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

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

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

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Introduction

In an era of great concern that patents may inhibit biomedical research, the intellectual property policies of the California Institute for Regenerative Medicine (“CIRM”), a state agency, will provide close to $3 billion over ten years for human embryonic stem cell research in California. Under CIRM’s regulations, grantees may patent inventions arising from state funds. However, as a condition of receiving public money, non-profit grantees must make any resulting patented inventions “readily available” to California institutions for non-commercial research purposes. In essence, CIRM has contracted with its non-profit grantees for a research exception to patent infringement. Rather than attempting to enact a general research exception, CIRM is embedding this policy objective in individualized quid pro quos: grantees get state funds while CIRM gets the assurance that state-funded patented inventions will be widely available to the research community. CIRM’s regulations reflect a significant trend in patent law that is the focus of this Article. Amidst great anxiety that patents may exclude researchers from using critical technologies, public institutions are leveraging their support for basic research to assert a patent right to include.

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 enable access constraints on those technologies. These constraints can have several deleterious effects. In the research context, patents on “research tools”—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 treatments. In other contexts, exclusive rights can substantially raise the price of essential medicines as well as hinder the commercialization of existing inventions.

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3 See infra Part IV.B.
5 17 Cal Code Regs. § 100306(a); CIRM, NON-PROFIT POLICY, supra note 4, at 18, 37.
6 Which, of course it could not do. See infra text accompanying notes 7
7 The National Institutes of Health (NIH) defines research tools as “tools that scientists use in the laboratory, including cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry and DNA libraries, clones and cloning tools (such as PCR), methods, laboratory equipment and machines.” Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice, 64 Fed. Reg. 72,090, 72,092 n.1 (Dec. 23, 1999) [hereinafter NIH, Principles and Guidelines].
The standard retort to this critique is that access constraints are simply the necessary tradeoff for motivating investment in new technology. However, this tradeoff does not necessarily exist. It is particularly questionable in the biomedical research sector, where government, academic, and non-profit institutions provide enormous support for research leading to patented biomedical inventions, and these institutions do so with relatively little regard for maximizing profits. Many patented biomedical research tools, for example, arise from taxpayer-funded research conducted at non-profit universities. This support undermines the notion that patent exclusivity is necessary to provide incentives to invent. Of course, market exclusivity may still be required to encourage private firms to develop existing inventions into commercial products. The policy challenge is to strike an appropriate balance between access and exclusivity for publicly-supported inventions. Various “public law” initiatives to address this challenge, such as invoking a doctrinal experimental use exception to patent infringement, have only achieved partial success.

This Article argues that an underappreciated model of private ordering is actively addressing the challenge of patents on biomedical research tools and that expanding this model promises significant gains. Specifically, it argues that public institutions are increasingly leveraging their enormous contributions to the biomedical research sector to require that recipients of these contributions share resulting patented inventions widely for noncommercial research purposes. In essence, these institutions are building, through contract-like quid pro quos, a research commons for biomedicine. This leveraging of valuable consideration to ensure access to patented technologies illustrates a general phenomenon that I call “consideration-based

9 See eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 396 (2006) (Kennedy, J., concurring) (discussing “patent trolls,” firms that assert patents but do not produce any goods or services); see also ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY 939-40 (4th ed. 2007) (noting that trolls may play a valuable role as “market makers”).
10 See Arti K. Rai & Rebecca S. Eisenberg, Bayh-Dole Reform and the Progress of Biomedicine, 66 LAW & CONTEMP. PROBS. 289, 300 (2003).
11 While some public institutions take financial interests in inventions, they do not fund research primarily to maximize returns on investment. See infra Part IV.
14 Rai & Eisenberg, supra note 10.
16 See infra Part II.
patent regulation.” This practice is often swifter, nimbler, and more precise than traditional patent regulation, and holds significant implications for patent law. While this Article focuses on maintaining a robust research commons, institutions are also utilizing consideration-based patent regulation to enhance access to essential medicines and preempt the threat of “patent trolls.”

This Article represents the first systematic analysis of the creation of a biomedical research commons by public institutions, by which I include federal and state agencies, universities, non-profit organizations, and disease advocacy groups. Within this effort, the National Institutes of Health (“NIH”) is leveraging its funds to compel grant recipients to freely share patented inventions with others engaged in noncommercial research. CIRM explicitly requires grantees to share patented research tools with noncommercial scientists. Increasingly, universities are reserving research exceptions for non-profit institutions when licensing technology to industry. Non-profit organizations and disease advocacy groups are conditioning receipt of money and tissue samples on assurances that patented inventions arising from these inputs will be freely available for research purposes. The potential for these concerted efforts is enormous. While others have identified roles for the NIH and universities to safeguard noncommercial research in their patent policies, this Article situates these institutions within a broader regulatory paradigm encompassing numerous additional policy actors. Furthermore, while others have argued for maintaining open access to data through contractual mechanisms, this Article focuses on the very different challenge of establishing a research commons for patented biomedical inventions.

Importantly, these efforts focus on exempting noncommercial research use from patent infringement rather than simply eliminating patents on publicly-supported research tools. This

18 See, e.g., 17 Cal Code Regs. § 100306(d) (requiring non-profit recipients of stem cell research funds to provide therapies and diagnostics to uninsured California patients at discounted prices); 17 Cal. Code Reg. § 100407 (requiring for-profit grantees to provide drugs to uninsured California patients at discounted prices).
20 Cf. Kapczynski et al., supra note 8, at 1037. Where necessary, I will distinguish among these “public” institutions.
23 Noncommercial research includes scientific investigations conducted by non-profit institutions as well as preliminary “internal” investigations at for-profit firms that are not directly commercialized.
approach allows wide access to research tools for academic inquiry but preserves commercial exclusivity to encourage private investment in product development. Human embryonic stem cells, for example, are both fully functioning research tools in their present state as well as precursors to many “value added” commercial therapeutics. Simply placing these assets in the public domain may undermine private incentives to develop marketable products. In most cases, distinguishing between noncommercial research and commercial sale allows for the optimal exploitation of publicly-developed research tools.

This inquiry adds a new dimension to “private ordering” that has long sought to resolve intellectual property holdup. It reveals that such behavior is not the exclusive domain of for-profit entities; governments, universities, and non-profits are also market players, and they are actively engaged in private ordering as well. This model of private ordering relies on three defining elements. In consideration-based patent regulation, institutions: 1) contribute valuable support to research leading to patented inventions; 2) advance norms emphasizing access to resulting technologies rather than strict exclusivity; and 3) implement these norms through “contractual” mechanisms to enhance access to patented inventions.

The contractual creation of a biomedical research commons is notable both substantively and procedurally. At a substantive level, these efforts reveal the vast importance of institutional norms in patent law. While traditional patent theory presumes that actors in the patent system are profit-maximizing entities, this mischaracterizes many public institutions that provide enormous research support. Consideration-based patent regulation both reveals and exploits the


While this Article distinguishes between noncommercial research use and commercial sale, that is not the only distinction that is relevant to the optimal licensing of patented biomedical resources. See NIH, Principles and Guidelines, 64 Fed. Reg. at 72094 (describing: 1) primary usefulness as a tool for discovery; 2) range of downstream activities enabled; and 3) immediate usefulness without further development as factors to consider in licensing a patented biomedical resource). See also Katherine J. Strandburg, What Does the Public Get? Experimental Use and the Patent Bargain, 2004 Wis. L. Rev. 81 (distinguishing between experimenting on research tools and experimenting with research tools) [hereinafter Strandburg, What Does the Public Get?].

Furthermore, some “value-added” assets, such as diagnostic tests, are both research tools as well as commercial applications. Charles Clift, Patenting and Licensing Research Tools, in INTELLECTUAL PROPERTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATION: A HANDBOOK OF BEST PRACTICES 82 (A. Krattinger et al. eds., 2007) [hereinafter HANDBOOK OF BEST PRACTICES].

Rai & Eisenberg, supra note 10, at 299; Kieff, Property Rights and Property Rules, supra note 13; but see Golden, supra note 13.

Along similar lines, this Article does not advocate a noncommercial research exception for privately-developed research tools. As I have argued elsewhere, other mechanisms are available to liberalize access to privately-developed inventions that have achieved “infrastructure status.” Peter Lee, The Evolution of Intellectual Infrastructure, 83 Wash. L. Rev. 39 (2008) [hereinafter Lee, The Evolution of Intellectual Infrastructure]. Some privately-developed tools, such as polymerase chain reaction (PCR), a process for copying DNA, may have never been developed if not for the incentive of market exclusivity. Joe Fore, Jr., et al., The Effects of Business Practices, Licensing, and Intellectual Property on Development and Dissemination of the Polymerase Chain Reaction: Case Study, 1 J. BIOMEDICAL DISCOVERY AND COLLABORATION 7 (July 3, 2006).

See generally Merges, A New Dynamism in the Public Domain, supra note 25.

unique upstream-downstream “normative hierarchy” of the biomedical research sector.\textsuperscript{32} Subject to exceptions,\textsuperscript{33} public institutions that provide “upstream” support for investigations leading to research tools are also generally committed to widely disseminating these discoveries.\textsuperscript{34} Alternatively, “downstream” entities that develop existing inventions into commercial products, such as pharmaceutical and biotechnology firms, tend to favor exclusivity and profit maximization.\textsuperscript{35} The confluence of significant upstream research support as well as norms favoring access creates a situation ripe with possibility.\textsuperscript{36} Normative considerations thus represent a powerful reason why the initial allocation of patent rights on research tools (or contractual claims on those rights) matters a great deal.\textsuperscript{37}

At a procedural level, consideration-based patent regulation reflects an important shift from broad-based property rules to individual contracts as a means for implementing patent policy. I use the term “contract” broadly to include both informal quid pro quos as well as explicit contracts, such as funding agreements and patent licenses. This model relies on mutual exchange between individual parties rather than on top-down regulation to promote public policy. One could call this the privatization of public policy in patent law. This approach offers considerable freedom to operate to public institutions, which can sidestep legislative and doctrinal constraints by embedding policy objectives in individual contracts. For example, the NIH informally ties research funding to expectations that grant recipients will forgo certain rights conferred under the Patent Act. This individualized approach also permits valuable context-specific distinctions. Ideally, patents on biomedical research tools function less like simple rights to exclude and more as complex governance regimes involving selective exclusion and access.\textsuperscript{38} These governance regimes, and the high information costs they entail, are better managed through \textit{in personam} contractual relationships rather than though general \textit{in rem} property rules.\textsuperscript{39}

Of course, the approach explored here faces several limitations. Any contractually-created research commons is only coextensive with the web of grantor-grantee and licensor-
licensee relationships defining it. Furthermore, a poorly managed research exception could chill public-private partnerships and incentives to develop existing inventions. Accordingly, technical competence issues loom large. Finally, conflicts may arise between an institution’s commitment to widely disseminate research tools and its desire to reap profits through exclusivity. Notwithstanding these challenges, through carefully crafted agreements and faithful adherence to self-articulated values, public institutions can help construct a commons for noncommercial biomedical research.

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

Part I examines access constraints inherent in the patent system and shows how patents may impede biomedical research. Part II assesses the challenges of public law mechanisms to address this problem. Part III examines the role of private ordering in tempering the excesses of intellectual property and explores a model by which public institutions can assert their normative commitments in market-based, contractual relationships. Part IV examines the creation of a biomedical research commons by public institutions. Applying the three-part model of consideration-based patent regulation, it considers the enormous contributions of public institutions to biomedical research, their normative commitments to open science, and contractual practices that limit the exclusive rights of downstream patentees to advance this norm. Part V assesses the opportunities and challenges posed by this endeavor and offers prescriptions for effectively managing it. Part VI explores implications of this phenomenon for patent law, institutions, and theory.

Part I. The Role of Patents in Inhibiting Biomedical Research

Patents embody an intrinsic conflict; they increase the supply of new inventions by constraining access to them. As is well-recognized, the technical knowledge inherent in an

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invention is a public good, which is nonrival\(^{44}\) (meaning that multiple parties can use it without diminishing its availability) and nonexcludable\(^{45}\) (meaning that absent legal intervention, it is difficult if not impossible to exclude others from appropriating it).\(^{46}\) Public goods such as new innovations are subject to undersupply in the absence of exclusive rights because non-innovating firms could simply free-ride on the research and development of others. Patents allow inventors to exclude free riders, thus enabling an adequate return on investment.\(^{47}\) The necessary trade-off is that exclusive rights may constrain access to patented inventions.\(^{48}\)

While access constraints on patented end-user goods may be problematic,\(^{49}\) access constraints on the technological inputs to research and development pathways can be particularly troublesome.\(^{50}\) In the biomedical realm, patents on upstream “research tools”\(^{51}\)—materials, protocols, and equipment that comprise critical inputs to scientific experimentation—may inhibit downstream research. Examples of patented biomedical research tools include: extracted and purified human embryonic stem cells; DNA sequences coding for specific proteins, called Expressed Sequence Tags (ESTs); DNA sequences that serve as genetic disease markers, such as Single Nucleotide Polymorphisms (SNPs); genetically modified mutants such as “knock-out” mice; genetically modified disease models, such as the OncoMouse; and techniques for transferring genes from one organism to another, known as recombinant DNA technology.\(^{52}\) These patented technologies are vital tools that scientists need to conduct biomedical research. Crucially, most of these technologies did not arise from applied, commercial research, but arose quite directly from basic biomedical investigations.

\(^{44}\) See VI THE WRITINGS OF THOMAS JEFFERSON 180–81 (H.A. Washington ed., 1871) (describing ideas as “expansible over all space, without lessening their density in any point”).

\(^{45}\) Of course, firms may attempt to protect valuable information as a trade secret. However, without legal intervention such as enforceable nondisclosure agreements, it may be difficult to maintain the secrecy of information and still exploit it.


\(^{47}\) The patent system also promotes efficiency by providing an incentive to disclose technical knowledge instead of protecting it as a trade secret. Additionally, patents may 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-Gra il, 71 Notre Dame L. Rev. 267 (1996) (same); Kitch, supra note 43 (elaborating prospect theory).


\(^{49}\) For example, patents on pharmaceuticals contribute to higher prices and decreased availability. See supra note 8.

\(^{50}\) See Rebecca S. Eisenberg, Proprietary Rights and the Norms of Science in Biotechnology Research, 97 Yale L.J. 177, 225 [hereinafter Eisenberg, Proprietary Rights and the Norms of Science]; Rebecca S. Eisenberg, Patents and Data-Sharing in Public Science, 15 INDUSTRIAL & CORPORATE CHANGE, 157, 1013, 1016 [hereinafter Eisenberg, Patents and Data-Sharing in Public Science]; cf. Mark A. Lemley, Patenting Nanotechnology, 58 STAN. L. REV. 601, 619-20 (2005) [hereinafter Lemley, Patenting Nanotechnology].

\(^{51}\) See supra note 7.

\(^{52}\) For additional examples, see John P. Walsh et al., Research Tool Patenting and Licensing and Biomedical Innovation, in PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285, 296 (2003) [hereinafter Walsh et al., Research Tool Patenting and Licensing].
Many developments have coalesced to significantly increase the patenting of research tools. First, courts have taken an exceedingly expansive view of patentable subject matter, such that in some cases the direct fruits of basic research can be patented. Second, advances in molecular biology have revealed a relatively clear path from “basic” discoveries to commercial products, thus enhancing their patentability. Third, the 1980 passage of the Bayh-Dole Act allowed and even encouraged federal contractors to patent taxpayer-financed inventions, thus leading to an explosion in university patenting. Finally, there is much money to be made. Biomedical patents are essential to the pharmaceutical and biotechnology industries, and profit expectations have motivated widespread patenting up and down the research and development chain.

Patents on biomedical research tools can hinder scientific inquiry in a variety of ways. First, a patent on a critical, “keystone” asset can singlehandedly hold up research. As I have argued elsewhere, patents on technological “infrastructure” have the potential to impede wide arrays of research and development. For example, the Wisconsin Alumni Research Foundation’s patents on extracted, purified human embryonic stem cells initially raised concerns from non-profit scientists who were unsure if they required a license to use these cells in basic research. Second, the need to bundle multiple licenses for various patented assets, all of which are necessary to conduct research, can generate transaction costs that render such investigations prohibitively expensive. This may produce a “tragedy of the anticommons” wherein too many upstream exclusive rights leads to wasteful underexploitation of resources, represented here by foregone research. For example, if a researcher needs to bundle many licenses for patented expressed sequence tags (ESTs), aggregate costs may render an intended...

53 See Rai & Eisenberg, supra note 10, at 291-95.
54 See Diamond v. Chakrabarty, 447 U.S. 303 (1980); infra notes and accompanying text.
56 Rebecca S. Eisenberg, Patents and Data-sharing in Public Science, supra note 50, at 1014.
57 See infra Part IV.A.C.
58 See Golden, supra note 13, at 106.
61 See Merges & Nelson, supra note 59, at 882 (discussing the Selden patent, which was used to control development of the automobile); see generally Scotchmer, supra note 1.
65 See Lee, Inverting the Logic of Scientific Discovery, supra note 1, at 90. The impasse was ultimately resolved by an agreement between the NIH and WiCell Research Institute. See infra Part IV.A.
66 For a discussion of the challenges of negotiating technology licenses, see Lee, The Evolution of Intellectual Infrastructure, supra note 29, at 97-99.
course of research unduly expensive.\textsuperscript{68} Third, similar to but distinct from the anticommons scenario is the challenge of patent thickets, where multiple overlapping patents cover a single technology.\textsuperscript{69} 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 subject to much debate. In a recent survey, Professor John Walsh and colleagues found that only 1\% of academic researchers suffered a project delay of more than one month due to patents on necessary inputs, and none had completely abandoned a project.\textsuperscript{70} An earlier survey found “almost no evidence” that the presence of multiple rights holders in biomedical research led to the complete cessation of projects.\textsuperscript{71} Similarly, royalty stacking from multiple licenses did not represent a significant or pervasive threat to such activity.\textsuperscript{72} However, the study 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.”\textsuperscript{73}

While rare, the potential for hindering noncommercial research is nonetheless significant. Restrictive licensing of critical research tools such as the OncoMouse\textsuperscript{74} and polymerase chain reaction (PCR),\textsuperscript{75} initially threatened to chill basic research. 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.\textsuperscript{76} Additionally, private ordering by the NIH and Merck has helped prevent widespread patenting of expressed sequence tags (ESTs), thus averting a potential tragedy of the anticommons.\textsuperscript{77} Given that biomedical research generates immense spillovers benefitting society at large,\textsuperscript{78} even slight research disruptions can have significant effects. Such research occupies “Pasteur’s Quadrant:” while it strives for deep understanding, it is also intrinsically oriented towards practical

\textsuperscript{68} See Heller & Eisenberg, supra note 1.
\textsuperscript{70} John P. Walsh et al., Patents, Material Transfers and Access to Research Inputs in Biomedical Research, Final Report to the National Academic of Sciences’ Committee [on] Intellectual Property Rights in Genomic and Protein-Related Inventions, Sept. 20, 2005, at 2 [hereinafter Walsh et al., Patents, Material Transfers and Access to Research Inputs]. The authors conclude that “friction” arising from material transfer agreements for physical property posed a much greater impediment to basic science. \textit{Id.}
\textsuperscript{71} Walsh et al., \textit{Research Tool Patenting and Licensing}, supra note 52, at 298.
\textsuperscript{72} \textit{Id.} at 299.
\textsuperscript{73} \textit{Id.} at 302.
\textsuperscript{75} See Cetus To Exact Royalties from PCR Sales; Probe Absolves Convicted Rapist, BIOTECH. NEWSWATCH, Sept. 5, 1988, at 7.
\textsuperscript{76} \textit{See infra} Part IV.A.I.
\textsuperscript{77} See Heller & Eisenberg, supra note 1, at 699.
\textsuperscript{78} See Mark A. Lemley & Brett M. Frischmann, \textit{Spillovers}, 100 COLUM. L. REV. 257, 257 (2007)
Of course, any critique of patent-enabled “access constraints” may appear nearsighted. These constraints are only “problematic” because there is some valuable new technology to access. Economic theory posits that exclusive rights are necessary to generate new inventions, and access constraints are simply the inherent tradeoff. However, this tradeoff does not necessarily exist in all contexts. In the biomedical field, public institutions fund and conduct the bulk of research that produces patented research tools. While exclusive rights may be warranted to encourage further private development of these assets, public support has already satisfied the incentive to invent many underlying tools. In the biomedical research context, the costs of access constraints on patented technologies may far outweigh their benefits.

Part II. Public Law Approaches to Addressing Patents on Biomedical Research Tools

The challenge of patents on biomedical research tools has elicited a number of actual and proposed “public law” responses. By “public law” mechanisms, I refer to traditional modes of patent regulation arising from broadly-applicable judicial decisions, legislative enactments, and administrative rules. Some public law initiatives have an explicit in rem character in that they alter the general meaning of what it means to own a patent. For reasons that will become clear, I distinguish these public law mechanisms from private law mechanisms, characterized by contracts that establish in personam rights and obligations between individual parties. 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, but none offers a complete solution. As an exhaustive review of all of these mechanisms is beyond the scope of this Article, I will focus on several prominent devices before briefly surveying others. As we will see, the gaps left by public law initiatives define a valuable role for consideration-based, private law approaches to play a supplementary role.

A. The Common Law Experimental Use Exception

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80 See, e.g., Nelson, supra note 55, at 455; Andrews et al., supra note 1, at 1396.
82 See Lemley, Patenting Nanotechnology, supra note 50, at 618 n. 81 (collecting authorities on this debate).
83 See Rai & Eisenberg, supra note 10, at 300; see also Strandburg, Users as Innovators, supra note 12, at .
84 Kieff, Property Rights and Property Rules, supra note 13, at .
86 As Professors Thomas Merrill and Henry Smith make clear, the distinction between in rem and in personam rights is one of degree rather than kind. See Merrill & Thomas, supra note 39, at 777.
A doctrine aimed directly at allowing unlicensed use of patented inventions for noncommercial purposes is the common law experimental use exception. Traditionally, the doctrine distinguished “philosophical,” noncommercial uses of patented inventions from commercial ones, exempting the former from infringement. While theoretically this exception might have safeguarded university research from patent infringement, recent court decisions have largely foreclosed that possibility.

Most prominently, in Madey v. Duke University, the Federal Circuit articulated a very narrow view of the experimental use exception. 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.” 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.


89 See Whitemore v. Cutter, 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600) (“[I]t could never have been the intention of the legislature to punish a man, who constructed such a[n allegedly infringing] machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.”); see Sawin v. Guild, 21 F. Cas. 554, 555 (C.C.D. Mass. 1813) (No. 12,391); Poppenhusen v. Falke, 19 F. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861) (No. 11,279); Roche Products, Inc. v. Bolar Pharmaceutical Co., 733 F.2d 858, 862-63 (Fed. Cir. 1984); see 3 WILLIAM C. ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS § 898, at 56 (1890).

90 See, e.g., Pitcairn, 547 F.2d 1106, 1125-26 (Ct. Cl. 1976); Roche Prods., 733 F.2d at 863; Deuterium Corp. v. United States, 19 Cl. Ct. 624, 633 (Ct. Cl. 1999); Embrex v. Serv. Eng’g Corp., 216 F. 1343, 1349 (Fed. Cir. 2000); see generally Armstrong, supra note 88.

91 307 F.3d 1351 (Fed. Cir. 2002).

92 307 F.3d at 1362. Several observers note that Madey simply extended previous Court of Claims and Federal Circuit jurisprudence on the experimental use exception to university research and did not truly “narrow” the exception. See supra note .

93 See Strandburg, What Does the Public Get?, supra note 26, 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 Appler 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). In addition, sovereign immunity is not a reliable mechanism for shielding state university researchers from infringement suits. See generally Gary Pulcinelli, 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).
exception,\textsuperscript{94} this narrowing exacerbates concerns about the viability of university research relying on patented inventions as inputs.\textsuperscript{95}

It is important to note that even if courts recognized a robust experimental use exception, it may be overly inclusive. As discussed, a general noncommercial research exception would jeopardize the incentives of private companies to develop research tools primarily used by academic and non-profit entities. However, patent doctrine has never distinguished between publicly-developed and privately-developed inventions in applying the experimental use exception.

B. The Statutory Experimental Use Exception

While Congress has enacted a \textit{statutory} experimental use exception, it is relatively narrow in scope. The 1984, Congress passed the Hatch-Waxman Act, which expedited the process by which firms may introduce generic versions of patented drugs.\textsuperscript{96} 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.”\textsuperscript{97} However, the Act does not establish a true experimental use exception. First, the act’s narrow safe harbor only applies to research activities leading to submitting information to the FDA or other regulatory body. Second, the Act exempts from infringement uses of patented materials that are decidedly \textit{commercial}—research leading to drug development—and may not reach far enough upstream to apply to foundational basic research. Recently, the Supreme Court has liberally construed the act, holding that it applies to the use of patented materials in \textit{preclinical} research reasonably related to an FDA submission.\textsuperscript{98} Nevertheless, the Hatch-Waxman Act falls far short of creating a noncommercial research exception from patent infringement.

C. The De Facto Experimental Use Exception

\textsuperscript{94} See Rowe, \textit{supra} note 88, at 923.


\textsuperscript{97} 35 U.S.C. § 271(e). To offset delays in FDA approval, the act also allows patent term extensions of up to five years. 35 U.S.C. § 156.

\textsuperscript{98} Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193 (2005).
In addition to formal doctrines, a *de facto* experimental use exception also prevents many patentees and exclusive licensees from suing university researchers for infringement. 99 Pharmaceutical and biotechnology firms rationally forbear from suing university researchers for several reasons. 100 First, private firms that routinely seek licenses from universities are naturally reluctant to antagonize the academic community with lawsuits. Second, university research on patented assets that does not lead directly to a competing commercial product may have little financial impact on a for-profit patentee. Indeed, patentees may seek to free ride on the basic research conducted by universities by allowing them to experiment on patented assets without a license. 101 Third, such suits are clearly problematic from a public relations standpoint. 102

While the infrequency of infringement suits against academic researchers calls into questions whether biomedical patents actually frustrate noncommercial research, the potential for significant holdup still exists. 103 Additionally, evidence suggests that industry’s willingness to forbear from enforcing patents against university researchers is waning. 104 Furthermore, as noted, NIH intervention has been required to resolve some of the most egregious instances of patent holdup. 105 In an increasingly proprietary biomedical landscape, a de facto research exception does not provide reliable protection for noncommercial biomedical research.

D. Modifications to Patentable Subject Matter

Shifting from various experimental use exceptions, a more drastic approach to eliminate access constraints on research tools is simply to remove them from patentable subject matter. 106 For example, courts could extend the traditional bar against patenting “products of nature” 107 to

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101 Ariad Pharmaceuticals is the exclusive licensee of a patent on NH-kB, a signaling protein. After the company sued Eli Lilly for infringement, Ariad CEO Harvey Berger stated, “We entirely encourage noncommercial use without a license.” Walsh et al., *Patents, Material Transfers and Access to Research Inputs in Biomedical Research, supra* note 70, at 30.

102 Furthermore, many patentees are simply unaware of university infringement. For their part, many university researchers are oblivious to whether the materials they use are patented. John P. Walsh et al., *View from the Bench: Patents and Material Transfers*, 309 SCIENCE 2002, 2002 (2005). Universities have little incentive to monitor infringement, as doing so may expose them to enhanced damages for willful infringement. Eisenberg, *Patents and Data-Sharing in Public Science, supra* note 50, at 1019.

103 See *supra* notes and accompanying text.


105 See *infra* Part IV.A.


107 See, e.g., Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948) (“The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men.”); Ex Parte Latimer, 889 Dec. Com. Pat. 123.
resources such as gene fragments and extracted, purified human embryonic stem cells.\(^{108}\) Alternatively, they could extend the doctrinal prohibition against patenting natural laws, physical phenomena, and abstract ideas\(^{109}\) to limit patents on research tools that are necessary to discover these elements.\(^{110}\) These proposals, however, raise difficulties in light of expansive patentable subject matter doctrine. In the seminal case of *Diamond v. Chakrabarty*, the Supreme Court drew from the legislative history of the 1952 Patent Act in stating that “anything under the sun that is made by man” is eligible for patenting.\(^{111}\) Other cases have reinforced this expansive view.\(^{112}\) Although recent Supreme Court\(^{113}\) and Federal Circuit\(^{114}\) pronouncements have signaled a potential narrowing of patentable subject matter, the exact extent of future modifications is unpredictable. While Congress is currently considering patent reform,\(^{115}\) curtailing patentable subject matter to eliminate research tool patents is not on the agenda.

Furthermore, summarily prohibiting patents on research tools would eviscerate private incentives to invent such technologies.\(^{116}\) Additionally, even where exclusive rights are not necessary to motivate invention, they may be necessary to motivate further investment in developing existing inventions.\(^{117}\) A more refined approach would distinguish between noncommercial research use of an existing invention and commercial sale, providing exclusivity only for the latter. Summarily eliminating research tools from patentable subject matter precludes this use-specific distinction.\(^{118}\)

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\(^{108}\) Rai & Eisenberg, *supra* note 10, at 299. Of course, this would rarely affect “process” research tools, such as techniques for copying DNA.


\(^{110}\) See *Lee, Inverting the Logic of Scientific Discovery*, *supra* note 1.

\(^{111}\) 447 U.S. 303 (1980).

\(^{112}\) See, *e.g.*, *Diamond v. Diehr*, 450 U.S. 175, 192 (1981); *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368 (Fed. Cir. 1998).


\(^{117}\) See Kieff, *Property Rights and Property Rules*, *supra* note 13, at 703.

\(^{118}\) A narrower approach could exempt non-profit researchers from remedies arising from infringing such patented inventions. Analogously, the Patent Act exempts health care professionals from remedies arising from infringing patented medical techniques. 35 U.S.C. § 287(e); see *Pallin v. Singer*, 1995 WL 608365, 36 U.S.P.Q. 2d 1050 (D. Vt. 1050 1995); *Chris J. Katopis, Patients v. Patents?: Policy Implications of Recent Patent Legislation*, 71 ST. JOHN’S L. REV. 329 (1997). However, there have been no congressional attempts to recreate this exception for noncommercial researchers, which in any event would be overinclusive.
E.  Additional Policy Levers for Tempering Patents on Research Tools

The requirements that a patented invention must be novel, useful, and nonobvious may also prevent undue patenting of research tools. In particular, the requirement that patentable inventions must be useful has in fact curbed patents on research tools. In 2001 the Patent and Trademark Office issued guidelines requiring a demonstrated specific and substantial utility for all patented inventions. These guidelines have made it more difficult to patent expressed sequence tags (ESTs) that encode proteins of no known biological activity. It is unclear, however, whether these guidelines have curtailed patenting of other types of research tools. Yet another mechanism for enhancing access to patented biomedical research tools is compulsory licensing, whereby a government agency could issue licenses to a third-party firm to practice a patented invention if the patentee did not disseminate it widely enough. While compulsory licenses are available pursuant to 28 U.S.C. § 1498 and antitrust consent decrees, they are rarely granted in this country and are not a promising candidate to liberalize access to patented research tools.

Another mechanism for tempering patents involves the law of patent infringement remedies. In eBay Inc. v. MercExchange, L.LC., the Supreme Court recently rejected the Federal Circuit’s “general rule” of granting injunctions upon a finding of patent infringement. Instead, it held that courts must apply a traditional four-factor equitable test to determine the appropriateness of an injunction. As I have recently argued, this change provides courts with greater latitude to protect inventions serving as critical “infrastructure” with a liability rule rather than a property rule. However, it is too early to tell if courts will fully embrace this proposal.

120 Nelson, supra note 55, at 466; see Golden, supra note 13, at 182; see Brenner v. Manson, 383 U.S. 519, 534 (1966).
122 In re Fisher, 421 F.3d 1365 (Fed. Cir. 2005).
123 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 12, at 536, 551.
128 547 U.S. at 391. In order to obtain an injunction, “A plaintiff must demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for 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.
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.\textsuperscript{130} Even if courts started protecting research tool patents with damages rather than injunctions, it is important to note that a remedies approach is best suited to cases where a patent on some single, keystone asset—such as human embryonic stem cells—is the cause of patent holdup. It is less suited to address anticommons scenarios arising from the need to bundle multiple licenses.

F. Summary

While valuable, public law attempts to temper patents on research tools face various limitations and uncertainties. Courts have taken an extremely narrow view of the common law experimental use exception, which even in its most robust form never distinguished between publicly- and privately-developed inventions. Statutory and de facto experimental use exceptions are alternatively too narrow and too unpredictable. Exempting research tools from patentable subject matter is doctrinally problematic and may undermine private incentives to invent and develop. While the PTO has heightened the utility requirement for obtaining a patent, its impact on research tools other than ESTs is unknown. Government bodies rarely grant compulsory licenses. Finally, remedies analysis allows protecting research tools with liability rules rather than property rules, but such an approach is ill-suited to anticommons situations. Given the inadequacy of public law mechanisms to address the excesses of patents,\textsuperscript{131} public institutions that support basic science are turning to markets and contracts, both implicitly and explicitly, to construct a noncommercial research commons for biomedicine.

Part III. Private Ordering by Public Institutions

Where the law fails to provide optimal resource management, interested parties often resort to private ordering.\textsuperscript{132} 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 (CROs) often emerge to address the “tangled, twisted mass” of intellectual property rights that impedes productivity in many patent and copyright industries.\textsuperscript{133} 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.\textsuperscript{134} 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-

\textsuperscript{131} See Nelson, supra note 55, at 466 (“I am not optimistic about how much of the problem can be dealt with by patent law.”).
\textsuperscript{132} See generally ROBERT ELLICKSON, ORDER WITHOUT LAW (1991); ELINOR OSTROM, GOVERNING THE COMMONS (1990).
\textsuperscript{134} Id. at1340-58.
accessible pool of licenses. In the biomedical research realm, some have argued for private collective action to resolve anticommons problems.

At the most drastic level, industry players have addressed increasing propertization through another type of private ordering: simply relegating materials to the public domain. For example, the recent trend by biotechnology companies to patent single nucleotide polymorphisms (SNPs), which are useful as genetic disease markers, raised concerns that such patents could block useful research. In response, pharmaceutical companies partnered with the Wellcome Trust to create the SNP Consortium. This coordinated effort identifies SNPs and places all resulting information in the public domain. 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. Merck’s initiative prevents patenting of these essential resources and has substantially eased potential anticommons threats.

Outside of the biomedical realm, the access-enhancing potential of private ordering is perhaps best illustrated by open source software. The most prominent open source license is the General Public License (“GPL”), which allows downstream users to make and distribute verbatim and modified versions of source code and requires users to grant a license to anyone who comes into possession of a copy. The license is considered “viral” because it “infects” all downstream iterations of code originally governed by the GPL. Commentators laud open source licensing as enabling collaborative “peer production” that may be nimbler, faster, and more robust than traditional firm structures. IBM, for example, has engaged in substantial “property pre-empting” investments by supporting open source software. Crucially, while the GPL enforces norms of open access, it is fundamentally predicated on the right to exclude inherent in copyright.

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135 Id. at 1328–40.
137 Rai & Eisenberg, supra note 10, at 298.
139 Rai & Eisenberg, supra note 10, at 298; Merges, A New Dynamism in the Public Domain, supra note 25, at 189-90.
140 See Merges, A New Dynamism in the Public Domain, supra note 25, at 188.
141 Id. at 188.
143 Id. at § 5.
146 See Merges, A New Dynamism in the Public Domain, supra note 25, at 192-93. IBM’s motives, however, are far from altruistic. See id.
147 Vetter, supra note 144, at 84; Boyle, supra note 25, at 65.
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. Creative Commons, at http://creativecommons.org/; Merges, A New Dynamism in the Public Domain, supra note 25, at 183-84.

These licenses extend beyond software to include all audio, video, images, and text; the power of these licenses to enhance access to otherwise proprietary material is enormous. But see Molly Shaffer Van Houweling, The New Servitudes, 96 GEORGETOWN L.J. 885, 923-49 (2008) (arguing that such licenses may raise problems similar to those associated with personal property servitudes).

As Professor Pamela Samuelson notes, “Open source, CC ["Creative Commons"], and similar licensed materials are best understood as a contractually constructed information commons.” As Professor Pamela Samuelson notes, “Open source, CC ["Creative Commons"], and similar licensed materials are best understood as a contractually constructed information commons.”

Most relevant for present purposes, Professors J.H. Reichman and Paul Uhlir have argued for using contracts to “reconstruct” a public domain for data that is increasingly subject to private control. As Professor Pamela Samuelson notes, “Open source, CC ["Creative Commons"], and similar licensed materials are best understood as a contractually constructed information commons.”

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. 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. 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.

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 moves do not necessarily enhance social welfare, as seen in the recent 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 primary drivers of private ordering. However, public institutions are market participants, too. 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 the model of private ordering to express norms favoring open science in contractual

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148 Creative Commons, at http://creativecommons.org/; Merges, A New Dynamism in the Public Domain, supra note 25, at 183-84.
149 But see Molly Shaffer Van Houweling, The New Servitudes, 96 GEORGETOWN L.J. 885, 923-49 (2008) (arguing that such licenses may raise problems similar to those associated with personal property servitudes).
150 Samuelson, Enriching Discourse, supra note 25, at 800.
151 Reichman & Uhlir, supra note 23.
154 Reichman & Franklin, supra note 153, at 939-51.
156 See Rai & Eisenberg, supra note 10, at 289.
relationships with patentees. Current debates on upstream-downstream dynamics in biomedical patenting have focused on potential productivity losses arising from upstream patents.157 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 and scientific communities often adhere to knowledge-sharing norms that contravene the exclusivity inherent in patents.158 To varying extents, the same holds true of certain institutions as well.

As a gross schematic (one that I complicate later), along the continuum spanning basic research, applied research, and development, institutions that fund and produce upstream biomedical research tools—those closest to basic scientific findings—are most likely to exhibit norms privileging widespread access to technology rather than exclusion and profit-maximization. The confluence of this normative hierarchy and the significant market power of public institutions creates enormous potential for market-based policy implementation. The next Part will explore how this is actually happening.

Part IV. The Contractual Creation of a Biomedical Research Commons

In the wake of limitations and uncertainties of public law mechanisms to shield noncommercial research from patent infringement, public institutions are increasingly filling this void through private law models. Given that this behavior includes government agencies acting pursuant to legislatively-enacted statutes, the terms “private law” and “private ordering” require some explanation in this context. The essence of this approach is that public institutions are advancing patent policy not through broadly-applicable laws, decisions, and rules, but by tying access requirements to the provision of research support in individual contractual relationships. These institutions are requiring, in a quid pro fashion, that recipients of money, patent rights, and materials allow liberal use of resulting patented inventions for noncommercial biomedical research. Rather than altering the in rem nature of patent rights, public institutions are creating in personam rights and obligations between themselves and patentees as a condition of granting support.

This Part surveys the contractual creation of a research commons in biomedicine. Following the three-part model of consideration-based patent regulation, it examines various institutions’: 1) support for biomedical research leading to patented research tools; 2) adherence to norms favoring wide access to research tools; 3) use of informal and formal contractual mechanisms to impose context-specific access requirements for these technologies. Part IV.A considers the NIH’s leveraging of funds and rights retained under the Bayh-Dole Act to ensure that publicly-financed research tools are widely available for research purposes. Part IV.B examines California’s requirements that recipients of state human embryonic stem cell research

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157 See supra Part I.A.
funding must share patented discoveries liberally with non-profit research institutions. Part IV.C considers the immense role of universities in conducting biomedical research and examines licensing practices ensuring wide access to patented research tools. Part IV.D explores the substantial contributions of non-profit organizations to biomedical research and examines their requirements that resulting patented research tools must be made widely available. Part IV.E highlights the growing importance of disease advocacy groups in supporting biomedical research and explores their practices for ensuring wide dissemination of patented research tools.

In all of these instances, an institution’s significant “upstream” contributions to the development of a patented invention establish claims on how a “downstream” partner may use it. Although the experimental use exception has withered as a public law creation, institutions are helping to create a more effective one through contract.

A. The Federal Government

The federal government provides enormous support for basic biomedical research and is leveraging its contributions to discourage grant recipients from asserting patents to impede noncommercial research. ¹⁵⁹ While the Bayh-Dole Act constrains the ability of funding agencies to directly regulate grantee patenting practices, the NIH has invoked informal quid pro quos to encourage open licensing and even prevent grantees from patenting key research resources. Liberalizing the substantive and procedural 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. ¹⁶⁰ In 2003, the NIH, the “primary focal point of federally sponsored biomedical research,”¹⁶¹ provided $26.4 billion for biomedical research, or 28% of the national total. ¹⁶² Similarly, in FY 2004, the NIH’s $28 billion budget comprised about one third of national biomedical research spending. ¹⁶³ While funding less aggregate biomedical research than private industry, the federal government actually funds more basic research, as opposed to applied research and development,

¹⁵⁹ Reichman & Uhlir, supra note 23, 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.”).
¹⁶¹ William H. Frist, Federal Funding for Biomedical Research: Commitment and Benefits, 287 JAMA 1722, 1724 (2002).
¹⁶² 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.
than all private sources combined. In 2004, 55% of NIH funds for research and development went to basic research. According to its Roadmap for Medical Research, basic biomedical research remains the top priority for NIH funding: “[M]uch of NIH funding supports the exploration of fundamental biological mechanisms that would otherwise not be pursued due to the lack of market incentives.” This basic research, moreover, produces many research tools critical to further inquiry.

In addition to direct funding, the NIH also significantly subsidizes research by allowing grantees to patent taxpayer-financed inventions pursuant to the Bayh-Dole Act. Prior to the Bayh-Dole Act, federal agencies possessed no uniform policy regarding the ownership of patents arising from taxpayer-funded ventures. Some agencies took title to inventions while other agencies granted title to outside contractors and only retained a license for their own use. Concerns grew that government-owned patents were stifling innovation because firms would not invest in developing existing inventions into commercial goods without having exclusive rights. In order to put government-funded inventions to good use, and amid concerns over lagging U.S. economic competitiveness relative to Europe and Japan, Congress passed the Bayh-Dole Act in 1980. The Act allowed and encouraged small businesses and non-profit organizations—including universities—to patent the results of government-sponsored research provided that they satisfy certain statutorily defined conditions. In a related vein, also in 1980, Congress passed the Stevenson-Wydler Technology Innovation Act, which required federal laboratories to take a more active role in transferring technology to private industry.

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165 Moses III et al., supra note 162, at 1338 table 4.
166 NIH, Report to Congress on Affordability of Inventions and Products, July 2004, at 3 [hereinafter NIH, Affordability of Inventions and Products].
167 NIH, Affordability of Inventions and Products, supra note 166, at 1355.
168 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).
The Bayh-Dole Act represents a significant federal subsidy for research and development.174 The act has led to an explosion of university patenting and has generated enormous income for some government contractors.175 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.”176 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.177 Nevertheless, under the current quid pro quo of government contracting, grant recipients stand to benefit substantially from patenting taxpayer-financed inventions.

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

While the NIH provides enormous financial support for biomedical research, it does not do so primarily to make money. The NIH defines its mission as “science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy life and reduce the burdens of illness and disability.”178 While one of the goals of the NIH is to enhance the nation’s economic well-being and ensure a high return on public investment in research,179 the agency does not seek to maximize short-term profits. Vannevar Bush, the original architect of U.S. research policy under President Franklin D. Roosevelt, envisioned the federal government taking an active role in creating a scientific “reservoir of knowledge.”180 This reservoir, the prototypical upstream resource, would then facilitate myriad downstream applications promoting scientific, economic, and military development. Similarly, the NIH funds research to create a knowledge base for life-enhancing applications, not for direct institutional monetary gain.181 Access is critical to achieving these goals, and in both policy and regulations, the NIH expresses access norms that directly contravene the exclusivity associated with private rent seeking.182

175 See infra Part IV.C.
182 As an example of these norms, in 1994 the NIH voluntarily withdrew patent applications on expressed sequence tags (ESTs) because of their research tool character. Steven M. Ferguson, Licensing and Distribution of Research Tools: National Institutes of Health Perspective, 41 J. CLIN. PHARMACOL. 110S, 111S (2001).
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.”\textsuperscript{183} 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 \textit{without unduly encumbering future research and discovery}.”\textsuperscript{184} Indeed, the possibility that taxpayer-financed patents could stymie valuable research seems antithetical to the Bayh-Dole Act. To advance its access-related policy objectives, the act ensures that the federal 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.”\textsuperscript{185}

The Bayh-Dole Act ensures these access and distribution objectives through several statutory provisions. First, under 35 U.S.C. § 202(a)(ii), a funding agency can restrict patenting by a grantee in “exceptional circumstances” when the agency determines that withholding title to the invention “will better promote the policy and goals” of the act.\textsuperscript{186} 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.\textsuperscript{187} Third, the federal government retains so-called “march-in rights” to issue compulsory licenses for inventions covered by the act if any of four statutorily-defined factors are met.\textsuperscript{188} Thus, in exchange for providing patent rights to taxpayer-funded inventions, funding agencies like the NIH retain formal access claims on those inventions. Significantly, these rights operate in a viral manner and apply not only to the government contractor that patents the invention, such as a university, but to licensees of that patent as well.\textsuperscript{189}

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

\textsuperscript{184} 35 U.S.C. § 200 (emphasis added).
\textsuperscript{186} 35 U.S.C. § 202(a)(ii).
\textsuperscript{187} 35 U.S.C. § 202(c)(4).
\textsuperscript{188} 35 U.S.C. § 203. The Bayh-Dole Act permits the federal government to issue a nonexclusive, partially exclusive, or exclusive license to a third party if the relevant federal agency determines that:
   (1) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;
   (2) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;
   (3) action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or
   (4) action is necessary because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204.
\textsuperscript{189} See Jaffe, \textit{supra} note 12, at 533 (“[T]he rules governing the patentability of federally supported research essentially control university patenting.”).
While the Bayh-Dole Act limits the NIH’s ability to dictate the patenting and licensing practices of its grantees, the NIH has found ways to leverage its funding power to encourage wide access to taxpayer-funded research tools. Indeed, the Bayh-Dole Act has been useful in this regard; the threat of invoking government rights has in some cases spurred compliance with non-binding policy guidelines.

The NIH is using its funding power to help address the problem of patent holdup. In 1999, the NIH issued principles and guidelines for the patenting and licensing of NIH-funded research tools by federal grant recipients (“Principles and Guidelines”). These Principles and Guidelines specifically promote wide dissemination of NIH-funded research resources. Notably, the Principles and Guidelines distinguish between “internal use by non-profit institutions” and “commercial development and sale or provision of services,” which may warrant some degree of exclusivity. The guidelines recommend transferring patented research tools to non-profits on terms no more onerous than the Uniform Biological Material Transfer Agreement (UBMTA), a standardized process for sharing biological materials developed by the NIH. Furthermore, they recommend transferring NIH-funded research tools to for-profit entities “with the fewest encumbrances possible.” Notably, these Principles and Guidelines reflect a shift away from viewing patents as simple rights to exclude and recast them as governance regimes of selective access and exclusivity.

These Principles and Guidelines also seek to implement the Bayh-Dole Act’s goal of maximizing utilization of research tools. 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.” For research tools not requiring additional development, the Principles and Guidelines recommend “publication, deposit in an appropriate databank, widespread non-exclusive licensing or any number of dissemination techniques.” While exclusive licenses may be appropriate for additional commercial development, they should ultimately aim for widespread dissemination of a resulting product.

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190 For a partial list arranged chronologically, see Ferguson, supra note 182, at 111s.
191 NIH, Principles and Guidelines, 64 Fed. Reg. 72,090; see Josephine Johnston & Angela A. Wasunna, Patents, Biomedical Research, and Treatments: Examining Concerns, Canvassing Solutions, HASTINGS CENTER REPORT, Jan.-Feb. 2007, at s11; Pressman et al., supra note 19, at 32.
192 NIH, Principles and Guidelines, 64 Fed. Reg. at 72,092-93 (“Progress in science depends upon prompt access to the unique research resources that arise from biomedical research laboratories through government, academia, and industry.”).
193 Id. at 72,093.
194 National Institutes of Health, Uniform Biological Material Transfer Agreement: Discussion of Comments Received; Publication of Final Format of the Agreement, 60 Fed. Reg. 12,771 (March 8, 1995) [hereinafter NIH, UBMTA].
195 NIH, Principles and Guidelines, 64 Fed. Reg. at 72,094.
196 Id. at 72,094
197 See Smith, supra note 38.
198 NIH, Principles and Guidelines, 64 Fed. Reg. at 72,092.
199 Ferguson, supra note 182, at 111s.
200 NIH, Principles and Guidelines, 64 Fed. Reg. at 72,093.
201 Id. at 72,093.
202 Id. at 72,093.
The NIH’s funding power ensures that these Principles and Guidelines have “real teeth.”\textsuperscript{203} The NIH explicitly considers compliance with the guidelines in awarding grants.\textsuperscript{204} Although the NIH may not \textit{generally} regulate the patenting practices of federal grantees,\textsuperscript{205} the NIH has incorporated these guidelines in reviewing individual applications.\textsuperscript{206} The possibility of denying funding is clearly present, and operates as a strong incentive to comply.\textsuperscript{207} 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 funds to produce mouse knockout genes.\textsuperscript{208} While commentators caution that the NIH may be exceeding its authority under the Bayh-Dole Act in “enforcing” these guidelines,\textsuperscript{209} the NIH suggests that widespread noncompliance may spur regulatory or statutory intervention.\textsuperscript{210}

Other NIH policies also encourage the widespread availability of taxpayer-funded research resources.\textsuperscript{211} In 2005, the NIH issued guidelines for licensing genomic inventions.\textsuperscript{212} 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.”\textsuperscript{213} These guidelines parallel practices at the NIH’s own Office of Technology Transfer and recommend nonexclusively licensing genomic inventions. Significantly, the guidelines recognize the appropriateness of exclusive licensing when necessary to facilitate post-invention commercialization.\textsuperscript{214} Additionally, the NIH explicitly requires that researchers applying for more than $500,000 in funding must submit a plan in their grant applications for sharing resulting data.\textsuperscript{215}

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

\textsuperscript{204} Pressman et al., \textit{supra} note 19, at 32.
\textsuperscript{205} Rai & Eisenberg, \textit{supra} note 10, at 308. Under the Bayh-Dole Act, only the Secretary of Commerce may promulgate general regulations for licensing federally owned inventions. 35 U.S.C. §208. The NIH may only make such determinations in the context of individual grants. See Arti K. Rai & Rebecca S. Eisenberg, The Public and the Private in Biopharmaceutical Research, at 172, available at http://www.law.duke.edu/pd/papers/raieisen.pdf
\textsuperscript{206} Flores, \textit{supra} note 203, at 820; David Malakoff, \textit{NIH Knocks Academe with Advice on Licensing DNA Patents}, 303 \textit{Science} 1757, 58 (2004).
\textsuperscript{207} Flores, supra note 23, at 820.
\textsuperscript{208} D.G., \textit{NIH Knocks Out Key Mouse House}, 312 \textit{Science} 1863, 1863 (2006).
\textsuperscript{209} Rai & Eisenberg, supra note 10, at 308-09.
\textsuperscript{213} NIH, NIH Grants Policy Statement 115 (2003).
\textsuperscript{214} Pressman et al., \textit{supra} note 19, at 32.
patents on extracted and purified human embryonic stem cells raised concerns that exclusive rights could inhibit scientific investigations using these basic research tools. To address these concerns, in 2001 the Public Health Service (PHS) entered into a Memorandum of Understanding (MOU) with the WiCell Research Institute, a University of Wisconsin affiliate holding licenses to the stem cell patents. Under the MOU, WiCell agreed to provide a research license for Wisconsin Patent Rights at low cost to PHS-supported researchers. Referring to the Bayh-Dole Act, the MOU states that “PHS funded the primate research studies at the University of Wisconsin – Madison that led to certain discoveries claimed in Wisconsin Patent Rights and therefore the Government has certain use and other rights to the intellectual property comprising the Wisconsin Patent Rights granted by law and regulation.”

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

A historical example predating the Bayh-Dole Act further reveals the NIH’s potential power to compel wide access to taxpayer-funded, privately-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. The NIH partially funded Axel’s research, but Columbia’s patent application preceded the Bayh-Dole Act by several months. Accordingly, pursuant to the pre-Bayh-Dole regime, the NIH assigned the patent to Columbia on condition that the university had to license it widely and nonexclusively and that it would not charge “unreasonable” royalties.

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. Furthermore, NHGRI explicitly discouraged grantees from patenting raw human genomic DNA sequences, which it believed

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217 See generally Hazuka, supra note 1.
218 The PHS is the umbrella agency housing the NIH.
220 Id. Some of the research was funded by Geron, a private biotechnology company, which received several commercial licenses for the patented human embryonic stem cells.
221 Id.
224 Id.
225 Id.
lacked the specific utility to warrant patentability. NHGRI stated that if grantees did in fact patent DNA sequences, it would consider invoking the exceptional circumstances provision of the Bayh-Dole Act to prohibit such patenting.

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. The NIH stated it would rely on this provision to prevent project grantees from patenting their results. This approach was aimed at ensuring that the results of NIH mutagenesis initiatives would be rapidly and freely accessible to the scientific community without any patent constraints.

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. As Professors Rai and Eisenberg observe, relaxing these administrative burdens could enhance the effectiveness of the exceptional circumstances provision. Similarly, while the Act’s march-in rights provide another potential route for consideration-based patent regulation, the NIH has never used them. In theory, the NIH could invoke these rights to compulsorily license patented research tools that were being underutilized. However, since Bayh-Dole’s enactment, the NIH has considered only a handful of petitions to exercise these rights, rejecting all of them. Again, as Professors Rai and Eisenberg argue, a chief difficulty in exercising march-in rights is that they can only take effect after elaborate administrative proceedings and exhaustion of court appeals. Reforming this process could enhance the NIH’s use of march-in rights to compel wide licensing of federally-funded research tools.

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229 See infra Part IV.A.2.b.
232 Moldin, supra note 231, at 580.
233 Moldin, supra note 231, at 580.
234 See also 35 U.S.C. § 202(b)(4); 37 C.F.R. § 401.4.
235 Rai & Eisenberg, supra note 10, at 293; see 35 U.S.C. § 203(2); see also 35 U.S.C. § 202(b)(4); 37 C.F.R. § 401.4.
238 Rai & Eisenberg, supra note 10, at .
While these examples illustrate the NIH’s leveraging of *extramural* funding to encourage access to patented research tools, the NIH’s own 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.239 The NIH observes that the success of this internal program could also extend to all federally funded research.240

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 scope of the NIH’s influence, the potential size of a contractually-created research commons is substantial.

Substantively, this leverage allows the NIH to act on norms that diverge sharply from that of the classic patentee or research financier. Rather than favoring exclusivity and profit maximization, the NIH has a “strong interest” in the availability of patented research tools.241 The NIH has exploited its funding power to advance this objective in transactions with grant recipients. The Bayh-Dole Act also represents a vehicle for advancing access norms. Here, money and patent rights provide “normative portals” for the NIH to promote widespread use of patented technologies for research purposes.

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 grantee; the NIH’s Principles and Guidelines are only relevant to federal grant recipients, not to patentees in general. This mode of regulation is less likely to disturb widely-held expectations than reforming *in rem* patent rights. Sidestepping constrained judicial interpretations of an experimental use exception and difficult congressional attempts to amend the Patent Act, the NIH is using its funding power to informally “contract” for a noncommercial research exception to patent infringement. Ultimately, the “NIH has decided to take matters into its own hands” to address patent holdup.242

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

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240 Ferguson, *supra* note 182, at 110S

241 Ferguson, *supra* note 182, at 110S.

particular bargain whereby contractors may patent taxpayer-funded inventions. While the NIH rarely exercises its Bayh-Dole rights, they provide an influential baseline for the NIH to negotiate informal access to patented research tools. As others have argued, reforms to the elaborate administrative procedures established by the act could significantly enhance the NIH’s ability to regulate the licensing of taxpayer-funded inventions.243

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 state research funds on the requirement of sharing resulting patented inventions liberally with noncommercial researchers.

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.244 However, the federal government’s ban on funding research on human embryonic stem cells derived after August 9, 2001245 has motivated several state initiatives to fill this void.246 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.247 Notwithstanding recent discoveries that adult stem cells can be reprogrammed to behave like embryonic stem cells,248 many researchers still feel that embryonic stem cells, which are the targets of these state initiatives, remain the “gold standard” for stem cell research.249

243 Rai & Eisenberg, supra note 10, at .
244 Moses III et al., supra note 162, 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 174, at 1135 n.3 (collecting state statutes related to funding research).
248 Nicholas Wade, Biologists Make Skin Cells Work Like Stem Cells, N.Y. TIMES, June 7, 2007, at .
249 Colin Nickerson, Caution Urged in New Method for Stem Cells, BOST. GLOBE, Dec. 17, 2007, at . Reprogramming these cells involves retroviruses, which may cause cancer.
This Subpart focuses on California’s stem cell initiative because: 1) it vastly exceeds the size of other state initiatives;\(^\text{250}\) 2) it is relatively mature in its development; 3) it is likely to be a model for other state initiatives; 4) and the high concentration of biomedical research in California means that state funding could significantly impact this field. In 2004, California voters resoundingly passed Proposition 71, which authorized $3 billion in state bond funds for stem cell research over a ten-year period.\(^\text{251}\) To administer the grants, Proposition 71 established the California Institute for Regenerative Medicine (“CIRM”),\(^\text{252}\) a state agency governed by a 29-member Independent Citizens Oversight Committee (“ICOC”) comprised of representatives from academia, government, business, and disease advocacy groups.\(^\text{253}\)

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

Not surprisingly, CIRM does not fund basic biomedical research with the primary aim of making money off of it. According to Proposition 71, the overriding purpose of CIRM is to fund stem cell research “to realize therapies, protocols, and/or substantial mitigation of, major diseases, injuries, and orphan diseases.”\(^\text{254}\) Proposition 71 identifies several additional objectives, including improving California’s health care system, reducing health care costs, and generating revenue from sponsored research.\(^\text{255}\) 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.\(^\text{256}\)

Relative to the NIH’s funding of basic biomedical research, CIRM’s mandate is less explicitly “altruistic”: California takes a financial stake in patented inventions. Nevertheless, CIRM seeks to ensure that patented, state-funded research tools do not inhibit scientific inquiry. These objectives are illustrated in CIRM’s intellectual property policies, which distinguish between

\(^\text{250}\) See National Conference of State Legislatures, \textit{supra} note 247.


\(^\text{253}\) \textit{Id.}

\(^\text{254}\) \textit{Id.}

\(^\text{255}\) \textit{Id.}

\(^\text{256}\) \textit{Id.} at 149.
non-profit and for-profit grantees. More recently, CIRM has codified these policies in regulations, to which we will now turn.

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

CIRM is addressing potential patent holdup by explicitly conditioning funds on grantees providing wide access to patented research tools. While CIRM has adopted a Bayh-Dole model allowing grantees to patent resulting inventions, it explicitly limits their rights to ensure that patents do not impede biomedical research.

CIRM regulations require that non-profit grantees provide any publicly-financed, patented inventions to other non-profit research institutions at reasonable cost. Unlike the NIH’s Principles and Guidelines, these regulations are legally enforceable. Non-profit grantees are required to reserve a basic research exception when licensing CIRM-funded patented inventions to third parties. Furthermore, non-profit grantees must agree to make all such inventions readily accessible to California research institutions for noncommercial purposes.

CIRM regulations further promote the availability of funded inventions by stating that non-profit “grantee organizations shall negotiate non-exclusive licenses whenever possible.”

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

257 CIRM, NON-PROFIT POLICY, supra note 4.
258 CIRM, FOR-PROFIT POLICY, supra note 4.
259 While these recent codifications are subject to change, it is unlikely that they will deviate significantly from the core provisions described here.
260 CIRM, Non-Profit Policy, supra note 4, at 2; CIRM, For-Profit Policy, supra note 4, at 4, 29; see Mireles, States as Innovation System Laboratories, supra note 174, at 1181-86.
261 17 Cal. Code Regs. § 100306(a); CIRM, Non-Profit Policy, supra note 4, at 18; see Mireles, States as Innovation System Laboratories, supra note 174, at 1190, 1199-1200.
262 17 Cal. Code Regs. § 100306(a); CIRM, NON-PROFIT POLICY, supra note 4, at 18, 37.
263 17 Cal. Code Regs. § 100306(b).
264 17 Cal Code Regs. § 100301(d). CIRM’s definition of “biomedical materials” is largely coextensive with the NIH’s definition of research tools.
268 See Mireles, States as Innovation System Laboratories, supra note 174, at 1191.
269 CIRM has also issued non-binding policy statements discouraging patenting of certain biomedical research tools such as transgenic mice, receptors, cell lines, hypothetical proteins, random single nucleotide polymorphisms (SNPs), halotypes, and proteins that have only research functions. CIRM, NON-PROFIT POLICY, supra note 4, at 32, 35.
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 purposes does not apply to for-profit grantees. Furthermore, CIRM does not require for-profit grantees to license their inventions non-exclusively. However, CIRM regulations still favor nonexclusive licensing, stating, “A [for-profit] Grantee may negotiate an Exclusive License if exclusivity is reasonably believed by Grantee to be an economic incentive necessary to achieve commercial development and availability of the invention.”

As with non-profit grantees, for-profit grantees must share CIRM-funded biomedical resources described in a publication within 60 days of a request to use such resources for research purposes. However, exceptions exist for for-profit entities. For example, such sharing is not required if “a sharing request is in direct conflict with the business of the Grantee.” Finally, CIRM maintains march-in rights for inventions developed by for-profit entities with state funds. Again, CIRM may exercise these rights if, among other reasons, “the Grantee or its exclusive licensee has failed to satisfy requirements for public use.”

4. Analysis

Exceeding the efforts of the NIH, CIRM explicitly requires broad access to state-funded, grantee-patented research tools. Although patent law and policy is a traditionally federal domain, CIRM’s regulations reveal that states may serve as important policy actors in consideration-based patent regulation. While California’s funding of embryonic stem cell research does not arise from purely “altruistic” motivations, CIRM’s policies reveal a deep commitment to ensuring the wide availability of essential 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 for non-profit grantees explicitly state, “By accepting a CIRM grant award, the grantee agrees to comply with the provisions of these regulations,” and virtually identical language applies to for-profit grantees. Clearly, California could not regulate licensing practices as general legislation applicable to all patented inventions in that state; federal patent law would preempt such a statute. However, as a market participant pursuing private ordering, CIRM has much greater flexibility to place conditions on its money to compel certain patentee behavior.
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 effectively creating one through contract. Furthermore, unlike NIH policy guidance, CIRM’s regulations are directly enforceable by law. The targeted, context specific nature of consideration-based patent regulation also offers advantages relative to broad-brushed approaches to simply eliminate patents on research tools. CIRM’s regulations, for example, distinguish between noncommercial research use and commercial sale of patented assets, allowing context-specific exclusivity of the latter to encourage commercialization.

However, CIRM’s regulations also reveal several limitations of consideration-based patent regulation. While such regulation relies on institutions privileging access over exclusivity, CIRM takes a financial stake in funded research, thus generating potential conflicts of interest. CIRM’s approach also illustrates the possibility of self-dealing inherent in a contractually-created research commons. While science is universal, jurisdiction is not. CIRM only requires non-profit grant recipients to provide patented research tools to institutions located in California. This preference may exacerbate a balkanization of science that has helped California draw resources and talent away from other states, which may undermine the interests of the national scientific community as a whole.  

C. Universities

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

1. University Contributions to Basic Biomedical Research

Universities play a predominant role in conducting basic biomedical research. In 2002, universities and colleges spent $19.6 billion on biomedical research. 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. Unlike commercial firms, which tend to focus on applied research and development, universities

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280 Nelson, supra note 55 at 467.


282 Moses III et al., supra note 162, at 1337. Federal expenditures accounted for 64% of the research support provided by universities. Id.

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

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, including: the Bayh-Dole Act; doctrinal reforms expanding the scope of patentable subject matter; advances in molecular biology revealing a relatively clear path from “basic” discoveries to commercial products; and market pressures on universities. University technology transfer offices, a relatively recent phenomenon, have become ubiquitous. Between 1991 and 2000, universities exhibited an 85% increase in inventions disclosed, a 238% increase in new patent applications, a 161% increase in licensing arrangements, and a 520% increase in royalties. By 2002, universities were awarded more than 3,000 patents a year, with licensing revenues exceeding $1.2 billion. The number of patents held and the number of licenses arranged by universities more than doubled between 1991 and 2005.

University patenting is particularly prevalent in the biopharmaceutical field. University research in genetics and molecular biology spawned the biotechnology industry; in that sector alone, universities hold approximately 18% of all patents. 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. In general, university patents are more likely to cover building blocks critical to innovation, including biomedical research tools, rather than particular downstream applications of a technology. Universities thus hold assets

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288 See notes - and accompanying text.
293 Powell & Owen-Smith, supra note 287, at 257; Gelijns & Thier, supra note 286, at 73; Jaffe, supra note 12, at 541; Eisenberg, *Patents, Product Exclusivity, and Information Dissemination*, supra note 96, at 479.
294 Gelijns & Thier, supra note 286, at 73; see G. Steven McMillan et al., *An Analysis of the Critical Role of Public Science in Innovation: The Case of Biotechnology*, 29 RESEARCH POLICY 1, 5 (2000).
296 Gelijns & Thier, supra note 286, at 74.
of immense value that private firms seek to exploit.\textsuperscript{298} The resulting leverage allows universities to advance institutional norms favoring a robust research commons in licensing arrangements with downstream parties.

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

While universities are traditionally seen as bastions of open science,\textsuperscript{299} recent increases in university patenting have raised anxieties that commercial interests may be eroding traditional norms.\textsuperscript{300} As a general matter, the increasing commercialization of universities has raised concerns over: financial interests unduly influencing research agendas,\textsuperscript{301} increased secrecy and publication delays,\textsuperscript{302} manipulation of results,\textsuperscript{303} decreases in academic productivity,\textsuperscript{304} conflicts of interest between universities and their faculties,\textsuperscript{305} weakening of academic freedom,\textsuperscript{306} the erosion of public confidence in university science,\textsuperscript{307} and even reduced dissemination of university research findings throughout the developing world.\textsuperscript{308} Complicating the rise of university patenting has been the independent, though related, rise in university-industry...

\textsuperscript{298} Kesselheim & Avorn, supra note 170, at 851; cf. Narin et al., supra note 79, at 318. Of course, knowledge transfer between academic and private-sector institutions is often complex and bidirectional. Golden, supra note 13, at 119; Gelijns & Thier, supra note 286, at 76.


\textsuperscript{300} See generally BOK, supra note 289; see also JENNIFER WASHBURN, UNIVERSITY, INC.: THE CORPORATE CORRUPTION OF HIGHER EDUCATION (2005); Gelijns & Thier, supra note 286, at 76; Catherine D. DeAngelis, The Influence of Money on Medical Science, 296 JAMA 996 (2006); Raymond S. Fersko & Hind Merabet, Sponsored Research and the Public’s Right to Know, 63 DRUG DEVELOPMENT RESEARCH 103 (2005); Steven Brint, Creating the Future: ‘New Directions’ in American Research Universities, 43 MINERVA 23 (2005); Michael Gibbons, Changing Patterns of University-Industry Relations, 38 MINERVA 1573 (2000); Melissa Healy, From Fundings to Findings, L.A. TIMES, Aug. 6, 2007, at .


\textsuperscript{302} BOK, supra note 289, at 64-76; Press & Washburn, supra note 301; David Blumenthal et al., Relationships Between Academic Institutions and Industry in the Life Sciences – An Industrial Survey, 334 NEW ENG. J. M. 368 (1996); Margo A. Bagley, Academic Discourse and Proprietary Rights: Putting Patents in Their Proper Place, 47 B.C. L. REV. 217, 217 (2006); Jon F. Merz et al., Diagnostic Testing Fails the Test, 415 NATURE 577, 579 (2002).

\textsuperscript{303} Press & Washburn, supra note 301.

\textsuperscript{304} David Blumenthal et al., Participation of Life-Science Faculty in Research Relationships in Industry, 335 NEW ENG. J. M. 1734, 1738 (1996).

\textsuperscript{305} David J. Triggle, Patenting the Sun: Enclosing the Scientific Commons and Transforming the University – Ethical Concerns, 63 DRUG DEVELOPMENT RESEARCH 139, 143-44 (2005).


\textsuperscript{307} Triggle, supra note 305, at 144-45.

\textsuperscript{308} Triggle, supra note 305, at 145.
partnerships. These partnerships often allow industry partners to obtain patent rights arising from industry-sponsored, university-conducted research.

Most salient for our purposes, university patenting and profit motives may be eroding traditional academic norms of open science. University-generated knowledge that would have previously entered the public domain is now being subject to intellectual property constraints, which may exacerbate anticommons problems. Additionally, Professor Lemley has questioned whether universities behave like “patent trolls,” entities that accumulate patents but do not manufacture goods, instead relying on licensing fees and the threat of litigation for revenue. Indeed, several high-profile cases reveal universities’ aggressive approach to enforcing their patents.

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

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311 See, e.g., Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997); Eolas Technologies v. Microsoft, 399 F.3d 1325 (Fed. Cir. 2005).
313 Thursby & Thursby, supra note 290, at 1052.
314 Eisenberg, Public Research and Private Development, supra note 167, at 1726.
315 Thursby & Thursby, supra note 290, at 1052.
316 Sobolski et al, supra note 315, at 3137.
317 Thursby & Thursby, supra note 290, at 1052.
318 Sobolski et al, supra note 315, at 3137-40.
319 Sobolski et al., supra note 315, at 3137; David Baltimore, On Over-Weighting the Bottom Line, 301 SCIENCE 1050, 1050 (2003); Leaf, supra note 171, at .
320 Sobolski et al., supra note 315, at 3138.
about 95% of all licensing revenues at Columbia University. 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. At an individual and group level, the scientific community has long been characterized by norms emphasizing openly sharing knowledge and ideas. These “public sector values” have been cultivated by the taxpayer-funded research system encompassing university and government laboratories. University knowledge production is motivated by a host of non-financial rewards, and is built on freely exchanging ideas and information. While some caution that patents have eroded this communal culture, others point out that informal sharing norms persist even within an increasingly proprietary environment.

It appears that a similar phenomenon applies at the institutional level as well. In some ways, the traditional research norms of open science have adapted themselves to the new patent-intensive environment in which universities currently operate. At a broad level, universities are still committed to widely and promptly disseminating research results. These principles also extend, at least in part, to intellectual property policies. 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. Harvard University’s intellectual property policy is representative in this fashion when it acknowledges the university’s “primary commitment” to the public interest. For its part, the Association of University Technology Managers (AUTM) observes that most of its members “would define

323 Gelijns & Thier, supra note 286, at 75.
324 See Baltimore, supra note 321, at 1050; Nelsen, supra note 55, at (“[M]ost universities insist that dissemination of research results is key to their identity and mission and will not agree to keep the project results secret.”). Of course, some view closer collaborations with private firms as intrinsically related to universities’ traditional mission to disseminate knowledge. Faley & Sharer, supra note 171, at 114.
325 See supra note 13.
326 Golden, supra note 145, at 90-93.
327 See Kahan, supra note 13, at 95-93.
328 Eisenberg, Proprietary Rights and the Norms of Science, supra note 50, at 182; Rai, Regulating Scientific Research, supra note 17.
330 Murray, supra note 74, at 42; cf. Merges, Property Rights Theory and the Commons, supra note 329, at 150.
332 See, e.g., Brewster et al., supra note 281, at 49, 51 (collecting intellectual property policies of the top four universities in terms of patent activity).
success through the criterion of public benefit.”

While the commercialization of universities is a real phenomenon, these norms suggest that universities can and do take a wider view of patenting than revenue maximization.

3. University Licensing Policies Favoring Access to Patented Research Tools

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

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. 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.” Typically, these provisions do not only reserve a research exemption for the licensing institution itself, but also provide for research licenses for all other non-profit research institutions as well. According to Andrew Neighbour of UCLA, technology transfer offices “always insist on a research exception not only for themselves, but for other nonprofit institutions; adding the other nonprofits into the research exception has been a trend.”

For example, a sample reservation of rights clause in an exclusive license from the University of California states, “Nothing in this Agreement will be deemed to limit 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.” Similar language appears in technology transfer agreements from universities around the country. Notably, these clauses directly respond to the Federal Circuit’s narrow conception of the

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334 Association of University Technology Managers, U.S. Licensing Activity Survey: FY 2006, at 13. For example, Public Intellectual Property Resources for Agriculture (PIPRA), a consortium of over 40 universities and research institutions, bundles and licenses agriculture-related patents for low-cost exploitation in the developing world.
335 See Lemley, Are Universities Patent Trolls?, supra note 22, 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.”).
336 See Benkler, Commons-Based Strategies, supra note 22, at 1110-11; Brewster et al., supra note 281, at 56; Murray, supra note 74, at 39.
337 Pressman et al., supra note 19, at 35.
338 See, e.g., id. at 35 (drawing examples from Harvard University, UCSD, UCLA, UCSF, and UC Berkeley).
339 Id. at 35.
340 Alan B. Bennett, Reservation of Rights for Humanitarian Uses, in HANDBOOK OF BEST PRACTICES, supra note 27, at 42. See also In the Public Interest: Nine Points to Consider in Licensing University Technology 10-12, available at news-service.stanford.edu/news/2007/march7/gifs/whitepaper.pdf [hereinafter, In the Public Interest].
experimental use exception articulated in *Madey v. Duke University*. Many of these clauses define the research exception by explicitly listing the types of activities that *Madey* held did not qualify for the common law experimental use exception.

This emerging practice is consistent with guidelines arising from a recent consortium of university technology transfer officers organized by Stanford University. The Stanford consortium recommends that universities reserve the right to practice licensed inventions and to allow other non-profit and governmental organizations to do so as well. The guidelines include this example provision:

\[
\text{INSTITUTION reserves the rights, for itself and others, to}
\]

\[
\begin{align*}
(i) & \text{ make and use, solely for NON-COMMERCIAL RESEARCH PURPOSES,} \\
& \text{ the subject matter described and claimed in PATENT RIGHTS and} \\
& \text{ covered by PROPERTY RIGHTS and} \\
(ii) & \text{ provide to OTHERS the BIOLOGICAL MATERIALS;} \\
& \text{ each solely for NON-COMMERCIAL RESEARCH PURPOSES.}
\end{align*}
\]

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

b. Exclusive Versus Nonexclusive Licensing

Universities are also promoting the wide availability of research tools by favoring nonexclusive licensing of such technologies. Universities have a long history of utilizing their intellectual property to advance basic research in this manner. As a case in point, Stanford University and the University of California nonexclusively licensed the Cohen-Boyer patents covering gene splicing, a fundamental research tool, for a relatively low rate of $10,000 per license. This appears to be a win-win situation in which widespread licensing of the gene splicing technology helped it become the single most profitable invention licensed by these two universities.

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.

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342 Bennett, *supra* note 340, at 42; *In the Public Interest, supra* note 340, at 11.
343 *In the Public Interest, supra* note 340, at 2.
344 *Id.* at 10.
345 *Id.* at 11.
349 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 POLICY & ECON. 187, 194 (2001); Smith Hughes, *supra* note 300, at 542. Columbia University also nonexclusively licensed the Axel patents related to gene insertion in mammalian cells, but only did so upon direct compulsion by the NIH. See *supra* Part IV.A.
and development; in the latter situation, exclusive licensing may be necessary to provide requisite incentives to innovate. While the majority of university licenses continue to be exclusive, universities are beginning to adopt policies drawing these distinctions and favoring nonexclusive licensing of fully functional research tools for noncommercial research purposes.

Consistent with the policies of the NIH and many academic journals, the Stanford consortium recommends that licenses should not curtail the availability of patented research tools for basic experimentation:

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

Following these guidelines, a university should insist that licenses for research reagents, kits, or devices are “exclusive for the sale, but not use” of such resources. In this manner, members of the scientific community may still use patented technologies for research purposes, but they may not sell them, thus maintaining the commercial incentives of exclusive licensees.

Evidence suggests that universities are already following these policies. A survey of university technology transfer offices revealed a preference for nonexclusively licensing most DNA research tools. Furthermore, respondents noted that the same patent could be licensed differently for research use versus commercial use. 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 commercialization costs associated with developing these products. However, universities are less likely to patent (and more likely to nonexclusively license) DNA sequences that are markers only, as the immediate utility of such inventions is unclear and the development costs associated with them are relatively small.

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,

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350 Jaffe, supra note 12, at 552; but see Golden supra note 13.
352 See Lemley, Patenting Nanotechnology, supra note 50, at 628 (suggesting utilizing the Bayh-Dole Act to restrict the ability of universities to exclusively license basic building block patents).
353 In the Public Interest, supra note 340, at 5.
354 Id. at 3.
355 Id. at 5.
356 Id. at 5.
357 See Golden, supra note 13, at 143 (“[G]overnment laboratories and universities have favored widespread granting of non-exclusive licenses, particularly for their more fundamental inventions.”).
358 Pressman et al., supra note 19, at 34-35.
359 Id. at 35.
360 Id. at 33.
361 Id. at 33-34.
universities are creating one through contract. Given the dominant role that universities play in research, patenting, and technology transfer, the potential impact of broad-based adoption of these policies is enormous.

The viability of this effort depends on the strength of access norms in the face of potential profits arising from exclusivity. In *Madey v. Duke University*, the Federal Circuit characterized universities as commercial entities with business objectives that included raising revenues. While this characterization is true to a certain extent, academic norms still persist. While it is beyond the scope of this Article to fully resolve the impact of patenting and commercial influences on university culture, it is fair to say that universities are a different sort of patentee than most commercial firms. The traditional goal of universities has been to serve the public interest with education and research, not to maximize profits. Indeed, the unique normative character of universities compared to private industry 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.

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

While universities have taken steps to act on these norms, more can be done. As Professor Lemley has argued, “universities must first recognize their proper role in society and how that role affects patent policies.” Public scrutiny and moral suasion can help reinforce open science licensing at universities. Perhaps aided by the realization that windfall profits are highly unlikely, university technology transfer offices can take a broader view of their role in technology transfer. While some are skeptical that universities would voluntarily adopt open licensing practices that may lower revenues, to varying extents, they are already doing so.

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363 Even this is a controversial assertion for some. For example, Columbia University has attracted significant criticism for its attempts to extend the life of the Axel patents on techniques for inserting genes in cells. See, e.g., Wysocki, Jr., *supra* note 223, at A1; Howard, *supra* note 222; *Ownership At Too High a Price*, 21 NATURE BIOTECH. 953, 953 (2003).
364 Baltimore, *supra* note 321, at 1050; see *In the Public Interest, supra* note 340, 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”).
366 Gelijns & Thier, *supra* note 286, at 77.
368 Jaffe, *supra* note 12, at 552.
370 Nelson, *supra* note at 55, 469.
Notably, the mechanism by which universities are articulating these norms and constructing a research commons is contracts. Universities are contractually protecting open science by reserving research rights for themselves and other non-profit institutions in patent licenses. Furthermore, universities are enhancing the availability of patented research tools by nonexclusively licensing them. There is an underlying legitimacy to using quid pro quos to advance policy objectives, which potential licensees voluntarily accept as part of a mutually beneficial bargain. While concerns over market dominance and unconscionable contracts must apply to universities as well as to any other patentee, accepting a noncommercial research exception as a condition of receiving a license appears less coercive than top-down regulation curtailing one’s patent rights.

Of course, university insistence on access conditions in licensing practices faces several challenges. First, the disconnect between university intellectual property policy and practice reflects in many ways a principal-agent problem. Technology transfer offices whose performance is measured by revenues have strong incentives to grant exclusive licenses. If these offices are to act consistently with lofty mission statements, universities must consider changing their incentive structures and performance metrics. Second, while best practices suggest that universities retain a research exemption for all non-profit research organizations, some licenses only reserve a research exemption for the particular institution itself, thus producing scientific “fiefdoms.” Third, as Professors Rai and Eisenberg have argued, university technology transfer offices (as opposed to the NIH) may lack the technical competence to optimally manage the licensing of patented biomedical inventions. Distinguishing among various technologies, licensees, and uses is crucial for ideal exploitation of biomedical inventions. This may be a challenging task for technology transfer offices that on average employ four professionals.

D. Non-Profit Funding Organizations

Non-profit organizations are also leveraging their support for biomedical research to insist that grant recipients refrain from asserting patent rights to impede basic research. In 2003, non-profit organizations provided $2.5 billion to support such research, and they are

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371 Lemley, Are Universities Patent Trolls?, supra note 22, at 616; see Faley & Sharer, supra note 171, at 125.
372 Rai & Eisenberg, supra note 10, at 305.
373 Bennett, supra note 340, at 42; Thursby & Thursby, supra note 290, at 1052; Yale University, supra note 333; see Pressman et al., supra note 19, at 37.
375 Foundations established by nineteenth-century industrialists played a major role in funding early biomedical research, but were eclipsed by government funding following World War II. See Robert I. Field et al., Toward a Policy Agenda on Medical Research Funding: Results of a Symposium, 22 Health Affairs 224, 225, 227 (2003); P. Balaram, Philanthropy and the Funding of Science, 83 Current Science 537, 537 (2002).
376 Moses III et al., supra note 162, at 1335. In 2006, the top five contributors to biomedical research in the United States were the Bill and Melinda Gates Foundation ($908 million), the Howard Hughes Medical Institute ($694 million), the Sowers Institution for Medical Research ($73 million), High Q and CHDI ($50 million), and the Ellison Medical Foundation ($36 million). Lucy Olding-Smee, The Money Tree, 447 Science 251, 251 (2007).
expected to grow in importance as funding sources. Furthermore, what they fund is oftentimes more important than how much they fund. Foundations fill gaps by funding research that is scientifically speculative, politically risky, or unpopular and where commercial value is low or not readily apparent. This “gap filling” function extends to funding new and interdisciplinary research that may not receive NIH support. The Howard Hughes Medical Institute (HHMI), for example, describes its culture as prizing “bold thinking and scientific risk taking.” Interestingly, the high tech boom of the 1990s produced a new generation of “venture philanthropists” who are particularly committed to strategic risk-taking. By providing venture capital in new, cutting edge areas of biomedical research, non-profits exert greater influence over research than their absolute dollar contributions suggest.

This monetary support, moreover, often comes with strings attached. As a case study, this Subpart will focus on HHMI, a “major force in funding biomedical research” that contributed $599 million to research in 2007. As with other non-profits, HHMI does not support biomedical research to profit from it. HHMI’s intellectual property policies state that it “conducts scientific research in the public interest,” and that it has adopted its policies “to help ensure that inventions, discoveries, and other fruits of HHMI’s research are made available for the benefit of the public.” Consistent with other public institutions, HHMI embeds access-related policy objectives in funding arrangements with private grantees.

HHMI maintains several policies ensuring wide access to patented research tools arising from its funding. HHMI possesses a unique structure in that it sponsors investigators at “host institutions”—usually universities—as well as conducts intramural research at its Janelia Farm Research Campus. HHMI claims an ownership interest in any invention where at least one inventor is an HHMI employee. Although grant recipients may patent their inventions, HHMI retains an institution-wide, paid-up, non-exclusive irrevocable license to use any HHMI-funded invention for noncommercial purposes. HHMI’s policy on research tools is consistent with NIH guidelines, and it “expects all HHMI research tools to be made available to the scientific research community on reasonable terms and in a manner that enhances their widespread availability.” HHMI is also a signatory of the NIH’s Uniform Biological Materials Transfer

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378 Moses III et al., supra note 162, at 1339; Field et al., supra note 375, at 227.
379 Moses III et al., supra note 162, at 1338.
380 Howard Hughes Medical Institute, 2007 Annual Report 2 (2007); see also Bill and Melinda Gates Foundation, Annual Report 2006, at 14 (2007) (“We try new ideas in the laboratory and in the field – sometimes taking risks that business and government can’t.”).
382 Balaram, supra note 375, at 538.
387 NIH, Principles and Guidelines, 64 Fed. Reg. at 72,092 n.1.
388 HHMI, Research Tools, supra note 386, at 1.
Agreement (UMBTA), and it encourages the use of a simplified one-page agreement to facilitate material transfers to non-profit organizations. Given the reach of HHMI funding throughout the biomedical research world, the scope of these policies is quite substantial.

As with CIRM, HHMI has also issued policies specific to materials, data, and software described in academic publications. Upon publication of HHMI-funded work, laboratory heads are “expected” to make materials, data, databases, and software available for research use within 60 days of receiving a request. 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.

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

HHMI policies on sharing of research tools and published materials also govern licensing of inventions developed at its Janelia Farm Research Campus. This includes reserving a

390 HHMI, Materials Transfers, supra note 389, at 1.
392 Id. at 2.
393 HHMI, Intellectual Property Policy, supra note 384, at 3.
397 HHMI, Intellectual Property Guide for Host Institutions, supra note 385, at 9; HHMI, Research Tools, supra note 386.
399 HHMI, Research Tools, supra note 386, 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 385.
research use exception in all licenses with downstream partners as well as favoring nonexclusive licensing of research tools.

1. Analysis

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

Non-profit funding agencies thus emerge as policy actors in creating a research commons for biomedicine. Experienced players such as HHMI are similar to the NIH in terms of technical competence and are well-equipped to draw meaningful distinctions between research use and commercial sale of patented assets. However, HHMI’s efforts also exhibit certain limitations. HHMI only reserves a paid-up research license for itself and requires transfer of patented materials to outside non-profits on “reasonable terms,” thus permitting a small degree of price discrimination. Widening the scope of reserved research rights could better advance the objective of open science, but may make HHMI funding less attractive to recipients. Also, while HHMI is a substantial player, the provisions upon which it insists are coextensive only with the reach of its grants.

E. Disease Advocacy Groups

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

The development of a diagnostic test for Canavan disease, a gene-linked cerebral degenerative disorder, demonstrates the vital upstream support that donors of biological

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materials can provide to biomedical research. 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. Greenberg provided Matalon with blood, brain, and urine samples from his own family. Along with the National Tay-Sachs and Allied Diseases Association of Chicago and Dor Yeshorim, an organization that provides genetic screening to Orthodox Jewish couples, Greenberg helped establish a registry of 160 Canavan-affected families. Utilizing these tissue donations, in 1993 Matalon isolated the aspartoacylase gene associated with Canavan disease and developed a genetic test to screen for the condition.

As the Canavan episode illustrates, however, the norms of the disease advocacy community can diverge sharply from that of most patentees. The Canavan Foundation began offering free Canavan screening in 1996. Matalon’s employer at the time of his discovery was Miami Children’s Hospital (MCH), which, unbeknownst to the families and patients’ organizations, applied for a patent on the Canavan gene in 1994, receiving it in 1997. 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. Greenberg and the patients’ organizations objected to these constraints. They brought suit in October 2000 against MCH, alleging a variety of claims, including misappropriation of trade secrets, based on Matalon’s use of the children’s blood and tissue. While upstream contributors favored norms of access and distribution, the downstream patentee favored exclusivity.

Ultimately, the disease advocates were able to leverage their contributions to basic research to carve a research exception out of MCH’s patent rights. In Greenberg v. Miami Children’s Hospital et al., Greenberg and the various non-profit groups argued that by virtue of their contributions, they had a right to control commercialization of the patent. The donors believed that any resulting genetic tests would be readily affordable “and that [the] research would remain in the public domain.” The court dismissed all of the plaintiffs’ claims except their claim for unjust enrichment. That issue was never resolved on the merits, however, as

405 Eliot Marshall, Families Sue Hospital, Scientist for Control of Canavan Gene, 290 SCIENCE 1041, 1062 (2000) [hereinafter Marshall, Families Sue Hospital].
407 Novas, supra note 402, at 299.
408 MCH planned to license the test to a large commercial lab that would dominate the market. Rao, supra note 404, at 373.
409 Marshall, Families Sue Hospital, supra note 47, at 1062; Canavan Foundation Joins Lawsuit against Miami Children’s Hospital, supra note 406
410 264 F. Supp. 2d 1064 (S.D. Fla. 2003); see Gitter, supra note 404, at 331-38; see Marshall, Families Sue Hospital, supra note 405, at 1062; Rao, supra note 404, at 373.
412 264 F. Supp. at 1066.
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.13

As the Canavan gene controversy illustrates, disease advocacy groups can make vital contributions to basic biomedical research. Furthermore, members of the patient community often privilege developing cures and facilitating further scientific investigation rather than maintaining exclusivity and maximizing profits.14 Ultimately, Greenberg and the disease advocacy groups were able to extract a research exception for MCH’s patented gene, although they did so in a very costly and indirect manner: litigation.

Contrary to the Canavan disease groups, the advocacy group associated with pseudoxanthoma elasticum (PXE) has had much more success leveraging upstream contributions of bodily tissues to control the availability of patented discoveries arising from them.15 In 1994, Patrick and Sharon Terry’s two children were diagnosed with PXE, a rare genetic disorder that affects connective tissue.16 Shortly thereafter, the Terrys “began to scheme about what we would do if we were managing research on this disease.”17 In 1995, the Terrys founded PXE International, which, among other functions,18 established a blood and tissue registry to facilitate research on the disease.

Responding in part to the Canavan disease episode, PXE International negotiated contracts with researchers whereby it would retain ownership rights in any patents arising from research based on access to its registry.19 This arrangement allowed PXE International to share in any revenue, ensure affordable genetic tests, and influence future licensing. The registry has thus served as a “significant relay of power” through which PXE International has been able to coordinate and influence scientific activities.20

Ultimately, PXE International was able to leverage its contributions to research to obtain patent rights in the PXE gene. The organization was instrumental in the 2000 discovery by University of Hawaii pathobiologist Charles Boyd of the transporter gene that causes PXE.21 In an unusual move, Sharon Terry was listed as a co-inventor on the patent application for the gene, along with four university researchers.22 As per standard practice, the University of Hawaii held

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15 See Gitter, supra note 404, at 315-24; Paul Smaglik, Tissue Donors Use Their Influence in Deal Over Gene Patent Terms, 407 NATURE 821, 821 (2000); Safrin, supra note 404, at 1934-35; Gina Kolata, Sharing of Profits is Debated As the Value of Tissue Rises, N.Y. TIMES, May 15, 2000, at .
17 Shannon F. Terry, Learning Genetics, HEALTH AFFAIRS, Vol. 22, No. 5, 166, 169 (2003). According to Shannon Terry, “We didn’t want to do the science without the ethics and the only way to make it all work was to have control of it ourselves.” Arthur Allen, Who Owns My Disease?, MotherJones.com, Nov/Dec 2001 (quoting Shannon Terry).
18 In the course of three years, the Terrys raised $500,000 for research. Allen, supra note 417, at .
20 Novas, supra note 402, at 296.
21 The gene is known alternatively as ABCC6 or MRP6.
22 Marshall, Patient Advocate, supra note 416, at 1226.
the rights to Boyd’s inventions. Initially, conflict arose between the university’s interest in selectively licensing the gene and PXE International’s commitment to broad and low-cost licensing. Ultimately, however, the two parties reached an agreement whereby PXE International would make all licensing decisions and the parties would split the royalties deriving from any diagnostic test or marketable product.

Significantly, through exercising control over the patented PXE gene, PXE International has ensured that scientists have access to the gene for research purposes. PXE International has licensed the gene to 19 laboratories and eight biotechnology companies. Such widespread licensing is consistent with PXE International’s aim to maximize “patient-centric opportunities.” In this case, PXE International has been able to exercise its ownership of the PXE gene to ensure its availability in a research commons.

1. Analysis

The experiences of groups associated with Canavan and PXE disease reveal how disease advocacy groups are actively engaged in private ordering to prevent patent holdup. These groups are leveraging their contribution of bodily materials to biomedical research to impose access requirements on resulting patented technologies. Although not normally seen as policy actors, these organizations are engaged in consideration-based patent regulation. While the contributions of advocacy groups to basic biomedical research are not new, the Terrys’ experience represents a powerful template for how such groups can aggressively promote scientific research and distribute its results. This promises to be a growing trend.

The contribution of disease advocacy groups to basic biomedical research allows them to express norms privileging access to resulting discoveries. As opposed to downstream patentees such as MCH and the University of Hawaii, disease advocates generally aim for the wide availability of patented assets. According to Shannon Terry, her co-ownership of the PXE gene patent ensures that PXE International is now “driving the boat;” she considers herself and her organization “stewards” of the gene. Norms matter a great deal to how these organizations utilize patents. In the basic research context, they are invoking patents to assert an ongoing right to include.

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423 Gitter, supra note 404, at 318.
424 Gitter, supra note 404, at 318.
425 Novas, supra note 402, at 297.
426 Novas, supra note 402, at 297.
427 A similar strategy has been used by the Alpha-1 Foundation, which represents Alpha-1 antitrypsin deficiency sufferers. Jasper Bovenberg, Whose Tissue Is It Anyway, 23 NATURE BIOTECH? 929, 931 (2005); Jon F. Merz et al., Protecting Subjects’ Interests in Genetic Research, 70(4) AMERICAN JOURNAL OF HUMAN GENETICS 965, 966 (2002) [hereinafter Merz et al., Protecting Subjects’ Interests].
428 Novas, supra note 402, at 297.
429 Gitter, supra note 404, at 318. Cure Autism Now and the Juvenile Diabetes Research Foundation International have also pooled members’ specimens to create biorepositories. Id. at 318-19. Shannon Terry is currently the President and CEO of the Genetic Alliance, a coalition of over 600 disease advocacy groups. PXE International, http://www.pxe.org/english/View.asp?x=1683.
430 Novas, supra note 402, at 303.
431 Marshall, Patient Advocate, supra note 416, at 1226.
432 Terry, supra note 417, at 170.
In a variety of ways, contracts are driving these efforts. First, in the most direct sense, PXE International’s ownership of the PXE gene patent ensures that it will be able to license the patent widely throughout the research community. Second, even aside from owning a patent on a gene itself, contractual conditions on accessing tissue registries provide leverage for advocacy groups to influence the disposition of patented inventions. While the Canavan plaintiffs did not own the Canavan gene patent, they were ultimately able to translate their contributions of unique bodily materials to ensure a research exception for MCH’s patented gene. More formally, PXE International explicitly conditioned access to its tissue registry on receiving some say in how resulting intellectual property would be used. The quid pro quo implicit in these registries is that if a scientist wants access, she must agree to provide any resulting patented materials widely for research purposes.

This approach portends many benefits for advancing basic scientific research. It expands the contractually-created research commons to biomedical resources affecting rare disease, which are unlikely to be the subject of NIH funding or large-scale university research. From the perspective of institutional competence, motivated disease groups may be well-positioned to distinguish between various uses of patented research tools, exclusively licensing technology when necessary to facilitate additional development. The entrepreneurial engagement of disease advocacy groups also serves 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.”

Providing tissue donors with some say in the availability of resulting patented inventions acknowledges their vital contributions to basic research.

Of course, the contractual creation of a research commons by disease advocacy groups faces several challenges. As in other contexts, control over intellectual property may facilitate parochialism. While investigating the PXE gene may reveal insights into macular degeneration, hypertension, and cardiovascular disease, it is conceivable that PXE International’s interest in the gene may only extend to its namesake disease, thus leaving other conditions unexplored. Additionally, tissue donors negotiating quid pro quos with researchers raise unique biomedical ethical concerns beyond the scope of this Article. This behavior substantially challenges the notion of the gift as the founding gesture of participation in biomedical research. Such “compensation” may conflict with the prohibition against “undue inducement” and may...

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433 Cf. Gitter, supra note 404, at 315.
434 Merz et al., Protecting Subjects’ Interests, supra note 427, at 969.
435 Novas, supra note 402, at 297; Rao, supra note 404, at 378; cf. Gitter, supra note 404, at 323; Bovenberg, supra note 427, at 932.
436 While Shannon Terry has stated that “we don’t just represent people with PXE, we represent anybody who has anything,” she nonetheless acknowledges that PXE International’s focus is to help develop a low-cost PXE diagnostic test and treatment. Fleischer, supra note 419, at 100.
438 Hayden, supra note 402, at 740.
discourage truly altruistic donations by patients whose tissues are necessary to conduct research.\footnote{\textsuperscript{440}Fleischer, supra note 419, at 87.}

**Part V. Opportunities, Challenges, and Prescriptions**

Across government, academia, and the non-profit sector, institutions are taking matters into their own hands to address potential patent holdup in biomedical research. At a macro level, these efforts reflect the privatization of public policy in patent law. In many ways, these actions respond directly to the perceived limitations of public law solutions, most notably the narrowing of the experimental use exception. This development exploits the enormous contributions of public institutions to biomedical research by embedding access requirements to patented inventions in quid pro quos with downstream partners. This Part critically assesses this trend, providing prescriptions for public institutions to better manage the contractual construction of a research commons. In so doing, it explores the promises and perils of consideration-based patent regulation more generally.

**A. Opportunities and Advantages**

The primary advantage of a contractual approach to exempting noncommercial research from patent infringement is that it is actually working. As explored in Part II, public law initiatives to address this problem, such as reinvigorating the common law experimental use exception or modifying patentable subject matter, are difficult to implement and may be overinclusive. On the contrary, tying access conditions to valuable consideration in individual contracts is an implementable approach that is less likely to disrupt settled expectations. While it cannot achieve the scope of public law initiatives, consideration-based patent regulation by individual institutions represents a supplementary working solution to the problem of patent holdup.

Further enhancing the viability and possible expansion of consideration-based patent regulation is its exploitation of the existing “normative hierarchy” of the biomedical research sector. Subject to exceptions, institutions that dominate upstream support for biomedical research generally share a commitment to widely disseminating the fruits of that research with secondary regard for profits. While the norms, objectives, and motivations of the institutions profiled here are certainly not homogenous\footnote{\textsuperscript{441}Merz et al., Protecting Subjects Interests’, supra note 427.}—frictions, for example, have arisen between the NIH and universities—in policy and practice they distinguish themselves from traditional rent-seeking patentees. The proposal here is not a request for private firms to “do the right thing” and forgo profits for the greater good.\footnote{\textsuperscript{442}Interestingly, firms are increasingly heeding these requests. See A Special Report on Corporate Social Responsibility, The Economist, Jan. 19, 2008; Joel C. Dobris, SRI—Shibboleth or Canard (Socially Responsible Investing, That Is), 42 REAL PROP. PROB. & TRUST J. 755, (2008).} Rather, it is a call for public institutions to wield their substantial market power to promote self-articulated values.

Of particular importance, consideration-based patent regulation provides considerable freedom to operate for governmental entities. Reforming in rem patent rights is cumbersome and
likely to embroil vested political interests. Potential judicial innovations are, of course, 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 even more salient to state governments. If California passed a statute subjecting all patented inventions in that state to a noncommercial research exemption, it would surely run afoul of federal preemption doctrine. However, by acting in a funding capacity rather than a “legislative” capacity, CIRM is free to impose just that restriction on its grantees.

Unlike traditional regulation, the in personam nature of this approach also allows for precise, highly contextualized policy interventions. Access and exclusivity both play important roles in optimally exploiting biomedical resources, which often requires distinguishing research use from commercial development and sale. As distinctions increase, information costs rise and patents begin to function less like simple rights to exclude and more like complex governance regimes. General legislation may lack the granularity to address individual situations. Ideally, these regimes would be managed on one-to-one bases between grantors and grantees or licensors and licensees. Through maintaining thousands of these relationships, public institutions are negotiating, monitoring, and fine-tuning arrangements to ensure that patented research tools are widely available for noncommercial research purposes while maintaining context-specific exclusivity to ensure commercial development.

B. Challenges and Prescriptions

Of course, consideration-based patent regulation in general, and the contractual creation of a research commons in particular, must address several challenges. First, such efforts only establish a research commons within the funding and licensing sphere of influence of certain public institutions. (As noted, however, this may be an advantage, as a research exception for privately-developed research tools may undermine incentives to invent.) Not all public institutions will voluntarily adopt these safeguards. Furthermore, the Bayh-Dole Act prevents the NIH from directly establishing a research exception for federally-funded biomedical inventions. The result is a patchwork arrangement rather than a general noncommercial research exception for publicly-developed research tools. As others have noted, streamlining the administrative requirements of the Bayh-Dole Act would strengthen the NIH’s authority to direct patentee licensing practices. Such reforms would enhance the NIH’s ability to compel recalcitrant public institutions—especially universities—to adopt open licensing policies.

A more serious challenge is that placing onerous burdens on grant recipients and patent licensees may chill public-private sector partnerships and technological development. After all, the primary motivation behind the Bayh-Dole Act was to provide property rights to the private sector to encourage commercialization of taxpayer-funded inventions. Excessive strings on money, patent rights, or materials could stifle these exchanges. However, carefully drafted

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443 See supra note 1.
444 See Smith, supra note 38.
445 Rai & Eisenberg, supra note 10.
noncommercial research exceptions can ensure exclusivity for sale of refined inventions to encourage investment in product development. For example, allowing patented human embryonic stem cells to be widely used for academic research, but allowing context-specific, exclusive licensing for commercial development leading to “value-added” products seems an appropriate approach to take.\footnote{I emphasize “context specific” because an exclusive licensee may not be well situated to coordinate the development of all commercial applications of assets so “pluripotent” as human embryonic stem cells. See Rai & Eisenberg, supra note 10, at 309-10.}

A related challenge is institutional competence. Distinctions are crucial for technologies that simultaneously represent fully-functional research tools as well as precursors to more refined commercial products. Some public entities, such as the NIH and non-profit funding agencies, may be better situated than others to draw these distinctions.\footnote{See Rai & Eisenberg, supra note 10.} As entities like CIRM gain more experience in monitoring grants, their technical capacity will increase. Furthermore, collective organizations like the Stanford consortium and the Association of University Technology Managers can provide technical assistance to university technology transfer offices to help implement the provisions described here.

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

Of course, a significant limitation on the contractual construction of a research commons is that it depends 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.\footnote{Cf. Oona Hathaway, Do Human Rights Treaties Make a Difference?, 111 YALE L.J. 1935 (2002) (arguing that countries sometimes enjoy the expressive benefits of ratifying human rights treaties without actually complying with them).} This criticism is particularly salient to universities, some of which espouse the ideals of open science while vigorously enforcing their patents.\footnote{See, e.g., Howard, supra note 222.} Second, institutions often subscribe to conflicting norms. Thus, for example while CIRM promotes the open sharing of discoveries, it also takes a financial stake in the research it funds. Finally, implementing organizational norms is subject to principal-agent problems. This is illustrated in the disconnect between lofty intellectual property policies and the behavior of some university technology transfer offices. For such offices to act consistently with stated policies, university leadership may need to modify their incentive structures and performance metrics. In a broad sense, disciplined focus on organizational objectives, coordinated action (to eliminate free riders), and compulsion from other public institutions (such as the NIH) can help reinforce upstream norms.
Part VI. Implications for Patent Law, Institutions, and Theory

In addition to providing an implementable solution to patent holdup, the contractual creation of a research commons holds several wider implications for patent law.

Most notably, it illustrates a significant shift from broadly-applicable property rules to individual contracts as a means for implementing patent policy. Unlike traditional judicial, legislative, or administrative regulation, this model relies on the quid pro quo of mutual exchange to promote public policy. This shift from property to contract, moreover, provides a new perspective on how patents achieve their policy objectives. At a primary level, patents promote technological progress through their property-like character; exclusive rights spur invention, disclosure, and commercialization, and promote efficient allocation of resources devoted to innovation. However, at a secondary level, certain policy objectives are best advanced by selectively curbing these exclusive rights through a contractually-enforced right to include.

Furthermore, consideration-based patent regulation reveals that money, labor, materials, and patent rights represent “normative portals” for injecting values other than profit maximization in the patent system. Patents, which have attracted criticism for facilitating economic monopolies, may be said to suffer from a normative monopoly in which preoccupation with exclusive rights overshadows broader social ends. Consideration-based patent regulation by upstream institutions is a means for enhancing “normative plurality” within patent law. This Article has focused on the norm of open science, but public institutions are also leveraging research support to promote access to essential medicines and commercialization of existing inventions. 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.

Consideration-based patent regulation also challenges prevailing characterizations of participants in the patent system and highlights the importance of institutional norms. A fundamental premise of the patent system is that parties investing in technology seek to maximize profits. While this is a reasonable assumption for many players, it is can be grossly inaccurate for others. Public institutions contributing enormous amounts of money, labor, and materials to research and development leading to patented inventions do so with only secondary regard for profits. Because of normative considerations, providing upstream institutions with

451 See supra note .
452 Of course, the desirability of normative plurality within patent law is itself a controversial normative question. A rival approach would allow strict patents on government-financed inventions, increase taxes on these patentees, and utilize these revenues to subsidize licenses for noncommercial researchers. While not resolving the merits of this approach, this Article points out that consideration-based patent regulation avoids the redundancy of taxpayers financing licenses for taxpayer-financed inventions.
453 See supra note .
454 See NIH, A Plan to Ensure Taxpayer’s Interests are Protected *10; Thomas A. Hemphill, Economic Considerations in Cooperative Research and Development Agreements (CRADA), 28 TECH. IN SOC’Y 321, 328-29 (2006); Sage, supra note 177, at 1742.
455 See Strandburg, Users as Innovators, supra note 12.
property rights on research tools (or legal claims on those rights) may significantly enhance the availability of these technologies to the scientific community.

Further upsetting institutional stereotypes, the creation of a biomedical research commons casts public institutions as dynamic, entrepreneurial market actors. In recent years, much useful commentary has revealed a new “dynamism in the public domain.”456 In the typical narrative, for-profit firms utilize private ordering to resolve intellectual property holdup, and public institutions may play a facilitative role in these efforts. However, consideration-based patent regulation reveals that public institutions, wielding enormous market power, can drive private ordering that advances broad policy objectives. In this regard, patent law exhibits a self-correcting feature in which frustrations over patent-enabled holdup have motivated “private” working solutions.457 In particular, the federal government is not only a “market maker” in that it grants patents, it is a market participant that funds a substantial amount of research leading to patented inventions. While the federal government can significantly impact patent practice by amending the Patent Act, it can also do so through the power of the purse.

Along these lines, this Article identifies a wider universe of “policy levers” beyond Congress, courts, and the PTO that are available to advance patent policy.458 Federal and state funding agencies, universities, non-profit funding organizations, and disease advocacy groups, are all actively enhancing the availability of patented biomedical inventions. Self-recognition as policy actors may spur public institutions to expand existing practices. For example, armed with this self-recognition, university technology transfer officials may be more likely to reserve broad research rights for patented research tools as well as to nonexclusively license them.459 Recent intellectual property scholarship has highlighted the benefits of decentralized peer production, in which loosely coordinated parties act on communal norms to contribute to value-generating programs.460 Open source software is a frequently cited example. Paralleling the benefits of decentralized production, the efforts described here represent decentralized patent regulation arising from the efforts of numerous independent institutions acting upon similar norms.

Finally, consideration-based patent regulation allows for more equitable distribution of the rewards of innovation.461 As Professor James Boyle has observed, intellectual property law consistently favors those who produce refined goods rather than the suppliers of the raw materials that make them possible.462 Furthermore, “[w]ithout legal recognition of the key contributions and rights of early stage researchers, the public credits and financial rewards based on their discoveries will inure exclusively to those who control the final step of production.”463 Taxpayers, universities, non-profit organizations, and tissue donors contribute much to biomedical research and should be able to expect something in return.464 Consideration-based patent regulation provides a path by which contracts can preserve what intellectual property

456 See Merges, A New Dynamism in the Public Domain, supra note 25.
457 See id.
458 See Burk & Lemley, supra note 40.
460 See generally Benkler, Coase’s Penguin, supra note 41.
461 See Sunder, supra note 42.
462 BOYLE, supra note 42.
463 Kesselheim & Avorn, supra note 170, at 850.
464 Merz et al., Protecting Subjects’ Interests, supra note 427, at 969.
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

Through a vast web of loosely-coordinated activities, public institutions are taking matters into their own hands to address patent holdup. While exclusive rights can help promote progress, patents on the technological inputs to biomedical research can inhibit scientific inquiry and the development of life-enhancing applications. The challenge of patents on biomedical research tools has resisted easy solution by “public law” mechanisms such as the common law experimental use exception or modifications to patentable subject matter. In the wake of these shortcomings, this Article argues that public institutions are leveraging both enormous upstream support for research as well as norms favoring wide access to technologies to contractually construct a biomedical research commons. This trend represents one significant application of the general phenomenon of consideration-based patent regulation.

In particular, this Article argues that public institutions—including federal and state funding agencies, universities, non-profit organizations, and disease advocacy groups—are conditioning receipt of significant research support on assurances that grantees and licensees will not assert patents to impede further scientific inquiry. While market actors have long utilized private ordering to temper the excesses of intellectual property rights, this Article reveals that public institutions are also productively engaged in private ordering. Through informal and formal mechanisms, the NIH and CIRM are compelling grant recipients to widely share patented research tools arising from public funds. Universities are reserving noncommercial research exceptions when licensing research tools and favoring nonexclusive rather than exclusive licensing of such inventions. Non-profit funding organizations and disease advocacy groups are conditioning access to funds and bodily tissues on requirements that recipients do not use resulting patents to inhibit biomedical research. In all of these instances, public institutions are leveraging upstream research support to advance norms of open science.

At a substantive level, this inquiry highlights the enduring importance of institutional norms in the patent system. Within the “normative hierarchy” of the biomedical research sector, institutions that play the most critical role in supporting 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 implementation of patent policy. At a procedural level, the mechanism for expressing these norms relies on the private law model of contracts. Rather than top-down regulation altering the in rem scope of patent rights, the approach described here advances public policy objectives through the faster, nimbler, and more palatable medium of individualized quid pro quo exchanges. Responding to the deficits of public law mechanisms, institutions are privatizing public policy in patent law.

In addition to providing working solutions to patent holdup, consideration-based patent regulation holds several broader implications for patent law. First, it signals an important shift from property to contract as a mechanism to advance patent policy. Furthermore, it provides a
means by which institutions can inject non-profit norms into a patent system often criticized for preoccupation with exclusivity and profit maximization. Additionally, consideration-based patent regulation moves beyond Congress, federal courts, and the PTO to reveal a wider universe of institutional actors that can advance patent policy. Finally, consideration-based patent regulation provides upstream contributors with a greater role in determining how patented inventions are used, thus democratizing the rewards of the patent system. Optimal exploitation of most research technologies requires both access and exclusivity, public and private norms; by asserting their values in the marketplace, upstream institutions are helping to strike a more fruitful balance between these complementary interests.