REGS. tit. 17, § 100306(a).

²⁷⁹ *Id.* § 100306(b).

²⁸⁰ *Id.* § 100301(d). CIRM's definition of "biomedical materials" is similar, but not identical, to the NIH's definition of research tools. *Id.*

²⁸¹ *Id.* § 100304; *see* Mireles, *States as Innovation System Laboratories*, *supra* note 181, at 1188–89.

²⁸² CAL. CODE REGS. tit. 17, § 100310.

²⁸³ *Id.* § 100310(a)(3).

²⁸⁴ *See* Mireles, *States as Innovation System Laboratories*, *supra* note 181, at 1191.

²⁸⁵ CIRM has also issued nonbinding policy statements discouraging the patenting of certain research tools such as transgenic mice, receptors, cell lines, hypothetical proteins, random SNPs, halotypes, and proteins that have only research functions. CIRM, INTELLECTUAL PROPERTY POLICY FOR NON-PROFIT ORGANIZATIONS 32, 35 (2006), *available at* http://www.cirm.ca.gov/meetings/pdf/2006/10/101106_item_10a.pdf. This recommendation is consistent with guidelines from the National Academy of Sciences. *See* Nov. 22, 2005 IP Task Force Minutes, *supra* note 270, at 73 (statement of Brian Wright, Professor, Department of Agricultural and Resource Economics, U.C. Berkeley).

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 nonexclusively. However, CIRM regulations still favor nonexclusive licensing, stating that 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.”²⁸⁶

As with nonprofit grantees, for-profit grantees must share CIRM-funded biomedical resources described in a publication within sixty days of a request to use them for research purposes.²⁸⁷ However, such sharing is not required if “a sharing request is in direct conflict with the business of the Grantee.”²⁸⁸ Finally, CIRM maintains march-in rights for inventions developed by for-profit entities with state funds.²⁸⁹ Again, CIRM may exercise these rights if, among other reasons, “the Grantee or its exclusive licensee has failed to satisfy requirements for public use.”²⁹⁰

4. Analysis

Exceeding the efforts of the NIH, CIRM explicitly requires broad access to publicly 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, its 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.”²⁹¹ Clearly,

²⁸⁶ CAL. CODE REGS. tit. 17, § 100406(c).

²⁸⁷ *Id.* §§ 100304, 100404; see Mireles, *States as Innovation System Laboratories*, *supra* note 181, at 1188–89.

²⁸⁸ CAL. CODE REGS. tit. 17, § 100404(c)(2).

²⁸⁹ *Id.* § 100410.

²⁹⁰ *Id.* § 100410(b)(3).

²⁹¹ *Id.* § 100300 (applying to nonprofit grantees); see also *id.* § 100400 (applying virtually identical language to for-profit grantees).

California could not enact a noncommercial research exception to patent infringement for inventions in that state; federal patent law would preempt such a statute.²⁹² 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. As opposed to NIH policy guidance, CIRM's regulations are directly enforceable by law. Unlike legislative solutions, the targeted, context-specific nature of consideration-based patent regulation allows CIRM to 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. While scientific advisory committees opposed an aggressive revenue sharing model,²⁹³ political considerations no doubt helped motivate the drafters of Proposition 71 to include this provision. Furthermore, while CIRM strictly distinguishes between for-profit and nonprofit 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 nonprofit grant recipients to freely provide patented research tools to institutions located in California. This preference, which may also reflect local political sensitivities, threatens to exacerbate a balkanization of science that has helped California draw resources and talent away from other states; such consolidation may undermine the interests of the national scientific community

²⁹² See *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 164–68 (1989); *Compco Corp. v. Day-Brite Lighting, Inc.*, 376 U.S. 234, 237 (1964); *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 228–31 (1964); Keith Aoki, *Balancing Act: Reflections on Justice O'Connor's Intellectual Property Jurisprudence*, 44 HOUS. L. REV. 965, 976–80 (2007); Mark A. Lemley, *Beyond Preemption, The Law and Policy of Intellectual Property Licensing*, 87 CAL. L. REV. 111, 138–39 (1999).

²⁹³ See, e.g., CCST, *supra* note 270.

as a whole.²⁹⁴ Expanding the scope of reserved research rights to *all* nonprofit institutions would enhance the effectiveness of this state-funded research commons.

C. Universities

Relative to 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.²⁹⁵ 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.²⁹⁶

1. University Contributions to Basic Biomedical Research

Universities play a dominant role in conducting basic biomedical research.²⁹⁷ In 2002, universities and colleges spent \$19.6 billion on biomedical research.²⁹⁸ 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.²⁹⁹ Unlike commercial firms, which tend to focus on applied research and development, universities particularly focus on basic research.³⁰⁰ As a result of the close nexus of basic biomedical research and tangible applications, moreover, university research has generated a significant number of research

²⁹⁴ See O'Connor, *supra* note 132, at 679; Sax, *supra* note 257, 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).

²⁹⁵ See Oct. 25, 2005 IP Task Force Minutes, *supra* note 253, at 134 (statement of Fred Dorey, Special Counsel, Godward Kronish, L.L.P.) (“The biotech industry doesn’t own anything they license from the universities. They own nothing. The universities own it all.”).

²⁹⁶ Nelson, *supra* note 60, at 467.

²⁹⁷ Amanda L. Brewster et al., *Facilitating Humanitarian Access to Pharmaceutical and Agricultural Innovation*, in 1 INTELLECTUAL PROPERTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATION, *supra* note 56, at 52.

²⁹⁸ Moses et al., *supra* note 169, at 1337. Federal expenditures accounted for 64% of the research support provided by universities. *Id.*

²⁹⁹ NIH, NIH Budget, <http://www.nih.gov/about/budget.htm> (last visited Nov. 16, 2008).

³⁰⁰ NAT'L SCI. FOUND., NATIONAL PATTERNS OF R&D RESOURCES: 2006 DATA UPDATE, at 26 (2007), available at <http://www.nsf.gov/statistics/nsf07331/pdf/nsf07331.pdf>.

tools.³⁰¹ These include recombinant DNA technology, extracted and purified human embryonic stem cells, and genetically modified disease models.³⁰²

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,³⁰³ including the Bayh–Dole Act; expansive patentable subject matter doctrine; advances in molecular biology that have revealed a relatively clear path from “basic” discoveries to commercial products,³⁰⁴ and market pressures on universities.³⁰⁵ University technology transfer offices, a relatively recent development, 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.³⁰⁶ By 2002, universities were awarded more than 3,600 patents a year, with licensing revenues exceeding \$1.2 billion.³⁰⁷

University patenting is particularly prevalent in the biopharmaceutical field.³⁰⁸ University research in genetics and molecular biology spawned the biotechnology industry;³⁰⁹ in that sector alone, universities hold approximately

³⁰¹ Cf. Lemley, *Are Universities Patent Trolls?*, *supra* note 22, at 614.

³⁰² See Annetine C. Gelijns & Samuel O. Thier, *Medical Innovation and Institutional Interdependence: Rethinking University-Industry Connections*, 287 JAMA 72, 74 (2002).

³⁰³ See Lita Nelsen, *The Rise of Intellectual Property Protection in the American University*, 279 SCIENCE 1460 (1998) (describing factors driving the increase in technology transfer in American universities); Walter W. Powell & Jason Owen-Smith, *Universities and the Market for Intellectual Property in the Life Sciences*, 17 J. POL'Y ANALYSIS & MGMT. 253 (1998) (detailing reasons for the rise in university technology transfer). Of course, university patenting did not begin with the Bayh–Dole Act. See generally Charles Weiner, *Patenting and Academic Research: Historical Case Studies*, 12 SCI. TECH. & HUMAN VALUES 50 (1987).

³⁰⁴ Rebecca S. Eisenberg, *Patents and Data-Sharing in Public Science*, *supra* note 51, at 1014.

³⁰⁵ See generally DEREK BOK, UNIVERSITIES IN THE MARKETPLACE: THE COMMERCIALIZATION OF HIGHER EDUCATION (2003) (warning of the dangers of excessive corporate influence on universities).

³⁰⁶ Jerry G. Thursby & Marie C. Thursby, *University Licensing and the Bayh-Dole Act*, 301 SCIENCE 1052, 1052 (2003).

³⁰⁷ AUTM, LICENSING SURVEY: FY 2002, SURVEY SUMMARY 12, 18 (2003), available at <http://www.provendis.info/fileadmin/info/pdfs/1252.pdf>.

³⁰⁸ See Powell & Owen-Smith, *supra* note 303, at 257 (discussing the complex intermingling of government and university research in the biopharmaceutical field); see also Eisenberg, *Patents, Product Exclusivity, and Information Dissemination*, *supra* note 109, at 479 (stating that the pharmaceutical industry considers patents to be crucial to the financial viability of research and development); Gelijns & Thier, *supra* note 302, at 73 (noting that academic research has catalyzed basic research in the pharmaceutical industry); Jaffe, *supra* note 11, at 541 (observing that university patenting is disproportionately concentrated in technology classes related to health sciences).

³⁰⁹ Gelijns & Thier, *supra* note 302, at 73; see G. Steven McMillan et al., *An Analysis of the Critical Role of Public Science in Innovation: The Case of Biotechnology*, 29 RES. POL'Y 1, 5 (2000) (noting the close link between public science and the biotechnology industry).

18% of all patents.³¹⁰ 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.³¹¹ In general, university patents are more likely to cover building blocks critical to innovation, including research tools, than particular downstream applications of a technology.³¹² Universities thus hold assets of immense value that private firms seek to exploit.³¹³ 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,³¹⁴ recent increases in university patenting have raised anxieties that commercial interests may be eroding traditional norms of freely sharing research results.³¹⁵ As a general matter, the increasing commercialization of universities has raised

³¹⁰ David E. Adelman & Kathryn L. DeAngelis, *Patent Metrics: The Mismeasure of Innovation in the Biotech Patent Debate*, 85 TEX. L. REV. 1677, 1687 n.44 (2007).

³¹¹ Gelijns & Thier, *supra* note 302, at 74.

³¹² Lemley, *Patenting Nanotechnology*, *supra* note 51, at 616.

³¹³ See Kesselheim & Avorn, *supra* note 177, at 851 (showing that private corporations depend on and commercialize scientific discoveries from universities); cf. Narin et al., *supra* note 88, at 318 (detailing the significant contributions of public science to industrial technology). Of course, knowledge transfer between academic and private-sector institutions is often complex and bidirectional. See Golden, *supra* note 12, at 119 (discussing cross-fertilization between “science” and “technology”); Gelijns & Thier, *supra* note 302, at 76 (describing the importance of close university–industry interactions for both sectors).

³¹⁴ See 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) (noting the cultural tensions arising from early efforts to commercialize the fruits of academic biology); Lemley, *Patenting Nanotechnology*, *supra* note 51, at 610 (discussing traditional academic norms discouraging patenting).

³¹⁵ See BOK, *supra* note 305 (arguing that universities may be jeopardizing their institutional mission by compromising basic academic values); JENNIFER WASHBURN, UNIVERSITY, INC.: THE CORPORATE CORRUPTION OF AMERICAN HIGHER EDUCATION (2005) (arguing that commercial values threaten the autonomy and traditional values of universities); see also Steven Brint, *Creating the Future: ‘New Directions’ in American Research Universities*, 43 MINERVA 23 (2005) (discussing the impact of economic competition on university research agendas); Catherine D. DeAngelis, *The Influence of Money on Medical Science*, 296 JAMA 996 (2006) (noting that for-profit sponsors of medical research have prevented academic scientists from publishing in certain journals); Raymond S. Fersko & Hind Merabet, *Sponsored Research and the Public’s Right to Know*, 63 DRUG DEV. RES. 103, 104 (2005) (arguing that researchers and their financial sponsors are “ethically” accountable to the public to present and distribute results); Gelijns & Thier, *supra* note 302, at 76 (discussing concerns that the costs of university–industry interactions might exceed their benefits); Michael Gibbons, *Changing Patterns of University-Industry Relations*, 38 MINERVA 1573 (2000) (discussing the implications of university efforts to restructure research capabilities to be more attractive to industry); Melissa Healy, *From Fundings to Findings*, L.A. TIMES, Aug. 6, 2007, at F3 (noting the impact of drug company research support on scholarly impartiality).

concerns over compromised research agendas,³¹⁶ increased secrecy and publication delays,³¹⁷ manipulation of results,³¹⁸ decreased academic productivity,³¹⁹ conflicts of interest between universities and their faculties,³²⁰ weakened academic freedom,³²¹ decreased public confidence in university science,³²² and even reduced dissemination of university research findings throughout the developing world.³²³ Complicating the rise of university patenting has been the independent, though related, rise in university–industry partnerships.³²⁴ These partnerships often allow industry partners to obtain patent rights arising from industry-sponsored, university-conducted research.³²⁵

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

³¹⁶ Eyal Press & Jennifer Washburn, *The Kept University*, ATLANTIC MONTHLY, March 2000, at 39; see also Brett M. Frischmann, *Commercializing University Research Systems in Economic Perspective: A View From the Demand Side*, in UNIVERSITY ENTREPRENEURSHIP AND TECHNOLOGY TRANSFER: PROCESS, DESIGN, AND INTELLECTUAL PROPERTY 155, 176–78 (Gary D. Libecap ed., 2005); Pierre Azouley et al., *The Impact of Academic Patenting on the Rate, Quality, and Direction of (Public) Research* (Nat'l Bureau of Econ. Research Working Paper No. 11917, 2006), <http://www.nber.org/papers/w11917> (examining the impact of faculty patenting on research agendas and quality); Powell & Owen-Smith, *supra* note 303, at 270 (discussing the conflicting interests of advancing knowledge and generating revenues).

³¹⁷ See, e.g., BOK, *supra* note 305, at 64–76; Margo A. Bagley, *Academic Discourse and Proprietary Rights: Putting Patents in Their Proper Place*, 47 B.C. L. REV. 217, 219 (2006) (noting the impact of patenting on stifling academic discourse and sharing norms); David Blumenthal et al., *Relationships Between Academic Institutions and Industry in the Life Sciences—An Industrial Survey*, 334 NEW ENG. J. MED. 368, 371 (1996) (discussing the prevalence of scientific data withholding in the context of academic–industry partnerships); Jon F. Merz et al., *Diagnostic Testing Fails the Test*, 415 NATURE 577, 579 (2002) (noting that patents have contributed to publication delays); Press & Washburn, *supra* note 316.

³¹⁸ See Press & Washburn, *supra* note 316 (discussing the impact of markets on scientific inquiry).

³¹⁹ See David Blumenthal et al., *Participation of Life-Science Faculty in Research Relationships with Industry*, 335 NEW ENG. J. MED. 1734, 1738 (1996) (“[F]aculty members who receive more than two thirds of their research support from industrial sources have lower academic productivity than those with less support from industry.”).

³²⁰ David J. Triggler, *Patenting the Sun: Enclosing the Scientific Commons and Transforming the University—Ethical Concerns*, 63 DRUG DEV. RES. 139, 143–44 (2005).

³²¹ Risa L. Lieberwitz, *The Marketing of Higher Education: The Price of the University's Soul*, 89 CORNELL L. REV. 763, 793–98 (2004).

³²² Triggler, *supra* note 320, at 144–45.

³²³ *Id.* at 145.

³²⁴ See, e.g., Press & Washburn, *supra* note 316, at 50; Jennifer Washburn, *Big Oil Buys Berkeley: The BP-UC Berkeley Research Deal Pushes Academic Integrity Aside for Profit*, L.A. TIMES, Mar. 24, 2007, at A21.

³²⁵ See, e.g., Marshall, *NIH Cuts Deal on Use of OncoMouse*, *supra* note 81 (discussing conflicts arising from a genetically modified organism financed by DuPont, patented by Harvard University, and then exclusively licensed to DuPont).

intellectual property constraints,³²⁶ which may exacerbate anticommons problems.³²⁷ Additionally, Professor Mark Lemley has questioned whether universities qualify as “patent trolls,” entities that accumulate patents but do not manufacture goods, instead relying on licensing fees and the threat of litigation for revenue.³²⁸ Indeed, several high-profile cases reveal universities’ aggressive approach to enforcing their patents.³²⁹ Not surprisingly, there is much variation in university approaches to licensing. As a general matter, older, savvier technology transfer offices with significant licensing experience tend to focus more on disseminating technology and less on maximizing revenue.³³⁰ Institutional cultures also differ. For example, Johns Hopkins has generally been skeptical of licensing,³³¹ while Columbia has attracted notable criticism for its aggressive enforcement of intellectual property rights.³³²

While some argue that profit motives are distorting academic norms, it is worth noting that university patents rarely generate significant revenues.³³³ As of 2003, university licenses produced over \$1 billion per year in revenue.³³⁴ Though significant, these “[p]atent revenues account for a trivial fraction of overall university research budgets, while public research funding remains of critical importance.”³³⁵ In one survey, median net licensing income for research institutions was only \$1.13 million per year.³³⁶ Of all university patent licenses in 2000, only 43% earned royalties, and 0.56% earned more than \$1 million.³³⁷ Among U.S. institutions, the ratio of licensing income to privately sponsored research was 5% or less in 2005.³³⁸ Furthermore, there is a

³²⁶ Triggie, *supra* note 320, at 143.

³²⁷ Rai & Eisenberg, *supra* note 9, at 295–303; *see also* Graff et al., *supra* note 173, at 995 (discussing the implications of fragmented ownership of upstream technological resources).

³²⁸ Lemley, *Are Universities Patent Trolls?*, *supra* note 22, at 619. Professor Lemley concludes that characterization as a troll should be determined by behavior, not institutional identity. *Id.*

³²⁹ *See, e.g.*, *Eolas Techs. Inc. v. Microsoft Corp.*, 399 F.3d 1325 (Fed. Cir. 2005) (involving an infringement suit by the University of California against a software manufacturer); *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997) (involving an infringement suit by the University of California against an insulin manufacturer).

³³⁰ Nov. 22, 2005 IP Task Force Minutes, *supra* note 268, at 81 (statement of Eisenberg).

³³¹ Gregory K. Sobolski et al., *Technology Licensing, Lessons from the U.S. Experience*, 294 JAMA 3137, 3138 (2005).

³³² *See, e.g.*, Wysocki, *supra* note 233.

³³³ Dave A. Chokshi & Rahul Rajkumar, *Leveraging University Research to Advance Global Health*, 298 JAMA 1934, 1936 (2007); Sobolski et al., *supra* note 331, at 3137.

³³⁴ Thursby & Thursby, *supra* note 306, at 1052.

³³⁵ Eisenberg, *Public Research and Private Development*, *supra* note 174, at 1726.

³³⁶ Sobolski et al., *supra* note 331, at 3137.

³³⁷ Thursby & Thursby, *supra* note 306, at 1052.

³³⁸ Sobolski et al., *supra* note 331, at 3138.

high degree of variability in university licensing revenues, which exhibits a “winner take all” dynamic where a few institutions and a few inventions earn most of the money.³³⁹ For example, the nine-campus University of California’s net licensing income of \$91 million far exceeds the average revenue for a university system.³⁴⁰ At Columbia University, five patented inventions account for about 95% of all licensing revenues.³⁴¹ 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.³⁴² At an individual and group level, the scientific community has long been characterized by norms emphasizing openly sharing knowledge and ideas.³⁴³ These “public sector values” have been cultivated by the taxpayer-funded research system encompassing university and government laboratories.³⁴⁴ University knowledge production is motivated by a host of nonfinancial rewards and is built on freely exchanging ideas and information.³⁴⁵ While some caution that patents have eroded this communal culture,³⁴⁶ others observe that informal sharing norms persist even within an increasingly proprietary environment.³⁴⁷

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.³⁴⁸ At a broad level, universities are still committed to

³³⁹ *Id.* at 3137; David Baltimore, *On Over-Weighting the Bottom Line*, 301 SCIENCE 1050, 1050 (2003); Leaf, *supra* note 178, at 259.

³⁴⁰ Sobolski et al., *supra* note 331, at 3138.

³⁴¹ Gelijns & Thier, *supra* note 302, at 75.

³⁴² See Baltimore, *supra* note 339, at 1050; Nelsen, *supra* note 303, at 1461 (“[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 178, at 114.

³⁴³ See WASHBURN, *supra* note 314, at 73 (discussing long-held values of freely sharing discoveries).

³⁴⁴ Golden, *supra* note 12, at 153.

³⁴⁵ See Kahan, *supra* note 153, at 90–93 (noting that reciprocal exchange is essential to scholarly production).

³⁴⁶ Eisenberg, *Proprietary Rights and the Norms of Science*, *supra* note 51, at 182; Rai, *Regulating Scientific Research*, *supra* note 17.

³⁴⁷ Robert P. Merges, *Property Rights Theory and the Commons: The Case of Scientific Research*, SOC. PHIL. & POL’Y, 145, 150 (1996) [hereinafter Merges, *Property Rights Theory and the Commons*].

³⁴⁸ Murray, *supra* note 81, at 42; cf. Merges, *Property Rights Theory and the Commons*, *supra* note 347, at 150.

widely and promptly disseminating research results.³⁴⁹ These principles also extend, at least in part, to intellectual property policies.³⁵⁰ While one must be skeptical of high-level rhetoric, the stated policies of virtually all universities espouse using intellectual property to advance social welfare with secondary regard for financial rewards.³⁵¹ For example, Harvard University's policy acknowledges the university's "primary commitment" to the public interest.³⁵² For its part, AUTM observes that most of its members "would define success through the criterion of public benefit."³⁵³ While the commercialization of universities is a real phenomenon and academic institutions may have legitimate reasons for pursuing licensing income,³⁵⁴ most universities can and do take a wider view of patenting than revenue maximization.³⁵⁵

3. *University Licensing Policies Favoring Access to Patented Research Tools*

Along these lines, universities are leveraging their ownership of research tool patents to ensure, in contractual transactions with external parties, a robust research commons in biomedicine.³⁵⁶

³⁴⁹ Chokshi & Rajkumar, *supra* note 333, at 1936 (collecting university mission statements); Eisenberg, *Patents and Data-Sharing in Public Science*, *supra* note 51, at 1013; Thursby & Thursby, *supra* note 306, at 1052; *see also* Robert E. Litan et al., *Commercializing University Inventions: A Better Way* (Nat'l Bureau of Econ. Research Working Paper, Apr. 2007), http://sites.kauffman.org/pdf/NBER_0407.pdf.

³⁵⁰ *See* AUTM, U.S. LICENSING ACTIVITY SURVEY: FY 2006, SURVEY SUMMARY 13 (2007), *available at* http://www.autm.net/AM/Template.cfm?Section=FY_2006_Licensing_Activity_Survey&Template=/CM/ContentDisplay.cfm&ContentID=1804 (indicating the high emphasis universities place on using patented inventions for public benefit).

³⁵¹ *See, e.g.*, Brewster et al., *supra* note 297, at 49, 51 (collecting policies of the top four universities in terms of patent activity).

³⁵² Harvard University, Statement of Policy in Regard to Intellectual Property (Feb. 4, 2008), <http://otd.harvard.edu/resources/policies/IP/IPPpolicy.pdf>; *see also* Yale University, Yale University Patent Policy (Feb. 1998), <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 Innovation Access, Office of Research, Licensing and Confidentiality, <http://www.innovationaccess.ucdavis.edu/home.cfm?id=ovc,23,1728,1718,1719,1725> (last visited Feb. 22, 2009) ("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.")

³⁵³ AUTM, *supra* note 349, at 13.

³⁵⁴ 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 22, at 620.

³⁵⁵ *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.")

³⁵⁶ Universities and research organizations have been particularly proactive in enhancing access to patented resources in agricultural biotechnology. The Public Intellectual Property Resource for Agriculture, a consortium of over forty 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:*

a. *Reserved Research Exemptions for Licensed Inventions*

Increasingly, universities are reserving research exceptions for themselves and other nonprofit organizations as a condition of licensing patented technologies to outside parties.³⁵⁷ 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.”³⁵⁸ Typically, these provisions not only reserve a research exemption for the licensing institution itself, but also provide for research licenses for all other nonprofit research institutions as well.³⁵⁹ According to Andrew Neighbour of UCLA, technology transfer offices “always insist on a research exemption not only for themselves, but for other nonprofit institutions; adding the other nonprofits into the research exception has been a trend.”³⁶⁰

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.”³⁶¹ Other universities take a slightly different approach, reserving research rights on behalf of nonprofits but establishing 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 educational and nonprofit institutions to do so for education and research purposes.”³⁶²

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: The CAMBIA BiOS Initiative*, INNOVATIONS, Fall 2006, at 13.

³⁵⁷ See Benkler, *Commons-Based Strategies*, *supra* note 22, at 1110–11 (discussing “publicly minded licensing” by universities); Brewster et al., *supra* note 297, at 56; Murray, *supra* note 81, at 39.

³⁵⁸ Pressman et al., *supra* note 199, at 35.

³⁵⁹ See, e.g., *id.* (drawing examples from Harvard University, UCSD, UCLA, UCSF, and U.C. Berkeley).

³⁶⁰ *Id.*

³⁶¹ Harvard University Office of Technology Development, *Licensing Harvard Patent Rights: A Guideline to the Essentials of Harvard’s License Agreements*, <http://www.techtransfer.harvard.edu/resources/guidelines/license> (last visited Nov. 16, 2008); see also Stanford University, *Exclusive Agreement 2* (Feb. 3, 2005), <http://otl.stanford.edu/industry/resources/exclusive.pdf> (“Stanford retains the right, on behalf of itself and all other non-profit academic research institutions, to practice the Licensed Patent and use Technology for any purpose, including sponsored research and collaborations.”).

³⁶² Alan B. Bennett, *Reservation of Rights for Humanitarian Uses*, in 1 INTELLECTUAL PROPERTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATION, *supra* note 56, at 42; see also Cal. Inst. of Tech. et al., *In the Public Interest: Nine Points to Consider in Licensing University Technology 10–12* (Mar. 6, 2007) [hereinafter *In the Public Interest*], available at <http://news-service.stanford.edu/news/2007/march7/gifs/>

Notably, these clauses directly respond to the Federal Circuit's narrow conception of the experimental use exception articulated in *Madey v. Duke University*.³⁶³ Many of these clauses define the research exception by explicitly permitting the kind of routine academic research that *Madey* held did not qualify for the common law experimental use exception.³⁶⁴ 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 scientific inquiry.

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 nonprofit and governmental organizations to do so as well.³⁶⁵ 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 RESEARCH PURPOSES.³⁶⁶

Again, the guidelines define "non-commercial research purposes" with explicit reference to *Madey*.³⁶⁷ The Stanford consortium also notes that reserving a research exemption corresponds with the NIH's recommendations for best practices for licensing genomic inventions.³⁶⁸

whitepaper.pdf; Wis. Alumni Research Found., Standard Non-Exclusive License Agreement 1, 9 (Oct. 2, 2003), available at http://www.warf.org/uploads/media/20031002132027680_Std_non_exclusive_license_agrmt.pdf; Baylor Coll. of Med., Exclusive License Agreement—Research Product 3 (Jan. 7, 2008), available at http://www.bcm.edu/blg/docs/lic_research.dot.

³⁶³ 307 F.3d 1351 (Fed. Cir. 2002); Bennett, *supra* note 362, at 42; In the Public Interest, *supra* note 362, at 11.

³⁶⁴ Bennett, *supra* note 362, at 42.

³⁶⁵ In the Public Interest, *supra* note 362, at 2; see Feldman & Nelson, *supra* note 28, at 19–22 (discussing the consortium's recommendations).

³⁶⁶ In the Public Interest, *supra* note 362, at 10 (emphasis omitted).

³⁶⁷ *Id.* at 11.

³⁶⁸ NIH, Best Practices for the Licensing of Genomic Inventions, 70 Fed. Reg. 18,414, 18,415 (Apr. 11, 2005).

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).³⁶⁹ Several decades ago, Stanford University and the University of California nonexclusively licensed the Cohen-Boyer patents covering gene splicing, a fundamental research tool, providing the technology to university scientists for free and to corporate researchers for a relatively low rate of \$10,000 per license.³⁷⁰ 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.³⁷¹

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 maintain private incentives to innovate.³⁷² While the majority of university licenses continue to be exclusive,³⁷³ universities are adopting policies drawing these distinctions and favoring nonexclusive licensing of research tools for noncommercial research purposes.³⁷⁴

Consistent with NIH policy, 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

³⁶⁹ Cf. Lemley, *Are Universities Patent Trolls?*, *supra* note 22, at 612. *But cf.* Lemley, *Patenting Nanotechnology*, *supra* note 51, at 627 (“The (admittedly meager) record so far is not promising. Of fifteen publicly announced nanotechnology license agreements in 2003, all but two or three were exclusive, and all nine of the licenses granted by universities were exclusive . . .”). 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 174.

³⁷⁰ *See* NAT’L RESEARCH COUNCIL, *supra* note 80; Lee, *The Evolution of Intellectual Infrastructure*, *supra* note 27, at 93–94.

³⁷¹ Hughes, *supra* note 314, at 542; 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 POL’Y & ECON. 187, 194 (2001). 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.1.

³⁷² Jaffe, *supra* note 11, at 552. *But see* Golden, *supra* note 12.

³⁷³ Lemley, *Are Universities Patent Trolls?*, *supra* note 22, at 617.

³⁷⁴ *See* Lemley, *Patenting Nanotechnology*, *supra* note 51, at 628 (suggesting utilizing the Bayh-Dole Act to restrict exclusive licensing of basic building block patents by universities).

benefits derived from those technologies, in part by removing obstacles to further innovation.³⁷⁵

However, context-specific exclusivity may be appropriate for research tools that would 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.³⁷⁶ In this manner, members of the scientific community may use these patented technologies for research purposes,³⁷⁷ but they may not *sell* them, thus maintaining the commercial incentives of exclusive licensees.

Evidence suggests that universities are already following these policies.³⁷⁸ A recent survey of university technology transfer offices revealed a preference for nonexclusively licensing most DNA research tools.³⁷⁹ Furthermore, respondents noted that the same patent could be licensed differently for research use versus commercial use.³⁸⁰ 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 high risk and costs associated with developing these products.³⁸¹ On the other hand, 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.³⁸²

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.

³⁷⁵ In the Public Interest, *supra* note 362, at 3.

³⁷⁶ *Id.* at 5.

³⁷⁷ *Id.*

³⁷⁸ 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.”).

³⁷⁹ Pressman et al., *supra* note 199, at 34–35.

³⁸⁰ *Id.* at 35.

³⁸¹ *Id.* at 33.

³⁸² *Id.* at 33–34.

The viability of these university efforts depends on the strength of access norms in the face of potential profits arising from exclusivity. In *Madey*, the Federal Circuit characterized universities as institutions with legitimate business objectives that include raising revenues.³⁸³ Although this characterization is true to a certain extent, traditional 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 type of patentee than most commercial firms.³⁸⁴ The traditional goal of universities has been to serve the public interest with education and research, not to maximize profits.³⁸⁵ 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.³⁸⁶

This observation reflects the belief that the “for-profit and not-for-profit sectors differ deeply in their missions, cultures, resources, and incentives, and these differences deserve respect.”³⁸⁷ 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, contracts are the mechanism by which universities are articulating these norms and constructing a research commons. Universities are reserving research rights for themselves and other nonprofit institutions in patent

³⁸³ *Madey v. Duke Univ.*, 307 F.3d 1351, 1362 (Fed. Cir. 2002) (“[M]ajor research universities, such as Duke, often sanction and fund research projects with arguably no commercial application whatsoever. However, these projects unmistakably further the institution’s legitimate business objectives, including . . . increas[ing] the status of the institution and lur[ing] lucrative research grants, students and faculty . . .”).

³⁸⁴ 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.*, Howard, *supra* note 232, at 955; *Ownership at Too High a Price?*, 21 NATURE BIOTECH. 953, 953 (2003); Wysocki, *supra* note 233, at A1.

³⁸⁵ Baltimore, *supra* note 339, at 1050; *see In the Public Interest*, *supra* note 362, 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”).

³⁸⁶ Eisenberg, *Public Research and Private Development*, *supra* note 174, at 1701.

³⁸⁷ Gelijns & Thier, *supra* note 302, at 77.

licenses. Furthermore, universities are enhancing the availability of patented research tools through nonexclusive licensing. Universities are actively “contracting around” *Madey* to place patented, university-generated inventions in a commons that is widely accessible to nonprofit researchers.³⁸⁸

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. Universities generally use revenues to measure the performance of technology transfer offices, thus giving these offices strong incentives to grant exclusive licenses.³⁸⁹ If these offices are to act consistently with lofty mission statements, universities must consider changing their incentive structures and performance metrics.³⁹⁰ In general, public scrutiny, moral suasion, and widespread recognition that licensing windfalls are unlikely can help universities take a broader view of their role in technology transfer.³⁹¹ Second, not all research exceptions apply to all third-party nonprofit institutions. To prevent the emergence of scientific “fiefdoms,” universities should ensure that reserved research exemptions automatically apply to *all* nonprofit research organizations (not just themselves). Finally, as Professors Rai and Eisenberg have argued, university technology transfer offices may lack the technical competence to optimally manage the licensing of patented biomedical inventions.³⁹² Distinguishing among various technologies, licensees, and uses is crucial for ideal exploitation of these inventions.³⁹³ Technical competence challenges, moreover, are likely exacerbated by understaffing at university

³⁸⁸ In the absence of such a provision, an exclusively licensed university invention may be unavailable for noncommercial research even by the university scientists who invented it. See Boettiger & Bennett, *supra* note 213, at 321.

³⁸⁹ Lemley, *Are Universities Patent Trolls?*, *supra* note 22, at 616; see Faley & Sharer, *supra* note 178, at 125 (discussing the varied and sometimes conflicting objectives of technology transfer offices).

³⁹⁰ See Boettiger & Bennett, *supra* note 213, at 320 (noting that such reforms have been “a slow and evolving process”).

³⁹¹ See Jaffe, *supra* note 11, at 552 (suggesting that public scrutiny and moral suasion may encourage universities and other public institutions to license research tools widely); Lemley, *Are Universities Patent Trolls?*, *supra* note 22, at 627 (“If we are to achieve the goal of maximizing the social benefit of a university invention to society, universities must first recognize their proper role in society and how that role affects patent policies.”); Anandashankar Mazumdar & Yousuf Siddiqui, *Witnesses Say Universities Too Rigid in Licensing Patent Rights Under Bayh-Dole*, 74 Pat. Trademark & Copyright J. (BNA), at 347 (July 20, 2007), *excerpt available at* <http://www.law.stanford.edu/news/details/1043> (quoting Mark Lemley as suggesting a greater role for federal oversight of university technology transfer).

³⁹² See Rai & Eisenberg, *supra* note 9, at 305.

³⁹³ See Bennett, *supra* note 362, at 42; Thursby & Thursby, *supra* note 306, at 1052 (recognizing the importance of asking “if and when” exclusive licensing is needed); Pressman et al., *supra* note 199, at 37 (presenting a variety of licensing options); Yale University, *supra* note 352.

technology transfer offices, which on average employ four professionals.³⁹⁴ To address these concerns, universities may need to devote more resources to these offices.

D. Nonprofit Funding Organizations

Nonprofit funding organizations play a substantial role in funding biomedical research, thus providing them with significant leverage in this sector.³⁹⁵ In 2003, nonprofit organizations provided \$2.5 billion to support biomedical research,³⁹⁶ and they are expected to grow in importance as funding sources.³⁹⁷ Furthermore, *what* they fund is oftentimes more important than *how much* they fund. Foundations “fill . . . gaps by funding research that is speculative scientifically, politically risky or unpopular, and where commercial value is low or not readily apparent.”³⁹⁸ This “gap filling” function extends to funding new and interdisciplinary research that may not receive NIH support.³⁹⁹ For example, by its own description, the Howard Hughes Medical Institute (HHMI) “prizes bold thinking and scientific risk taking” in awarding grants.⁴⁰⁰ Interestingly, the high tech boom of the 1990s produced a new generation of “venture philanthropists” who are particularly committed to strategic risk-taking.⁴⁰¹ By providing venture capital in new, cutting edge

³⁹⁴ Lorelei Ritchie de Larena, *The Price of Progress: Are Universities Adding to the Cost?*, 43 HOUS. L. REV. 1373, 1387, 1412 (2007).

³⁹⁵ 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 P. Balaram, *Philanthropy and the Funding of Science*, 83 CURRENT SCI. 537, 537 (2002); Robert I. Field et al., *Toward a Policy Agenda on Medical Research Funding: Results of a Symposium*, 22 HEALTH AFF. 224, 225, 227 (2003) (evaluating the current and historic roles of government, industry, and foundations in biomedical research).

³⁹⁶ Moses et al., *supra* note 169, 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 Odling-Smee, *The Money Tree*, 447 NATURE 251, 251 (2007).

³⁹⁷ See Jeffrey Mervis, *U.S. Science Adviser Tells Researchers to Look Elsewhere*, 316 SCIENCE 817, 817 (2007); Moses et al., *supra* note 169, at 1338–39.

³⁹⁸ Moses et al., *supra* note 169, at 1339; see also Field et al., *supra* note 395, at 227 (describing the unique funding role of foundations due to the fact that they are accountable only to their boards of directors and are therefore free from restraints arising from public opinion or profit motivations).

³⁹⁹ Moses et al., *supra* note 169, at 1338.

⁴⁰⁰ HHMI, 2007 ANNUAL REPORT 2 (2007) [hereinafter HHMI, 2007 ANNUAL REPORT], available at http://www.hhmi.org/home/HHMI_AR07.pdf; see also BILL & MELINDA GATES FOUND., 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.”).

⁴⁰¹ Trisha Gura, *Biomedical Philanthropy, Silicon Valley Style*, 410 NATURE 140, 140–43 (2001).

areas of biomedical research, nonprofits exert greater influence over research than their absolute dollar contributions suggest.

This monetary support, moreover, often comes with strings attached. Similar to the NIH and CIRM, nonprofit organizations are tying funds to requirements that grant recipients share patented (and unpatented) research tools widely for noncommercial use. As a case study, this section will focus on HHMI, a “major force in funding biomedical research”⁴⁰² that contributed \$599 million to research in 2007.⁴⁰³ As with other nonprofits, HHMI does not support biomedical research for financial gain. 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 the benefit of the public.”⁴⁰⁴ Consistent with other public institutions, HHMI embeds access requirements in its funding arrangements to help achieve these goals.

HHMI maintains several policies ensuring wide access to patented and unpatented 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.⁴⁰⁵ HHMI claims an ownership interest in any invention where at least one inventor is an HHMI employee.⁴⁰⁶ Although HHMI investigators may patent their inventions, HHMI retains an institution-wide, paid-up, nonexclusive, irrevocable license to use any HHMI-funded invention for noncommercial purposes.⁴⁰⁷

HHMI’s policy on research tools parallels the NIH’s Principles and Guidelines,⁴⁰⁸ and it “expects all HHMI research tools to be made available to

⁴⁰² Balaram, *supra* note 395, at 538.

⁴⁰³ HHMI, 2007 ANNUAL REPORT, *supra* note 400, at 78.

⁴⁰⁴ HHMI, SCIENCE POLICIES: INTELLECTUAL PROPERTY POLICY (SC-600) 1 (2007) [hereinafter HHMI, INTELLECTUAL PROPERTY POLICY], available at <http://www.hhmi.org/about/research/sc600.pdf>.

⁴⁰⁵ HHMI investigators at host universities are considered HHMI employees and do not receive a university salary. While these investigators often obtain non-HHMI funding as well, such as NIH and National Science Foundation grants, they may not accept corporate funding (unless that funding arises from an unrestricted gift).

⁴⁰⁶ HHMI, INTELLECTUAL PROPERTY AND HHMI EMPLOYEES: A GUIDE FOR HOST INSTITUTIONS 3 (2008) [hereinafter HHMI, INTELLECTUAL PROPERTY GUIDE FOR HOST INSTITUTIONS], available at <http://www.hhmi.org/pdf/host-guide.pdf>.

⁴⁰⁷ *Id.* at 7; HHMI, RESEARCH POLICIES: RESEARCH TOOLS (SC-310) 1 (2007) [hereinafter HHMI, RESEARCH TOOLS], available at http://www.hhmi.org/about/research/sc_310.pdf.

⁴⁰⁸ NIH, Principles and Guidelines, *supra* note 6, at 72,092.

the scientific research community on reasonable terms and in a manner that enhances their widespread availability.”⁴⁰⁹ As a general matter, this translates to sharing research tools with nonprofit researchers for free and sharing them with commercial entities for a nominal fee. Anecdotal evidence suggests a high degree of compliance with this policy among HHMI investigators. Additionally, HHMI utilizes the NIH’s Uniform Biological Materials Transfer Agreement⁴¹⁰ and broadly encourages streamlined material transfers to nonprofit organizations.⁴¹¹ 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.⁴¹² Upon publication of HHMI-funded work, laboratory heads are “expected” to make materials, data, databases, and software available for research use within sixty days of receiving a request.⁴¹³ 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.⁴¹⁴ As evidence of HHMI’s institutional commitment to such dissemination, Thomas Cech, the president of HHMI, chaired a National Academy of Sciences panel that called for timely and free releases of data and DNA sequences described in academic publications.⁴¹⁵

HHMI policies also apply to institutions hosting HHMI investigators. In such situations, the investigator assigns his or her patent rights to HHMI, which then assigns the rights to the host institution—usually a university—and allows the host institution to coordinate technology transfer decisions.⁴¹⁶ However, host institutions have an “obligation to include certain provisions for HHMI’s benefit” in any license of an HHMI invention to a company.⁴¹⁷ This includes HHMI’s irrevocable license to use any subject property for research

⁴⁰⁹ HHMI, RESEARCH TOOLS, *supra* note 407, at 1.

⁴¹⁰ HHMI, RESEARCH TOOLS: MATERIALS TRANSFERS (SC-330) 2 (2007) [hereinafter HHMI, MATERIAL TRANSFERS], *available at* <http://www.hhmi.org/about/research/sc330.pdf>.

⁴¹¹ *Id.* at 1.

⁴¹² HHMI, RESEARCH POLICIES: SHARING OF PUBLICATION-RELATED MATERIALS, DATA AND SOFTWARE (SC-300) (2007) [hereinafter HHMI, SHARING OF PUBLICATION-RELATED MATERIALS], *available at* http://www.hhmi.org/about/research/sc_300.pdf. As 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 236, at 107.1.

⁴¹³ HHMI, SHARING OF PUBLICATION-RELATED MATERIALS, *supra* note 412, at 1–2.

⁴¹⁴ *Id.* at 2.

⁴¹⁵ Marshall, *The UPSIDE of Good Behavior*, *supra* note 21, at 990.

⁴¹⁶ HHMI, INTELLECTUAL PROPERTY POLICY, *supra* note 404, at 3.

⁴¹⁷ HHMI, INTELLECTUAL PROPERTY GUIDE FOR HOST INSTITUTIONS, *supra* note 406, at 6.

purposes.⁴¹⁸ In addition, HHMI prohibits host institutions from licensing rights to *future* technology in a manner that exceeds what is necessary to commercialize an invention.⁴¹⁹ This underscores HHMI's commitment to preserving the widest zone of unconstrained research uses for patented inventions while still maintaining the profitability of commercial applications. Furthermore, consistent with its research tools policy, HHMI states that host institutions should make resources developed by HHMI investigators available to scientists at nonprofit organizations and to for-profit companies for use in internal research on reasonable terms.⁴²⁰ When a host institution proposes to license an HHMI research tool on an exclusive basis, HHMI requires a licensing plan showing how the tool will be made widely available to the scientific community.⁴²¹

HHMI policies on sharing research tools and materials described in publications also govern licensing of inventions developed at its Janelia Farm Research Campus.⁴²² This includes reserving a research use exception in all licenses with downstream partners as well as favoring nonexclusive licensing of research tools.

While contracts governing nonprofit 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 nonprofit organizations to biomedical research are strategically important and growing. 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 nonprofits exert this influence. In accepting money, funding recipients (and, in some cases, their host institutions) must also accept claims by the funding organization over the disposition of resulting inventions.

Nonprofit funding agencies thus emerge as policy actors in creating a research commons for biomedicine. Experienced players such as HHMI are

⁴¹⁸ HHMI, INTELLECTUAL PROPERTY POLICY, *supra* note 404, at 3; *see also* HHMI, RESEARCH TOOLS, *supra* note 407.

⁴¹⁹ HHMI, INTELLECTUAL PROPERTY GUIDE FOR HOST INSTITUTIONS, *supra* note 406, at 6.

⁴²⁰ *Id.* at 9; HHMI, RESEARCH TOOLS, *supra* note 407.

⁴²¹ HHMI, RESEARCH TOOLS, *supra* note 407, 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 406, at 7.

⁴²² HHMI, INTELLECTUAL PROPERTY POLICY, *supra* note 404, at 1, 4.

comparable 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. While HHMI reserves a paid-up research license for itself, it requires transferring patented materials to outside nonprofits for free or at "low cost," but does not define that term. Furthermore, while HHMI has structured its policies to dovetail with prevailing NIH and university practice, mixed funding arrangements can sometimes give rise to conflicts. For example, some disease advocacy groups may be quite aggressive in patenting all resources arising from sponsored research, and some nonprofits, unlike HHMI, allow grantees to license out options for future technology. To the extent that an HHMI investigator receives funds from these other organizations, negotiations may be necessary to resolve conflicting patent policies from diverse research sponsors.

E. Disease Advocacy Groups

A surprising example of the convergence of upstream contributions, norms of open science, and quid pro quos ensuring wide access to patented research tools arises in the context of disease advocacy groups. These groups make a wide variety of valuable contributions to biomedical research, such as facilitating communication between the patient and research communities; coordinating disparate research efforts;⁴²³ and providing scientists with money,⁴²⁴ technical expertise,⁴²⁵ and, perhaps most saliently, 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 advancements.⁴²⁶ Two case studies illustrate the role of disease advocacy groups in contractually creating a noncommercial biomedical research commons.

⁴²³ Sharon F. Terry & Patrick F. Terry, *A Consumer Perspective on Forensic DNA Banking*, 34 J.L. MED. & ETHICS 408, 409 (2006).

⁴²⁴ By 1999, the Cystic Fibrosis Foundation's annual income had grown to \$150 million, rendering it equal in importance to the NIH as a funder of cystic fibrosis research. Alan Stockdale & Sharon F. Terry, *Advocacy Groups and the New Genetics*, in *THE DOUBLE-EDGED HELIX: SOCIAL IMPLICATIONS OF GENETICS IN A DIVERSE SOCIETY* 80, 84 (Joseph S. Alper et al. eds., 2002).

⁴²⁵ See Sharon F. Terry et al., *Advocacy Groups as Research Organizations: The PXE International Example*, 8 NATURE REV. GENETICS 157, 158–59 (2007) (discussing the history of advocacy organizations).

⁴²⁶ 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 SOC. STUD. SCI. 729, 738–39 (2007) (noting PXE International as an example of benefit-sharing by the dominant advocacy organization in a particular field).

The development of a diagnostic test for Canavan disease, a gene-linked cerebral degenerative disorder,⁴²⁷ demonstrates the vital support that tissue donors can provide to biomedical research.⁴²⁸ In 1987, Daniel Greenberg, the father of two children suffering from Canavan disease, persuaded scientist Reuben Matalon to develop molecular probes to trace the disease to its source.⁴²⁹ 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.⁴³⁰ In 1993, utilizing these tissue donations, 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. 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 1997.⁴³¹ Unaware of MCH's patent, the Canavan Foundation began offering free Canavan screening in 1996. 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.⁴³² Greenberg, the Canavan Foundation, and other 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

⁴²⁷ Office of Communications and Public Liaison, National Institutes of Neurological Disorders and Stroke, What Is Canavan Disease?, <http://www.ninds.nih.gov/disorders/canavan/canavan.htm> (last visited Nov. 16, 2008).

⁴²⁸ 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, 325–30 (2004) (describing insights gained into Canavan disease through donated blood, urine, and tissue samples); Radhika Rao, *Genes and Spleens: Property, Contract, or Privacy Rights in the Human Body?*, J.L. MED. & ETHICS 371, 372–74 (2007) (same); Sabrina Safrin, *Chain Reaction: How Property Begets Property*, 82 NOTRE DAME L. REV. 1917, 1933–34 (2007) (same).

⁴²⁹ Eliot Marshall, *Families Sue Hospital, Scientist for Control of Canavan Gene*, 290 SCIENCE 1062, 1062 (2000) [hereinafter Marshall, *Families Sue Hospital*].

⁴³⁰ Novas, *supra* note 426, at 299; Marshall, *Families Sue Hospital*, *supra* note 429, at 1062; Canavan Foundation, Canavan Foundation Joins Lawsuit Against Miami Children's Hospital (Oct. 30, 2000), http://www.canavanfoundation.org/news/10-00_miamihospital.php [hereinafter Canavan Foundation, *Lawsuit*].

⁴³¹ Novas, *supra* note 426, at 299.

⁴³² Ultimately, MCH planned to exclusively license the test to a large commercial lab. Rao, *supra* note 428, at 373.

children's blood and tissue.⁴³³ While upstream contributors favored wide access to the patented gene, the downstream patentee favored exclusivity.

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 Research Institute*, Greenberg and the various nonprofit groups argued that by virtue of their contributions, they had a right to control commercialization of the patent.⁴³⁴ The donors believed that any resulting genetic tests would be readily affordable "and that [the] research would remain in the public domain."⁴³⁵ The court dismissed all of the plaintiffs' claims except their claim for unjust enrichment.⁴³⁶ 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.⁴³⁷

As the Canavan gene controversy illustrates, disease advocacy groups can provide vital inputs to basic biomedical research. Furthermore, members of the patient community often favor developing cures and facilitating further scientific investigation rather than maintaining exclusivity and maximizing profits.⁴³⁸ Ultimately, Greenberg and the disease advocacy groups were able to leverage their contributions to create a research exception for MCH's patented gene, although they did so in a very costly and indirect manner: litigation.

Compared to the Canavan disease groups, the advocacy group associated with pseudoxanthoma elasticum (PXE) has more directly leveraged its provision of upstream resources to maintain the availability of patented

⁴³³ Marshall, *Families Sue Hospital*, *supra* note 429, at 1062; Canavan Foundation, Lawsuit, *supra* note 430.

⁴³⁴ The plaintiffs contended that they did not consent to commercializing the patent and that they donated their blood and tissue with the intention of facilitating research to benefit patients at large, not to enable profits. *Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064 (S.D. Fla. 2003); *see* Gitter, *supra* note 428, at 331–38 (analyzing *Greenberg*); Marshall, *Families Sue Hospital*, *supra* note 429, at 1062 (same); Rao, *supra* note 428, at 373 (same).

⁴³⁵ *Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 208 F. Supp. 2d 918, 921 (N.D. Ill. 2002), *transferred*, 264 F. Supp. 2d 1064 (S.D. Fla. 2003).

⁴³⁶ *Greenberg*, 264 F. Supp. 2d at 1066.

⁴³⁷ Joint Press Release, Canavan Foundation, Gene Patent Lawsuit May Radically Affect Research (Sept. 29, 2003), http://www.canavanfoundation.org/news/09-03_miami.php; Novas, *supra* note 426, at 301.

⁴³⁸ *Cf.* Terry et al., *supra* note 425, at 158 (stating that PXE International's goal was "to achieve positive health outcomes for their members . . . rather than focusing on the wealth and longevity of the organization").

technologies for noncommercial research.⁴³⁹ In 1994, Patrick and Sharon Terry's two children were diagnosed with PXE, a rare genetic disorder that affects connective tissue.⁴⁴⁰ After investigating PXE and discovering a highly fragmented research field, the Terrys "began to scheme about what [they] would do if [they] were managing research on this disease."⁴⁴¹ In 1995, the Terrys founded PXE International, a community-building organization dedicated to serving the needs of PXE patients and their families.⁴⁴² In addition to raising money, PXE International established a patient registry as well as a blood and tissue bank to facilitate PXE research.⁴⁴³ As of 2002, the bank held 1,500 DNA samples and 100 tissue samples.⁴⁴⁴

The registry and bank lie at the heart of the "community engagement" model of biomedical research, wherein individual donors affected by genetic research are stakeholders in determining the use of DNA samples.⁴⁴⁵ The PXE bank is the result of a conscientious "commodification of genetic information," and represents the "principle bargaining tool" in PXE International's dealings with others.⁴⁴⁶ Within this model, contracts play a key role, for they define the relationships of donors and researchers with the bank and delineate specific approaches to benefit sharing.⁴⁴⁷

The registry has served as a "significant relay of power" through which PXE International has been able to coordinate and influence scientific

⁴³⁹ See Gitter, *supra* note 428, at 315–24 (describing PXE International's partial ownership claims on the PXE gene patent and the use of those ownership claims to ensure continued research on PXE); Safrin, *supra* note 428, at 1934–35 (same); Paul Smaglik, *Tissue Donors Use Their Influence in Deal over Gene Patent Terms*, 407 NATURE 821, 821 (2000) ("PXE International set up its own blood and tissue bank. Researchers wanting to use the samples must agree to the group's terms, which include joint possession of any intellectual property that might result."); see also Gina Kolata, *Sharing of Profits Is Debated as the Value of Tissue Rises*, N.Y. TIMES, May 15, 2000, at A1.

⁴⁴⁰ Eliot Marshall, *Patient Advocate Named Co-Inventor on Patent for the PXE Disease Gene*, 305 SCIENCE 1226, 1226 (2004) [hereinafter Marshall, *Patient Advocate*]; Sharon F. Terry, *Learning Genetics*, 22 HEALTH AFF. 166, 166 (2003) [hereinafter Terry, *Learning Genetics*].

⁴⁴¹ Terry, *Learning Genetics*, *supra* note 440, at 169. According to Sharon 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?*, MOTHER JONES, Nov.–Dec. 2001, at 54.

⁴⁴² Gitter, *supra* note 428, at 315–16.

⁴⁴³ In the course of three years, the Terrys raised \$500,000 for research. Allen, *supra* note 441, at 54.

⁴⁴⁴ Stockdale & Terry, *supra* note 424, at 95.

⁴⁴⁵ Terry & Terry, *supra* note 423, at 409. Contrary to published accounts, the Terrys did not structure PXE International in "response" to the Canavan disease controversy; some of the early groundwork establishing PXE International predated that controversy. *Id.* at 411.

⁴⁴⁶ *Id.* at 409.

⁴⁴⁷ *Id.*

activities.⁴⁴⁸ PXE International provides DNA samples to scientists via material transfer agreements (MTAs) that, among other conditions, prohibit scientists from sharing tissue and DNA samples with other laboratories and impose various reporting requirements on researchers.⁴⁴⁹ Contrary to published reports, PXE International does not negotiate with scientists seeking DNA and tissue samples for “co-inventorship” of any resulting patented inventions.⁴⁵⁰ However, researchers using the bank sign an agreement recognizing PXE International’s role as a collaborator in the discovery process.⁴⁵¹ According to the PXE International Blood and Tissue Bank’s policy, if PXE International contributes to an invention, then the organization should be listed as a co-assignee on any patent application.⁴⁵² According to Sharon and Patrick Terry, “Researchers share benefits arising from the use of samples with PXE International because expectations are clarified contractually prior to research being undertaken.”⁴⁵³

Based partly on its tissue and DNA bank, PXE International played an instrumental role in discovering the PXE gene. In 2000, University of Hawaii pathobiologist Charles Boyd led a team of researchers that discovered the transporter gene that causes PXE.⁴⁵⁴ Sharon Terry, who conducted laboratory procedures and helped author accounts of the discovery, was listed as a co-inventor on the patent application along with four university researchers.⁴⁵⁵ Terry and PXE International negotiated an agreement with the University of Hawaii whereby PXE International would control licensing decisions relating to the PXE gene and split any profits with the university arising from diagnostic tests or marketable products.⁴⁵⁶

⁴⁴⁸ Novas, *supra* note 426, at 296.

⁴⁴⁹ Terry & Terry, *supra* note 423, at 411.

⁴⁵⁰ *Id.* Under U.S. patent law, a party may not be named a co-inventor (as opposed to an assignee) through contract. The MTAs state that if PXE International personnel contribute to a patentable discovery, that person should, in accordance with the law, be named a co-inventor. Email from Sharon Terry to Peter Lee (Oct. 12, 2008) (on file with author) [hereinafter Terry Email].

⁴⁵¹ Stockdale & Terry, *supra* note 424, at 95.

⁴⁵² Terry Email, *supra* note 450.

⁴⁵³ Terry & Terry, *supra* note 423, at 411.

⁴⁵⁴ The gene is known alternatively as ABCC6 or MRP6. Marshall, *Patient Advocate*, *supra* note 440, at 1226.

⁴⁵⁵ *Id.* Although Sharon Terry holds an undergraduate degree in geology, she has no formal educational background in molecular biology. Sharon Terry, Doctoral Acceptance Speech at Iona College (2006) available at <http://www.pxe.org/CMFiles/STDctoralAcceptanceSpeech38NDA-6102007-155.pdf>.

⁴⁵⁶ Terry Email, *supra* note 450.

Significantly, through exercising control over the patented PXE gene, PXE International has ensured its wide accessibility for research purposes.⁴⁵⁷ In this regard, the organization's "primary concern is to accelerate research,"⁴⁵⁸ and it has licensed the gene to nineteen laboratories and eight biotechnology companies.⁴⁵⁹ Notably, however, PXE International has granted a few exclusive licenses in order to motivate commercial development of treatments arising from the PXE gene.⁴⁶⁰ This strategy of broad nonexclusive licensing for research purposes, coupled with selective exclusive licensing to encourage product development, reflects PXE International's aim to maximize patient-centric opportunities.⁴⁶¹

The experiences of groups associated with Canavan disease and PXE reveal that disease advocacy groups are actively engaged in private ordering to prevent patent holdup. 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 represents a powerful template for how such groups can enhance the availability of resulting discoveries.⁴⁶² Significantly, this promises to be a growing trend.⁴⁶³

These episodes reflect disease advocacy groups' deep commitment to access norms.⁴⁶⁴ Greenberg and his fellow plaintiffs sought broad licensing of the Canavan disease gene for diagnostic tests.⁴⁶⁵ According to Sharon Terry, PXE International's co-ownership of the PXE gene patent ensures that the organization is now "driving the boat";⁴⁶⁶ she considers herself and her

⁴⁵⁷ Novas, *supra* note 426, at 297.

⁴⁵⁸ Terry & Terry, *supra* note 423, at 411.

⁴⁵⁹ Novas, *supra* note 426, at 297.

⁴⁶⁰ Stockdale & Terry, *supra* note 424, at 96.

⁴⁶¹ Jon F. Merz et al., *Protecting Subjects' Interests in Genetics Research*, 70 AM. J. HUM. GENETICS 965, 966 (2002) [hereinafter Merz et al., *Protecting Subjects' Interests*]. A similar strategy has been used by the Alpha-1 Foundation, which represents patients with Alpha-1 antitrypsin deficiency. Jasper Bovenberg, *Whose Tissue Is It Anyway?*, 23 NATURE BIOTECH. 929, 931 (2005).

⁴⁶² Novas, *supra* note 426, at 297.

⁴⁶³ Gitter, *supra* note 428, at 318. Cure Autism Now and the Juvenile Diabetes Research Foundation International have also pooled members' specimens to create biorepositories. *Id.* at 318–19. Sharon Terry is currently the President and CEO of the Genetic Alliance, a coalition of more than 600 disease advocacy groups. PXE International, Sharon F. Terry, <http://www.pxe.org/english/View.asp?x=1683> (last visited Nov. 16, 2008).

⁴⁶⁴ Novas, *supra* note 426, at 303.

⁴⁶⁵ See text accompanying *supra* note 435.

⁴⁶⁶ Marshall, *Patient Advocate*, *supra* note 440, at 1226.

organization “stewards” of the gene.⁴⁶⁷ 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 for research purposes. However, these organizations also recognize the appropriateness of exclusive licensing to foster commercial development of value-added products.⁴⁶⁸

In a variety of ways, “contracts” are driving these efforts.⁴⁶⁹ First, in the most direct sense, PXE International’s control over the PXE gene patent allows it to license this valuable resource 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 leverage their contributions of unique bodily materials to ensure a research exception for MCH’s patented gene. Furthermore, policies governing access to PXE International’s tissue and DNA bank ensure that scientists receiving these materials accede to the norms of the PXE patient community.

This approach portends many benefits for advancing research. It expands the contractually created commons to biomedical resources affecting rare diseases, 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, arranging exclusive licenses 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.”⁴⁷⁰ Providing tissue donors with some say in the availability of resulting patented inventions acknowledges their vital contributions to basic research.

⁴⁶⁷ Terry, *supra* note 440, at 170.

⁴⁶⁸ See *supra* note 459 and accompanying text.

⁴⁶⁹ Cf. Gitter, *supra* note 428, at 315 (discussing PXE International’s “contractual property rights model” for asserting ownership claims on donated bodily materials).

⁴⁷⁰ Merz et al., *Protecting Subjects’ Interests*, *supra* note 460, at 969.

Of course, these efforts face several challenges. As in other contexts, an institution's control over intellectual property ties that resource to the institution's particular norms and objectives. For example, while investigating the PXE gene may reveal insights into macular degeneration, hypertension, and cardiovascular disease,⁴⁷¹ it is conceivable that PXE International's interest in the gene may only extend to its namesake disease, thus leaving other conditions unexplored.⁴⁷² For their part, the leaders of PXE International explicitly disavow such a claim.⁴⁷³ More subtly, disease advocacy groups, which seek immediate and practical applications, may have a different normative agenda than members of the basic research community, who may be more interested in developing fundamental biological knowledge.⁴⁷⁴ In a different vein, claims by previously "altruistic" tissue donors add another layer of negotiation to the costs of conducting research.⁴⁷⁵ Additionally, tissue donors negotiating quid pro quos raise unique biomedical ethical concerns beyond the scope of this Article.⁴⁷⁶ This behavior substantially challenges the notion of the gift as the founding gesture of participation in biomedical research.⁴⁷⁷ Such "compensation" may conflict with prohibitions against "undue inducement"⁴⁷⁸ and may discourage truly altruistic donations by patients whose tissues are necessary to conduct research.⁴⁷⁹

⁴⁷¹ Bovenberg, *supra* note 460, at 932; Gitter, *supra* note 428, at 323; Novas, *supra* note 426, at 297; Rao, *supra* note 428, at 378.

⁴⁷² Matt Fleischer, *Patent Thyself*, AM. LAW., June 21, 2001, at 84. Sharon and Patrick Terry dispute these claims, noting that the Genetic Alliance BioBank, an expanded umbrella organization that includes PXE International, facilitates cross-disease research and has provided DNA samples as controls across a wide range of diseases. Terry & Terry, *supra* note 423, at 412.

⁴⁷³ Terry & Terry, *supra* note 423, at 412.

⁴⁷⁴ Cf. Stockdale & Terry, *supra* note 424, at 80 ("Advocacy groups therefore must decide how to effectively balance research, with its potential for long-term benefits, with the immediate social and medical issues inherent in living with a genetic condition.").

⁴⁷⁵ Cf. Kolata, *supra* note 439, at A1.

⁴⁷⁶ The Human Genome Organisation has cautiously endorsed benefit-sharing for participants in biomedical research. HUGO Ethics Committee, *Statement on Benefit Sharing*, 10 EUBIOS J. ASIAN & INT'L BIOETHICS 70, 70-71 (2000), available at http://www.unescobkk.org/fileadmin/user_upload/shs/EJAIB/EJAIB52000.pdf.

⁴⁷⁷ Hayden, *supra* note 426, at 740.

⁴⁷⁸ *Id.* at 739; Bartha Maria Knoppers, *Status, Sale and Patenting of Human Genetic Material: An International Survey*, 22 NATURE GENETICS 23, 24 (1999).

⁴⁷⁹ Fleischer, *supra* note 472, at 87.

V. OPPORTUNITIES, CHALLENGES, AND PRESCRIPTIONS

Across government, academia, and the nonprofit sector, upstream institutions are taking matters into their own hands to prevent patent holdup in biomedical research. In many ways, these efforts respond directly to the perceived limitations of public law approaches, most notably the narrowing of the experimental use exception. 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*

Through contracts, public institutions are achieving working solutions to the problem of patent holdup.⁴⁸⁰ Existing public law initiatives to address this problem have proven inadequate, and crafting a comprehensive legislative solution would be technically and politically difficult. Furthermore, while noncommercial researchers currently enjoy a de facto experimental use exception, this exception relies on voluntary patentee forbearance from bringing suit⁴⁸¹ and does not provide certain access to patented resources. On the contrary, tying access conditions to valuable consideration in individual contracts is an implementable approach that provides certain, ex ante access to at least a subset of patented research tools. While it cannot achieve the scope of public law initiatives, consideration-based patent regulation represents an effective working solution to patent holdup.

These efforts are less intrinsically coercive than traditional regulation, for they embed policy objectives in quid pro quos that materially benefit patentees and licensees. Rather than curtail patent rights through judicial, legislative, or executive fiat, thus undermining investment-backed expectations, public institutions are bundling a research exception together with transfers of valuable money, licenses, and materials to downstream parties. There is a recursive dynamic at play here, in which expectations of access to patented research tools only arise when public support has helped satisfy the incentive to invent. While concerns over market power must apply to public institutions

⁴⁸⁰ 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 having to finance licenses for taxpayer-financed inventions.

⁴⁸¹ Rai & Eisenberg, *supra* note 9, at 296.

just as they do to any other market actors, a quid pro quo approach to creating a biomedical research commons appears more palatable to patentees than unilaterally limiting patent rights.

Of particular importance, consideration-based patent regulation provides government entities with substantial freedom to operate. 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 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 statewide noncommercial research exception to patent infringement, such an act would surely run afoul of federal preemption doctrine.⁴⁸² However, by acting in a funding capacity rather than a “legislative” capacity, CIRM is free to impose just that restriction when it spends public money.

Unlike traditional regulation, the *in personam* nature of this approach also facilitates 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.⁴⁸³ Broad-based rules, such as 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.

Commentators naturally look for public law solutions to public policy challenges.⁴⁸⁴ However, the enormous role of public institutions in supporting biomedical research suggests that their intellectual property policies—which span the governmental and nongovernmental realms—warrant

⁴⁸² See *supra* note 292 and accompanying text.

⁴⁸³ See Smith, *supra* note 38, at S457.

⁴⁸⁴ See, e.g., ADAM B. JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS: HOW OUR BROKEN PATENT SYSTEM IS ENDANGERING INNOVATION AND PROGRESS, AND WHAT TO DO ABOUT IT 151 (2004) (offering suggestions for comprehensive public law patent reform).

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 nongovernmental players such as universities, nonprofit foundations, and disease advocacy groups. At the very least, such awareness counsels for a cautious approach to centralized patent reform; institutional working solutions can curb some of the most egregious instances of patent holdup without the need for legislative, doctrinal, or regulatory intervention.

B. Challenges and Prescriptions

To be truly effective, consideration-based patent regulation in general, and the contractual creation of a research commons in particular, must address several challenges. One of the primary obstacles to exempting certain uses of patented research tools from infringement is the difficulty of defining terms. This definitional problem has several dimensions. First, there is no universally accepted definition of a “research tool.” The NIH and CIRM, for example, differ slightly in how they define patented resources that should be made widely available for noncommercial research.⁴⁸⁵ As noted above, precise, ex ante definitions of research tools are particularly challenging given that status as a research tool is context-dependent; an extracted and purified human embryonic stem cell is a research tool when used as basic tool for discovery but a pre-commercial product when used as source material for a value-added therapeutic.⁴⁸⁶

Second, and relatedly, is the challenge of defining the circumstances under which a publicly supported research tool should be widely available for others to use. This raises the threshold question of whether a publicly supported research tool should be patented in the first place. The current Bayh–Dole framework, which has heavily influenced state, university, and nonprofit intellectual property policies, implicitly endorses a default rule in favor of patenting publicly supported inventions. However, there are cases in which

⁴⁸⁵ Compare NIH, Principles and Guidelines, *supra* note 6, at 72,092 n.1, with CAL. CODE REGS. tit. 17, § 100301(d) (2008). Furthermore, most commentators regard data as a research tool as well. While many of the access-enhancing provisions described here may also apply to data, this Article leaves sustained treatment of that nonpatentable research tool to more focused inquiries. See, e.g., Eisenberg, *Patents and Data-Sharing in Public Science*, *supra* note 51 (examining attempts to exercise exclusive rights over data and their implications for research science); Eisenberg & Rai, *supra* note 294 (discussing data sharing in California’s stem cell initiative as well as other data sharing efforts); Reichman & Uhler, *supra* note 22 (advocating contractual mechanisms to ensure access to scientific data).

⁴⁸⁶ See *supra* Part I.

patenting is unwarranted and research tools should instead be openly available in the public domain. Here, incentives should guide the patenting analysis. Assuming that public support has already satisfied the incentive to invent a research tool, patent protection can only be justified to provide ex post incentives to develop. However, some existing research tools function solely as discovery aids for which no additional development (or incentives to encourage development) is necessary. Illustrative in this regard, the NIH invoked its Bayh–Dole rights to discourage participants in the Human Genome Project from patenting raw genomic DNA.⁴⁸⁷ CIRM expressly discourages grantees from patenting biomedical resources that only have a research function.⁴⁸⁸ Some universities voluntarily refrain from patenting DNA sequences that serve only as markers and are not candidates for additional commercial development.⁴⁸⁹ Notwithstanding the pro-patent tenor of the Bayh–Dole Act, public institutions should conscientiously apply incentives-based analyses to determine whether certain research tools warrant any patent protection at all.

For research tools that *do* satisfy the incentives threshold for patenting, the question remains as to what particular *uses* of these resources should be exempt from infringement. Most of the policies described here sharply distinguish between noncommercial and commercial uses of patented research tools. However, there is no bright line separating noncommercial from commercial activities, both of which represent overlapping regions along a continuum. To avoid such line-drawing questions, existing policies focus not on the character of a particular use, but on the identity of the party performing it; as a general matter, these policies require openly sharing research tools with nonprofit organizations but not with for-profit entities. While this distinction is an easily administrable, bright-line rule, it is far from clear that an institution's *tax-exempt status* is an accurate proxy for the range of *uses* of patented research tools that should be insulated from infringement.⁴⁹⁰ For example, commercial firms may use research tools as discovery aids in internal research or for quality control purposes with no immediate commercial application. Recognizing this, the NIH encourages grantees to share patented research tools not only with nonprofit organizations, but with for-profit entities

⁴⁸⁷ See *supra* notes 236–40 and accompanying text.

⁴⁸⁸ See CIRM, *supra* note 283, at 32, 35.

⁴⁸⁹ See *supra* note 382 and accompanying text.

⁴⁹⁰ Cf. Lemley, *Are Universities Patent Trolls?*, *supra* note 22 (arguing that characterization as a patent troll should depend on an institution's behavior, not on whether it is a university, commercial firm, or some other kind of entity).

using them for “internal” purposes.⁴⁹¹ Again, this Article argues that incentives analysis should determine what *uses* of patented research tools should be shielded from infringement. By and large, this would leave intact a per se rule that grantees and licensees must share patented research tools with nonprofit entities. However, it would expand the situations where public institutions would compel grantees and licensees to share patented research tools with for-profit entities. Where such use does not undermine an exclusive licensee’s specific incentive to develop a value-added product, for-profit entities should have broader reign to use publicly supported research tools.

Given the definitional challenges of exempting certain biomedical resources, in some contexts, from patent infringement, standardization of terms can offer significant benefits. As a general matter, one of the advantages of a contractual approach to creating a biomedical research commons is that, unlike legislative approaches, precise, ex ante definitions may be less necessary; contracting parties can negotiate the meaning of terms over time in particular contexts.⁴⁹² Nevertheless, a disparity of terms has produced the current situation where the efforts described here do not create a uniform biomedical research commons, but multiple commons that overlap and intersect. While diversity of terms may have its advantages,⁴⁹³ there are also clear gains from standardization.⁴⁹⁴ Researchers bundling funding, licenses, and materials from disparate sources would be well-served by having a single set of expectations for making patented inventions widely available. For precisely this reason, contributors to CIRM’s intellectual property policy urged consistency with prevailing Bayh–Dole policy.⁴⁹⁵ The NIH is particularly well-suited to coordinate this standardization. By virtue of the Bayh–Dole Act, the NIH’s intellectual property policies substantially impact universities that receive federal grants.⁴⁹⁶ Furthermore, nonprofits such as HHMI have already

⁴⁹¹ NIH, Principles and Guidelines, *supra* note 6, at 72,094.

⁴⁹² See *supra* note 52.

⁴⁹³ Cf. John F. Duffy, *Harmony and Diversity in Global Patent Law*, 17 BERKELEY TECH. L.J. 685, 685 (2002) (identifying several benefits of cross-jurisdictional diversity in patent law).

⁴⁹⁴ See Thomas W. Merrill & Henry E. Smith, *Optimal Standardization in the Law of Property: The Numerus Clausus Principle*, 110 YALE L.J. 1, 38 (2000).

⁴⁹⁵ See, e.g., CCST, *supra* note 270, at 12, 21; Nov. 22, 2005 IP Task Force Minutes, *supra* note 270, at 38 (statement of Alan Bennett, Public Intellectual Property Resource for Agriculture); *id.* at 80–82 (statement of Eisenberg); *id.* at 49 (statement of Samuelson).

⁴⁹⁶ See CCST, *supra* note 270, at 27; Nov. 22, 2005 IP Task Force Minutes, *supra* note 270, at 35 (statement of Bennett) (“[M]ost of the universities have intellectual property policies that mirror these federally mandated obligations.”). According to the so-called “One Dollar” rule, the provisions of the Bayh–Dole Act apply to any project that receives even \$1 of federal funding. Therefore, the Bayh–Dole Act would apply in mixed funding arrangements involving significant amounts of private support.

modeled their intellectual property policies on NIH policy.⁴⁹⁷ Ultimately, consistent definitions of research tools, as well as standardized guidelines for when they should be widely shared, would reduce administrative and transactions costs and help create an expansive, coherent biomedical research commons.⁴⁹⁸

Aside from standardization, an additional challenge of the contractual creation of a biomedical research commons is that this effort only establishes a research commons within the funding and licensing sphere of certain public institutions. Not all institutions will voluntarily adopt these policies, 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.⁴⁹⁹ As others have noted, liberalizing the substantive and procedural requirements of the Bayh–Dole Act would strengthen the NIH’s authority to direct patentee licensing practices.⁵⁰⁰ Such reforms would also enhance the NIH’s ability to compel recalcitrant public institutions—including universities—to adopt open licensing policies. Along these lines, industry-wide organizations such as AUTM can help facilitate widespread adoption of open science “best practices.”

A more serious challenge is that placing onerous burdens on grant recipients, patent licensees, and scientists working with donated DNA 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 private sector entities to encourage commercializing taxpayer-funded inventions.⁵⁰¹ Excessive strings on money, patent rights, or materials could stifle these exchanges.⁵⁰² However, carefully drafted *noncommercial research* exceptions can ensure exclusivity for sale of refined inventions to encourage private investment in product development. For example, allowing patented human embryonic stem cells to be widely used for academic research, while permitting context-specific, exclusive licensing for

⁴⁹⁷ See *supra* notes 408–11 and accompanying text.

⁴⁹⁸ See NAT’L RESEARCH COUNCIL, *supra* note 80, at 136–40 (endorsing the NIH’s guidelines for disseminating research tools, recommending wider use of retained research rights by universities, and encouraging greater standardization across government, academia, and the nonprofit sector).

⁴⁹⁹ See Rai & Eisenberg, *supra* note 9, at 308.

⁵⁰⁰ *Id.* at 310.

⁵⁰¹ See Faley & Sharer, *supra* note 178, at 113; Leaf, *supra* note 178.

⁵⁰² Cf. Constance Holden, *Universities Find Too Many Strings Attached to Foundation’s Offer*, 312 SCIENCE 1127 (2006).

commercial development leading to “value added” products, is an appropriate approach to take.⁵⁰³

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, such as between academic use and commercial sale, are crucial for technologies that simultaneously represent fully functional research tools as well as precursors to refined consumer products. Some entities, such as the NIH and HHMI, are better situated than others to draw these distinctions.⁵⁰⁴ As organizations like CIRM gain more experience in monitoring grants, their technical capacity will increase. Furthermore, collective organizations like the Stanford consortium and AUTM can provide technical assistance to university technology transfer offices to help implement the best practices described here.

A consistent challenge of private law mechanisms is the specter of parochialism. CIRM’s contractually constructed research commons only applies in California.⁵⁰⁵ Furthermore, some university licenses only automatically grant research exceptions to *their own* scientists rather than to nonprofit researchers in general.⁵⁰⁶ To fully advance open science, public institutions should draft funding arrangements and licenses to allow *all* noncommercial research uses of publicly developed inventions.⁵⁰⁷ Of course, political sensitivities may render this difficult, particularly in situations such as CIRM’s funding of human embryonic stem cell research. However, public institutions will need to weigh the perceived benefits of local preferential treatment with the massive spillovers that may arise from cross-jurisdictional and cross-institutional access to biomedical research tools.

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.⁵⁰⁸ This criticism is particularly salient to universities,

⁵⁰³ I emphasize “context specific” because a single 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.

⁵⁰⁴ *Id.* at 305.

⁵⁰⁵ See *supra* note 294 and accompanying text.

⁵⁰⁶ See, e.g., Alan B. Bennett, *Reservation of Rights for Humanitarian Uses*, in 1 INTELLECTUAL PROPERTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATION, *supra* note 56, at 42.

⁵⁰⁷ This includes noncommercial use by commercial firms. See *supra* note 491 and accompanying text.

⁵⁰⁸ Cf. Oona A. 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).

some of which espouse the ideals of open science while vigorously enforcing their patents.⁵⁰⁹ 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.⁵¹⁰ Finally, implementing organizational norms is subject to principal–agent problems. This is illustrated by 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. More broadly, 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.

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 the privatization of public policy. Consideration-based patent regulation reveals a significant shift from legislatively defined property rights to the private law of contracts as a means for advancing patent policy. Unlike traditional judicial, legislative, or administrative regulation, this model embeds policy objectives in contractual *quid pro quos*. Further reflecting the “private” nature of consideration-based patent regulation, such behavior recasts public institutions as dynamic, entrepreneurial market actors. Recent scholarship highlighting a new “dynamism in the public domain”⁵¹¹ has generally focused on for-profit firms rather than public institutions as the primary drivers of private ordering. However, consideration-based patent regulation reveals that public institutions, wielding enormous market power, are fruitfully engaging in private ordering as well. While Congress can significantly impact patent practice by amending the Patent Act, the NIH can also do so through the power of the purse.

Furthermore, this trend reveals the existence of a wider universe of “policy levers”—beyond those within the direct control of Congress, courts, and the

⁵⁰⁹ See, e.g., Howard, *supra* note 232 (discussing a joint lawsuit filed by biotech companies seeking to invalidate Columbia University’s aggressively enforced patent on gene-splicing technology).

⁵¹⁰ See CAL. CODE REGS. tit. 17, §§ 100308(b), 100408 (2008).

⁵¹¹ See Merges, *A New Dynamism in the Public Domain*, *supra* note 23 (discussing private initiatives that are contributing to the public domain).

PTO—that is available to advance patent policy.⁵¹² States, universities, nonprofits, and disease advocacy groups can profoundly impact the availability of patented biomedical research tools; self-recognition as policy actors may spur these institutions to expand open science best practices. For example, armed with this self-recognition, university technology transfer officials may be more likely to reserve broad research rights for patented tools as well as to nonexclusively license them.⁵¹³ Recent intellectual property scholarship has highlighted the benefits of decentralized peer production, in which loosely coordinated parties act on communal norms to contribute to broad, value-generating projects.⁵¹⁴ Open source software is a frequently cited example.⁵¹⁵ Paralleling the benefits of decentralized production, the efforts described here reflect decentralized patent *regulation* arising from numerous independent institutions acting upon similar norms. While decentralization allows wide participation in the policy implementation process, catalytic standardization by the NIH, as noted above, can help realize the full potential of these disparate efforts.

In addition to illustrating the privatization of public policy, consideration-based patent regulation also reveals the deep importance of institutional norms in the patent system. This Article challenges prevailing presumptions that parties investing in technology seek to maximize profits. 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.⁵¹⁶ While the norms and motivations of the institutions profiled here are not homogenous⁵¹⁷—frictions, for example, have arisen between the NIH and universities—in policy and practice they distinguish themselves from traditional rent-seeking patentees.

In some sense, these observations represent an endorsement of the Coase Theorem, but with a normative twist. Coase famously posited that in the absence of transaction costs, parties would freely negotiate over the disposition of resources to achieve efficient outcomes.⁵¹⁸ Here, left to their own devices, public institutions such as the NIH, CIRM, universities, nonprofit

⁵¹² See Burk & Lemley, *supra* note 41, at 1579.

⁵¹³ Lemley, *Are Universities Patent Trolls?*, *supra* note 22, at 611.

⁵¹⁴ See, e.g., Benkler, *Coase's Penguin*, *supra* note 153, at 381–400 (analyzing several examples of peer production).

⁵¹⁵ See *id.* at 381.

⁵¹⁶ See Strandburg, *Users as Innovators*, *supra* note 11, at 470–71.

⁵¹⁷ Merz et al., *Protecting Subjects' Interests*, *supra* note 461, at 966.

⁵¹⁸ Coase, *supra* note 37. Coase, however, recognized that transaction costs are ubiquitous. *Id.*

organizations, and disease advocacy groups are negotiating with grantees, licensees, and recipients of material support for a valuable noncommercial research exception to patent infringement. The policy implication here is familiar to students of the Coase Theorem; instead of attempting to ensure “correct” ex ante allocations of property rights, perhaps policymakers should focus on reducing transaction costs so as to allow market actors, ex post, to negotiate freely. Significantly, the norms of contracting parties will deeply impact the “efficient” outcomes that arise from these negotiations. The noncommercial research commons emerging from these quid pro quos is a direct consequence of the normative character of the public institutions involved.

These efforts also reveal that industry structure can vastly affect the role of patents in innovation, and they shed light on a long-running debate over whether patent law is industry-specific.⁵¹⁹ Consideration-based patent regulation has particular traction in the biomedical sector because of the prominent role of public institutions in that field. This model may be applicable to other industries with significant public input, such as the defense industry and even the software sector, much of which rests on university patents. This type of private ordering, however, is less relevant to more privately financed industries such as the automotive industry, although other private ordering mechanisms such as patent pools may apply there with greater force.⁵²⁰ Ultimately, patent law and doctrine play out in an industrial context, and the unique attributes of particular industries can substantially impact the effective scope of patents.

Indeed, it is the enormous market power of public institutions in the biomedical research sector that makes normatively oriented, consideration-based regulation particularly viable there. As the single dominant “purchaser” of biomedical research,⁵²¹ the NIH represents a monopsonist with which virtually all basic biomedical researchers must deal. While other funding sources also exist, such as states and nonprofits, there is far from perfect competition in the market for providing research funds.⁵²² This reduces transaction costs, as researchers know they have to deal with the NIH and a

⁵¹⁹ See Burk & Lemley, *supra* note 41, at 1589–95.

⁵²⁰ See Merges & Nelson, *supra* note 64, at 890–91 (describing cross-licensing in the automotive and airplane industries).

⁵²¹ See *supra* notes 167–73 and accompanying text.

⁵²² Furthermore, many of these entities offer funding on terms similar to or identical to the NIH. See *supra* Part IV.B–D.

limited number of additional players. The NIH further reduces transaction costs through widespread, ex ante publication of policies and guidelines. The NIH's market power also prevents deleterious races to the bottom; in the alternative, multiple funding sources would have to "compete" to fund biomedical researchers by offering more favorable terms, such as guaranteeing that grantees would retain full patent rights in any invention.⁵²³

Similarly, on a smaller scale, CIRM exercises significant market power in California; if scientists want to conduct human embryonic stem cell research in that state, they almost certainly have to deal with CIRM and its licensing policies.⁵²⁴ Likewise, given the unique character of intellectual property, universities seeking to license out specific research tools exercise significant leverage vis à vis private sector partners. Interestingly, it is the noncompetitive nature of upstream support in the biomedical research sector that makes the contractual creation of a biomedical research commons so feasible. While market dominance is ordinarily cause for concern, the normative commitments of market dominators can vastly impact whether it yields socially beneficial or deleterious results.

While this Article has focused on the policy objective of open science, institutions may utilize consideration-based patent regulation to advance other policy objectives as well. As a general matter, this study reveals that money, licenses, and materials represent "normative portals" for injecting public values into the patent system. Public institutions are also leveraging research support to promote access to essential medicines⁵²⁵ and to require licensees to diligently commercialize inventions, thus preempting the threat of patent trolls.⁵²⁶

⁵²³ See CCST, *supra* note 270, at 18.

⁵²⁴ Of course, it remains to be seen how much this situation will change given the Obama administration's new funding policies. See Stolberg, *supra* note 262.

⁵²⁵ See, e.g., CAL. CODE REGS. tit. 17, § 100306(d) (2008) (requiring licensees of nonprofit grantees to provide patented therapies and diagnostics to uninsured California patients at discounted prices); *id.* § 100407 (requiring licensees of for-profit grantees to provide patented drugs to uninsured California patients at discounted prices).

⁵²⁶ See, e.g., Pressman et al., *supra* note 199, at 37 (describing "diligence milestones" in university licenses requiring commercial development of inventions). 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. See Thomas A. Hemphill, *Economic Considerations in Cooperative Research and Development Agreements (CRADA): The Case of Taxol, NIH, and Technology Transfer*, 28 TECH. SOC'Y 321, 328-29 (2006); Sage, *supra* note 184, at 1742; NIH, A Plan to Ensure Taxpayers' Interests Are Protected (July 2001), available at <http://www.nih.gov/news/>

Finally, consideration-based patent regulation helps democratize the rewards of innovation.⁵²⁷ As Professor James Boyle has observed, intellectual property law primarily benefits those who produce refined goods rather than the suppliers of the upstream inputs that make those goods possible.⁵²⁸ Furthermore, “without legal recognition of the key contributions and rights of early stage researchers, the public credit and financial rewards based on their discoveries will inure exclusively to those who control the final step in production.”⁵²⁹ Taxpayers, universities, nonprofit organizations, and tissue donors contribute significantly to biomedical research and should be able to expect something in return.⁵³⁰ Consideration-based patent regulation provides a mechanism 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.

CONCLUSION

Ironically, while patents aim to promote scientific and technological progress, patents on the inputs to biomedical research can inhibit academic 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. Drawing on the unique 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, nonprofit organizations, and disease advocacy groups—are conditioning 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

070101wyden.htm (contending that the NIH is ill-suited to regulate the prices of health technologies arising from its funding).

⁵²⁷ See Sunder, *supra* note 43.

⁵²⁸ BOYLE, *supra* note 43.

⁵²⁹ Kesselheim & Avorn, *supra* note 177, at 850.

⁵³⁰ Merz et al., *Protecting Subjects' Interests*, *supra* note 461, at 969.

from public funds. Universities are reserving noncommercial research exceptions when licensing research tools and favoring nonexclusive rather than exclusive licensing of such inventions. Nonprofit funding organizations and disease advocacy groups are leveraging contributions of money and bodily tissues to help ensure that recipients share resulting patented resources widely for noncommercial research.

At a substantive level, this inquiry highlights the importance of institutional norms in the patent system. Within the “normative structure” 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. Incentives-based patenting analyses, standardization and coordination by the NIH, conscientious drafting of contractual arrangements, and enhanced technical competence 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. These efforts reflect the privatization of public policy, whereby a decentralized network of governmental and nongovernmental entities are utilizing market power and contracts to advance public objectives. This phenomenon reveals that industry structure may deeply impact the effective scope and breadth of patents in particular sectors. Furthermore, institutions are using contracts not only to promote open science, but also to enhance access to essential medicines and ensure commercialization of inventions. 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 tools 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.

