

**Public Norms and Private Ordering:  
The Contractual Creation of a Biomedical Research Commons**

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**Introduction**

A persistent critique of intellectual property law is that it privileges exclusivity and profit maximization at the expense of broader social objectives it might otherwise serve.<sup>1</sup> This criticism is particularly relevant to patents, which provide twenty years of exclusive rights on novel, nonobvious, and useful inventions. Ironically, while patents are intended to promote scientific and technological progress,<sup>2</sup> strict exclusive rights on inventions used as inputs in research and development may hinder this goal.<sup>3</sup> In the biomedical research context, patents on

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<sup>1</sup> See, e.g., Rochelle Cooper Dreyfuss, *Expressive Genericity: Trademarks as Language in the Pepsi Generation*, 65 NOTRE DAME L. REV. 397 (1990); Leslie Kurtz, *Commentary: Copyright and the Human Condition*, 40 U.C. DAVIS L. REV. 1233 (2007).

<sup>2</sup> U.S. CONST. art. I, § 8, cl. 8.

<sup>3</sup> Peter Yun-hyoung Lee, *Inverting the Logic of Scientific Discovery*, 19 Harv. J.L. & Tech. 79, 81 (2005) [hereinafter Lee, *Inverting the Logic of Scientific Discovery*].

“research tools”<sup>4</sup> used as inputs to experimentation, such as gene fragments, extracted and purified human embryonic stem cells, and processes for copying DNA, may hinder scientific research and technological advance.<sup>5</sup> The problem of excessive patent exclusivity, however, is not limited to the research context: exclusive rights can also undermine distributive justice aims by constraining access to essential medicines<sup>6</sup> as well as hinder commercial development of existing inventions.<sup>7</sup>

A standard retort to this critique is that patents, and the market exclusivity they confer, are necessary to provide incentives to invent and develop new technologies. Between a patentless world where novel research tools and medicines did not exist and the current one where they do exist but are subject to access constraints, surely the latter is preferable. However, this retort relies on a tradeoff that may not always exist. It is particularly questionable in the biomedical research sector, which is the subject of this Article.<sup>8</sup> In this field, government, academic, and non-profit institutions provide enormous financial, personal, and material support for research leading to patented biomedical inventions, and these institutions do so with relatively little regard for maximizing profits.<sup>9</sup> Many patented biomedical research tools, for example, arise from taxpayer-funded research conducted at non-profit universities. This support

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<sup>4</sup> 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*].

<sup>5</sup> See Part I; see generally Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 698–701 (1998); Suzanne Scotchmer, *Standing on the Shoulders of Giants: Cumulative Research and the Patent Law*, 5 J. ECON. PERSP. 29, 39-30 (1991); Lee, *Inverting the Logic of Scientific Discovery*, supra note , at 81; Christopher D. Hazuka, *Supporting the Work of Lesser Geniuses: An Argument for Removing Obstructions to Human Embryonic Stem Cell Research*, 57 U. MIAMI L. REV. 157, 157-58 (2002); Roberto Mazzoleni & Richard R. Nelson, *The Benefits and Costs of Strong Patent Protection: A Contribution to the Current Debate*, 27 Res. Pol’y 273, 282 (1998); Lori Andrews et al., *When Patents Threaten Science*, 314 Science 1395, 1395-96 (2006).

<sup>6</sup> See, e.g., Madhavi Sunder & Anupam Chander, *The Romance of the Public Domain*, 92 CAL. L. REV. 1331, 1332 (2004) (emphasizing distributional concerns in intellectual property law); Keith Aoki, *Distributive and Syncretic Motives in Intellectual Property Law (with Special Reference to Coercion, Agency, and Development)*, 40 U.C. DAVIS L. REV. 717, 726–38 (2007); Amy Kapczynski et al., *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, 20 Berkeley Tech. L.J. 1031, 1046-51 (2005) [hereinafter Kapczynski et al., *Addressing Global Health Inequities*]; Margaret Chon, *Intellectual Property and the Development Divide*, 27 Cardozo L. Rev. 2821, 2832 (2006); Symposium, *Intellectual Property and Social Justice*, 40 U.C. DAVIS L. REV. 559 (2006); Michael E. Gluck, *Federal Policies Affecting the Cost and Availability of New Pharmaceuticals*, July 2002; Note, *Patents for Critical Pharmaceuticals: The AZT Case*, 17 Am. J.L. & Med. 145, 168-69 (1991).

<sup>7</sup> Perhaps the clearest illustration of this phenomenon is so-called “patent trolls,” firms that hold but do not practice patents, deriving revenue from licensing income and infringement suits. See *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 396 (2006) (Kennedy, J., concurring); but see James F. McDonough III, *The Myth of the Patent Troll: An Alternative View of the Function of Patent Dealers in an Idea Economy*, 56 Emory L.J. 189 (2006) (arguing that trolls play a salutary role as “market makers”); see generally Robert Patrick Merges & John Fitzgerald Duffy, *Patent Law and Policy* 939-40 (4th ed. 2007).

<sup>8</sup> See Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289, 300 (2003).

<sup>9</sup> While some public institutions take financial interests in inventions, I argue that they do not fund research primarily to maximize returns on investment. See Part IV.

undermines the notion that patent exclusivity is necessary to provide incentives to create these technologies.<sup>10</sup> Of course, market exclusivity may still be required to encourage firms to develop existing inventions into refined commercial products.<sup>11</sup> As others have noted, the policy challenge is to strike an appropriate balance between access and exclusivity for publicly-supported inventions.<sup>12</sup>

While various real and proposed “public law” initiatives to temper exclusive rights can help address this challenge, they face certain limitations and uncertainties. By “public law initiatives,” I refer to traditional modes of patent regulation involving judicial decisions, legislative enactments, or administrative rulemaking.<sup>13</sup> For example, a longstanding common law experimental use exception historically held promise for allowing unlicensed use of patented inventions for noncommercial research purposes.<sup>14</sup> However, recent court decisions have largely narrowed this doctrine out of existence.<sup>15</sup> Similarly, proposals to simply remove research tools from patentable subject matter are problematic for both doctrinal and policy reasons.<sup>16</sup>

Amidst these considerations, the intellectual property policies of the California Institute for Regenerative Medicine (CIRM) suggest an underappreciated approach to addressing the challenge of patents on biomedical research tools.<sup>17</sup> CIRM, a state agency, will provide close to \$3 billion over ten years to support stem cell research in California.<sup>18</sup> Under CIRM’s policies, grantees may patent inventions arising from state funds.<sup>19</sup> However, as a condition of receiving public money, non-profit grantees must make any resulting patented inventions “readily available” to other California research institutions for noncommercial research purposes.<sup>20</sup> In essence, CIRM has contracted with its non-profit grantees for a partial research exception to patent infringement. Rather than attempting to enact a general research exception,<sup>21</sup> CIRM is

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<sup>10</sup> Rai & Eisenberg, *supra* note , at 300; Adam B. Jaffe, *The U.S. Patent System in Transition: Policy Innovation and the Innovation Process*, 29 *Research Policy* 531, 552 (2000); cf. Katherine J. Strandburg, *Users as Innovators: Implications for Patent Doctrine*, (Mar. 2007) (unpublished manuscript), *available at* <http://ssrn.com/abstract=969399>.

<sup>11</sup> F. Scott Kieff, *Property Rights and Property Rules for Commercializing Inventions*, 85 *Minn. L. Rev.* 697 (2001) [hereinafter Kieff, *Property Rights and Property Rules*]; but see John M. Golden, *Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System*, 50 *Emory L. J.* 101, 166 (2001) (arguing that the patentability of processes or refined products obviate the need for patents on foundational research tools to spur commercial development).

<sup>12</sup> Rai & Eisenberg, *supra* note , at .

<sup>13</sup> These efforts often alter the general meaning of what it means to own a patent. In contrast, I use “private law” to refer to arrangements that create legal rights and obligations between individual parties. Cf. Orin S. Kerr, *Rethinking Patent Law in the Administrative State*, 42 *William & Mary L. Rev.* 127, 129 n.129 (2000).

<sup>14</sup> See *infra* Part II.

<sup>15</sup> See *Madey v. Duke University*, 307 F.3d 1351 (Fed. Cir. 2002); *infra* Part II.

<sup>16</sup> See Part II.

<sup>17</sup> See generally 17 Cal. Code Reg. § 100300-100310 (addressing non-profit grantees); 17 Cal. Code Reg. § 100400-100410 (addressing for-profit grantees).

<sup>18</sup> See *infra* Part IV.B.

<sup>19</sup> CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE, *INTELLECTUAL PROPERTY POLICY FOR NON-PROFIT ORGANIZATIONS* 2, 22 (2006), *available at* <http://www.cirm.ca.gov/faq/pdf/IPPNPO.pdf> (last visited July 30, 2007) [hereinafter CIRM, *NON-PROFIT POLICY*]; CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE, *POLICY FOR FOR-PROFIT ORGANIZATIONS* 29 (2006), *available at* <http://www.cirm.ca.gov/faq/pdf/ForProfitOrg.pdf> (last visited July 30, 2007) [hereinafter CIRM, *FOR-PROFIT POLICY*].

<sup>20</sup> 17 Cal Code Regs. § 100306(a); CIRM, *NON-PROFIT POLICY*, *supra* note , at 18, 37.

<sup>21</sup> Which, of course it could not do. See *infra* text accompanying notes - .

embedding such an exception 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 approach to patent regulation reflects a significant trend that is the focus of this Article.

This Article argues that an underappreciated model of private ordering is helping to address the challenge of patent-enabled research holdup 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 do not assert resulting patents to impede scientific inquiry. In essence, these institutions are building, through contract-like quid pro quos, a noncommercial research commons for biomedicine. In an era where parallel processing and open source software have revealed the immense potential for distributed production,<sup>22</sup> the efforts described here illustrate decentralized, distributed *regulation*. This model brings to light a set of policy tools that transcends the formal realm of congressionally-enacted, judicially-interpreted, and administratively-codified patent law and offers a swifter, nimbler, and more precise mechanism for providing wide access to patented research tools in an increasingly proprietary landscape.<sup>23</sup>

This Article focuses on creating a biomedical research commons as one significant application of a broad, new paradigm of patent regulation. As opposed to traditional, top-down regulation, this new model advances policy objectives in the context of individualized, voluntary, quid pro quos. Institutions that provide enormous support leading to patented inventions, and that are committed to widely disseminating these technologies, are increasingly conditioning their contributions on recipients agreeing to limit their exclusive rights in order to promote various policy objectives. I refer to this phenomenon as “consideration-based patent regulation.” This paradigm holds important ramifications not only for advancing scientific inquiry, but for advancing other access-related policy objectives as well. For example, institutions are also leveraging their support of biomedical research to ensure that resulting patents are used consistently with public health<sup>24</sup> and commercialization<sup>25</sup> goals. This Article explores this new paradigm by examining its application to advance the norm of open science.

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.<sup>26</sup> Within this effort, the NIH is leveraging its funding power to compel grant recipients to freely share patented inventions for

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<sup>22</sup> Yochai Benkler, *Coase’s Penguin, or, Linux and the Nature of the Firm*, 112 Yale L.J. 369 (2002) [hereinafter Benkler, *Coase’s Penguin*].

<sup>23</sup> Cf. Arti K. Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 Nw. U. L. Rev. 77, 142 (1999) [hereinafter Rai, *Regulating Scientific Research*] (“[M]odifying patent doctrine in order to address specific difficulties in basic biotechnology research is a very blunt approach.”).

<sup>24</sup> See, e.g., 17 Cal Code Regs. § 100306(d) (requiring non-profit recipients of stem cell research funds to provide resulting 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).

<sup>25</sup> See, e.g., Lori Pressman et al., *The Licensing of DNA Patents by U.S. Academic Institutions: An Empirical Study*, 24 Nature Biotech. 31, 37 (2006) (describing “diligence milestones” in university technology transfer licenses).

<sup>26</sup> Cf. Kapczynski et al., *Addressing Global Health Inequities*, supra note , at 1037. Where necessary, I will distinguish among these “public” institutions.

noncommercial research purposes. California, the leader in state-funded human embryonic stem cell research, explicitly requires grantees to openly share patented research tools with noncommercial scientists. Increasingly, universities are reserving research exceptions for themselves and other non-profit institutions when licensing technology to private industry. Non-profit organizations and disease advocacy groups are conditioning receipt of money and tissue samples on assurances that patented inventions arising from those materials will be freely available for research purposes. The potential for these concerted efforts is enormous. While others have identified roles for the NIH<sup>27</sup> and universities<sup>28</sup> to safeguard noncommercial research in their patent policies, this Article situates these institutions within a broader trend encompassing numerous additional policy actors. Furthermore, while others have explored the potential for maintaining open access to *data* through contractual mechanisms,<sup>29</sup> this Article focuses on the very different challenge of establishing a research commons for patented biomedical inventions.<sup>30</sup>

Before proceeding, some distinctions are in order. In some cases, biomedical research is best advanced by simply restricting patenting of certain foundational technologies.<sup>31</sup> However, as a general matter, Article does not advocate, and public institutions are not actively engaged in, simply relegating publicly-developed biomedical research tools to the public domain.<sup>32</sup> The efforts described here focus on exempting *noncommercial research use*<sup>33</sup> from infringement, not on completely preempting patents by allowing open access to technologies.<sup>34</sup> Patented technologies may simultaneously represent both highly useful research tools in their present state as well as inputs into more refined, “value added” products.<sup>35</sup> For example, a patented human embryonic stem cell is both a fully-functioning research tool as well as a precursor to a host of commercial therapeutics. Exclusivity for *sale* of refined inventions arising from research tools

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<sup>27</sup> Rai & Eisenberg, *supra* note , at 310.

<sup>28</sup> See, e.g., Mark A. Lemley, *Are Universities Patent Trolls?*, Fordham Intell. Prop. Media & Ent. L.J. 611 (2008) [hereinafter Lemley, *Are Universities Patent Trolls?*]; Yochai Benkler, *Commons-Based Strategies and the Problem of Patents*, 305 Science 1110, 1110-11 (2004) [hereinafter Benkler, *Commons-Based Strategies and the Problems of Patents*].

<sup>29</sup> J.H. Reichman & Paul F. Uhler, *A Contractually Reconstructed Research Commons for Scientific Data in a Highly Protectionist Intellectual Property Environment*, 66 L. & Contemp. Probs. 315 (2003).

<sup>30</sup> Among other distinctions, while data have not traditionally been subject to intellectual property protection (although that bar is eroding), biomedical inventions have long been the target of widespread and aggressive patenting.

<sup>31</sup> Cf. Lee, *Inverting the Logic of Scientific Discovery*, *supra* note (offering this interpretative gloss on the nonpatentability of natural laws, physical phenomena, and abstract ideas).

<sup>32</sup> However, such an approach may be appropriate for particular publicly-developed research tools.

<sup>33</sup> 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

<sup>34</sup> On efforts to preempt patents, see Robert P. Merges, *A New Dynamism in the Public Domain*, 71 U. Chi. L. Rev. 183 (2004) [hereinafter Merges, *A New Dynamism in the Public Domain*]. Of course, the erosion of the public domain is itself a significant problem. See generally Jessica Litman, *The Public Domain*, 39 EMORY L.J. 965 (1990); James Boyle, *The Second Enclosure Movement and the Construction of the Public Domain*, 66 LAW & CONTEMP. PROBS. 33 (2003); Pamela Samuelson, *Challenges in Mapping the Public Domain*, in THE FUTURE OF THE PUBLIC DOMAIN: IDENTIFYING THE COMMONS IN INFORMATION LAW (Lucie Guibault & P. Bernt Hugenholtz eds., 2006); Pamela Samuelson, *Enriching Discourse on Public Domains*, 55 Duke L.J. 783 (2006).

<sup>35</sup> 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).

may be necessary to foster additional investments in development.<sup>36</sup> Accordingly, this Article focuses on ensuring a *noncommercial research* exception from patent infringement for publicly-developed research tools.<sup>37</sup> Along similar lines, this Article does not necessarily advocate a noncommercial research exception for *privately-developed* research tools.<sup>38</sup> Some privately-developed tools, such as polymerase chain reaction (PCR), a technique for generating many copies of DNA, may have never seen the light of day if not for the incentive of market exclusivity.<sup>39</sup> The subject of this Article is thus a *noncommercial research* exception for *publicly-developed* inventions.

This inquiry adds a new dimension to “private ordering” that has long sought to temper the excesses of exclusive rights. Such behavior generally involves private, for-profit entities resorting to markets and contracts to resolve intellectual property holdup.<sup>40</sup> This Article, however, reveals that public institutions such as governments, universities, and non-profits are also market players, and that 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 and development leading to patented inventions; 2) seek to advance norms that privilege access to resulting technologies rather than strict exclusivity; and 3) utilize “contractual” mechanisms to limit exclusive rights on patented inventions to advance access-related policy objectives.

The contractual creation of a biomedical research commons is notable both substantively and procedurally. At a substantive level, it reveals the vast importance of institutional norms in patent law. Consideration-based patent regulation both reveals and exploits the unique upstream-downstream “normative structure” of biomedical research.<sup>41</sup> Subject to exceptions,<sup>42</sup> institutions involved in the upstream, foundational support of research leading to research tools are also generally committed to disseminating such discoveries widely rather than maintaining strict exclusivity over them.<sup>43</sup> Alternatively, “downstream” entities that commercialize existing

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<sup>36</sup> Rai & Eisenberg, *supra* note , at 299; Kieff, Property Rights and Property Rules, *supra* note .

<sup>37</sup> 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 when determining how to license 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?*].

<sup>38</sup> However, as I have argued elsewhere, other mechanisms are available to liberalize access to privately-developed inventions that have achieved “infrastructural status.” See Peter Lee, *The Evolution of Intellectual Infrastructure*, 83 Wash. L. Rev. 39 (2008) [hereinafter Lee, *The Evolution of Intellectual Infrastructure*].

<sup>39</sup> 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).

<sup>40</sup> See generally Merges, A New Dynamism in the Public Domain, *supra* note .

<sup>41</sup> While I offer this upstream-downstream structure as a useful schematic, the distinctions among basic research, applied research, and development are increasingly blurry. See, e.g., Golden, *supra* note , at 119. Nevertheless, public institutions still support an inordinate amount of basic research that feeds private sector development.

<sup>42</sup> See Part IV.

<sup>43</sup> Cf. Golden, *supra* note , at 110 (2001) (“[O]ver-emphasis on patent protection risks displacing a system of public sector values that appears to have served science and society well.”).

inventions into refined products, such as pharmaceutical and biotechnology firms, tend to favor exclusivity and profit maximization.<sup>44</sup> The confluence of significant upstream material support as well as norms favoring access creates a situation ripe with possibility.<sup>45</sup> Normative considerations thus represent a powerful reason why the initial allocation of patent rights (or contractual claims on those rights) matters a great deal.<sup>46</sup>

At a procedural level, consideration-based patent regulation reflects an important shift from property to contract 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 new model relies on mutual exchange between individual parties rather than on top-down regulation to promote public policy goals. One could describe this as 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 with downstream patentees. 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.<sup>47</sup> These governance regimes, and the high information costs they entail, are better managed through *in personam* contractual relationships rather than through general *in rem* property rules.<sup>48</sup>

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, technical competence concerns loom large; a poorly managed research exception could chill public-private partnerships and incentives to develop existing inventions. Finally, conflicts may arise between an institution’s commitment to widely disseminating research tools and its natural desire to reap profits through exclusivity. Notwithstanding these challenges, through carefully crafted agreements and faithful adherence to self-articulated values, public institutions can play a valuable role in safeguarding a commons for noncommercial biomedical research.

In addition to helping address patent holdup, consideration-based patent regulation holds several broader implications for patent law. First, it illustrates a mechanism for injecting access

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<sup>44</sup> Golden, *supra* note , at 106, 131, 133.

<sup>45</sup> Golden, *supra* note, at 109 (“[Legal commentators] have largely ignored the details of the multi-billion dollar system of investment, mostly public and university-based, that provides most of the researchers and basic research that drives modern biotechnology”).

<sup>46</sup> See R.H. Coase, *The Problem of Social Cost*, 3 J.L. & Econ. 1 (1960) (positing that without transaction costs, the initial allocation of property rights does not matter because costless transfers will produce an efficient outcome); Clarisa Long, *Proprietary Rights and Why Initial Allocations Matter*, 49 Emory L.J. 823, 823 (2000) (noting that transactions are costly and so initial allocations matter). I suggest that the initial allocation of property rights, or of contractual claims on those rights, also matters based on the *normative* character of the entity holding them. Quite simply, the life of a patented research tool will unfold differently if it is controlled by the NIH as opposed to a private biotechnology company. Cf. Fore, Jr. et al., *supra* note , at \*2 (analyzing the development of PCR by Cetus, a private firm).

<sup>47</sup> See Henry E. Smith, *Exclusion Versus Governance: Two Strategies for Delineating Property Rights*, 31 J. Leg. Stud. S453 (2003).

<sup>48</sup> On the distinction between *in rem* and *in personam* rights, see Thomas W. Merrill & Henry E. Smith, *The Property/Contract Interface*, 101 Colum. L. Rev. 773, 780-89 (2001).

norms in a patent system often criticized for narrowly emphasizing exclusivity.<sup>49</sup> While this Article focuses on maintaining a robust research commons, such regulation may also advance objectives relating to distributive justice and commercialization. Furthermore, this model vastly widens the range of “policy levers” in patent law.<sup>50</sup> While federal and state funding agencies, universities, non-profit foundations, and disease advocacy groups may not have all traditionally viewed themselves as patent policy actors, this Article strives to change this self-perception. Significantly, consideration-based patent regulation provides these “upstream” contributors with a greater role in managing the fruits of innovation, generally the exclusive province of downstream patentees.<sup>51</sup>

Part I provides an overview of access constraints inherent in the patent system and in particular focuses on 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 through consideration-based patent regulation. Applying the three-part model outlined above, it considers the enormous contributions of federal and state governments, universities, non-profit funding agencies, and disease advocacy groups to basic 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 provides a critical assessment of this application of consideration-based patent regulation. 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 allowing patentees to constrain access to them.<sup>52</sup> As is well-recognized, the technical knowledge inherent in an invention is a public good, which is nonrival<sup>53</sup> (meaning that multiple parties can use it without diminishing its availability) and nonexcludable<sup>54</sup> (meaning that absent legal intervention, it is difficult if not impossible to exclude others from appropriating it).<sup>55</sup> Public goods such as new innovations are subject to undersupply in the absence of exclusive rights

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<sup>49</sup> Cf. *State v. Shack*, 277 A.2d 369, 372 (N.J. 1971) (“Property rights serve human values. They are recognized to that end, and are limited by it.”).

<sup>50</sup> Cf. Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 Va. L. Rev. 1575 (2003).

<sup>51</sup> See James Boyle, *Shamans, Software, and Spleens* 119-143 (1996); Madhavi Sunder, *IP<sup>3</sup>*, 59 STAN. L. REV. 257, 284 (2006).

<sup>52</sup> Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & Econ. 265, 282 (1977); Rai, *Regulating Scientific Research*, supra note , at 117; Frederic M. Scherer, *Industrial Market Structure and Economic Performance* 442 (2d ed. 1980).

<sup>53</sup> 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”).

<sup>54</sup> Of course, firms with valuable information may attempt to maintain it as a trade secret. However, without legal intervention in the form of enforceable nondisclosure agreements, it may be difficult to maintain the secrecy of valuable information and still exploit it.

<sup>55</sup> See generally Kenneth J. Arrow, *Economics of Welfare and the Allocation of Resources for Invention*, in National Bureau of Economic Research, *The Rate and Direction of Inventive Activity* (1962).



because non-innovating firms could simply free-ride on the research and development of others.<sup>56</sup> Patents allow inventors to exclude free riders, thus enabling an adequate return on investment and maintaining incentives to invent and develop.<sup>57</sup> The necessary trade-off is that exclusive rights enable access constraints on patented inventions.<sup>58</sup>

While access constraints on patented end-user goods may be problematic,<sup>59</sup> access constraints on the technological *inputs* to research and development pathways can be particularly troublesome.<sup>60</sup> In the biomedical realm, patents on upstream “research tools”<sup>61</sup>—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, which are useful for studying gene function and disease; genetically modified disease models, such as the Harvard OncoMouse, which are useful for studying cancer; techniques for transferring genes from one organism to another, known as recombinant DNA technology; and techniques for copying particular DNA strands such as polymerase chain reaction (PCR).<sup>62</sup> 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.

Many developments have coalesced to significantly increase the patenting of foundational biomedical discoveries, including research tools.<sup>63</sup> First, courts have taken an

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<sup>56</sup> See Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. Health Econ. 151, 166 (2003) (estimating the average cost to develop a new drug is \$802 million); but see Public Citizen, Rx R&D Myths: The Case Against the Drug Industry’s R&D “Scare Card” 6 tbl.2 (2001), available at <http://www.citizen.org/documents/acfdc.pdf>. (estimating drug development costs to be \$56.5 to \$71.0 million).

<sup>57</sup> 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 several prevailing patent theories); A. Samuel Oddi, *Un-Unified Economic Theories of Patents—The Not-Quite-Holy-Grail*, 71 Notre Dame L. Rev. 267 (1996) (same); Kitch, *supra* note (elaborating prospect theory).

<sup>58</sup> In this regard, patents represent a realistic, “second-best” solution that constrains access to existing inventions in order to encourage creating new ones. Cf. Carol M. Rose, *The Moral Subject of Property*, 48 Wm. & Mary L. Rev. 1897, (2007).

<sup>59</sup> For example, patents on pharmaceuticals contribute to higher prices and decreased availability of drugs. See *supra* note .

<sup>60</sup> See Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 Yale L.J. 177, 225 [hereinafter Eisenberg, *Proprietary Rights and the Norms of Science*]; Rebecca S. Eisenberg, *Patents and Data-Sharing in Public Science*, 15 Industrial & Corporate Change, 1013, 1016 [hereinafter Eisenberg, *Patents and Data-Sharing in Public Science*]; cf. Mark A. Lemley, *Patenting Nanotechnology*, 58 Stan. L. Rev. 601, 619-20 (2005) [hereinafter Lemley, *Patenting Nanotechnology*].

<sup>61</sup> See *supra* note .

<sup>62</sup> 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*].

<sup>63</sup> See Rai & Eisenberg, *supra* note , at 291-95.

exceedingly expansive view of patentable subject matter,<sup>64</sup> such that in some cases the direct fruits of basic research can be patented.<sup>65</sup> Second, advances in molecular biology have revealed a relatively clear path from “basic” discoveries to commercial products, thus enhancing their patentability.<sup>66</sup> Third, the 1980 passage of the Bayh-Dole Act significantly shifted U.S. research and development policy, allowing and even encouraging universities and other recipients of federal grants to patent taxpayer-financed inventions.<sup>67</sup> On a related note, as Professor Mark Lemley observes, “university-owned patents are logically more likely to be upstream patents on building blocks that are of critical importance to innovation than particular downstream implementations of a technology.”<sup>68</sup> Finally, there is much money to be made. Biomedical patents are essential to the pharmaceutical and biotechnology industries,<sup>69</sup> and the profit expectations of universities and private companies have motivated widespread patenting up and down the research and development chain.<sup>70</sup>

Patents on biomedical research tools can hinder scientific inquiry in a variety of ways.<sup>71</sup> First, a patent on a critical, “keystone” asset can raise the cost of downstream research.<sup>72</sup> As I have argued elsewhere, patents on foundational technological “infrastructure”<sup>73</sup> have the potential to impede research and development.<sup>74</sup> For example, the Wisconsin Alumni Research Foundation’s patents on extracted, purified human embryonic stem cells<sup>75</sup> initially raised concerns from non-profit scientists who were unsure if they required a license to use these cells in basic research.<sup>76</sup>

Second, the need to bundle multiple licenses for various patented assets, all of which are necessary to conduct a particular line of research, can generate transaction costs that render such research prohibitively expensive.<sup>77</sup> This may produce a “tragedy of the anticommons” wherein too many upstream exclusive rights leads to wasteful underexploitation of resources, represented

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<sup>64</sup> See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980); *infra* notes and accompanying text.

<sup>65</sup> Richard R. Nelson, *The Market Economy, and the Scientific Commons*, 33 *Research Pol’y* 455, 462 (2004).

<sup>66</sup> Rebecca S. Eisenberg, *Patents and Data-sharing in Public Science*, *supra* note , at 1014.

<sup>67</sup> See *infra* Part IV.A.C.

<sup>68</sup> Lemley, *Patenting Nanotechnology*, *supra* note , at 616.

<sup>69</sup> See Golden, *supra* note , at 106.

<sup>70</sup> Further exacerbating the problem of patents on cutting-edge biomedical research tools, they tend to be quite broad. See Rai & Eisenberg, *supra* note , at 296; Burk & Lemley, *supra* note , at 1656; Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 *Colum. L. Rev.* 839, 848-49 (1990); Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 *Tex. L. Rev.* 989, 1072-73 (1997). Patrick L. Taylor, *Research Sharing, Ethics and Public Benefit*, 24 *Nature Biotechnology* 398, 399 (2007).

<sup>71</sup> See Robert C. Levin et al., *Appropriating the Returns from Industrial Research and Development*, 1987 *Brookings Papers on Economic Activity*, 783, 788 (1987).

<sup>72</sup> See Merges & Nelson, *supra* note , at 882 (discussing the Selden patent, which was used to control development of the automobile); see generally Suzanne Scotchmer, *Standing on the Shoulders of Giants: Cumulative Research and the Patent Law*, 5 *J. ECON. PERSP.* 29 (1991).

<sup>73</sup> See Brett M. Frischmann, *An Economic Theory of Infrastructure and Commons Management*, 89 *MINN. L. REV.* 917, 956 (2005).

<sup>74</sup> Lee, *The Evolution of Intellectual Infrastructure*, *supra* note , at .

<sup>75</sup> U.S. Patent No. 5,843,780 (filed Jan. 18, 1996); U.S. Patent No. 6,200,806 (filed June 26, 1998).

<sup>76</sup> See Lee, *Inverting the Logic of Scientific Discovery*, *supra* note , at 90. The impasse was ultimately resolved by an agreement between the NIH and WiCell Research Institute. See *infra* Part IV.A.1.

<sup>77</sup> For a discussion of the challenges of negotiating technology licenses, see Lee, *The Evolution of Intellectual Infrastructure*, *supra* note , at 97-99.

here by foregone research.<sup>78</sup> For example, patents on expressed sequence tags (ESTs), gene fragments that code for particular proteins, may not be problematic when considered individually. However, if a researcher needs to bundle many licenses for patented ESTs together, aggregate costs may render an intended course of research unduly expensive.<sup>79</sup>

Third, similar to but distinct from the anticommons scenario is the challenge of patent thickets, where multiple overlapping patents cover a single technology.<sup>80</sup> This is most likely to occur in component industries, where, for example, a single semiconductor may infringe hundreds of patents. Given the cumulative nature of basic biomedical research,<sup>81</sup> lack of access to patented research tools can seriously impede progress.

The role of patents in inhibiting noncommercial biomedical research is a controversial topic subject to much debate. In a recent survey, 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.<sup>82</sup> They concluded that patents produced minimal blocking effects and that “friction” arising from material transfer agreements for *physical* property posed a much greater impediment to basic science.<sup>83</sup> In an earlier survey, Walsh and a different team of colleagues found “almost no evidence” that the presence of multiple rights holders in biomedical research and development led to the complete cessation of projects.<sup>84</sup> Similarly, royalty stacking from multiple licenses did not represent a significant or pervasive threat to ongoing research and development.<sup>85</sup> However, the researchers 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.”<sup>86</sup>

While certainly rare, the potential for blocking noncommercial research, including basic research, is nonetheless significant. Restrictive licensing of critical research tools such as the OncoMouse<sup>87</sup> and polymerase chain reaction technology (PCR)<sup>88</sup> initially threatened to chill

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<sup>78</sup> Heller & Eisenberg, *supra* note ; National Research Council, *Intellectual Property Rights and Research Tools in Molecular Biology* (1997); see generally Michael A. Heller, *The Tragedy of the Anticommons: Property in the Transition from Marx to Markets*, 111 Harv. L. Rev. 621 (1998).

<sup>79</sup> See Heller & Eisenberg, *supra* note .

<sup>80</sup> See generally Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting* 119, in Adam B. Jaffe et al. eds. 1 *Innovation Policy and the Economy* (2001). While many observers discuss the tragedy of the anticommons and patent thickets interchangeably, they are analytically distinct. Burk & Lemley, *supra* note , at 1627.

<sup>81</sup> Walsh et al., *Research Tool Patenting and Licensing*, *supra* note , at 289.

<sup>82</sup> 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*].

<sup>83</sup> Walsh et al., *Patents, Material Transfers and Access to Research Inputs*, *supra* note , at 2.

<sup>84</sup> Walsh et al., *Research Tool Patenting and Licensing*, *supra* note , at 298.

<sup>85</sup> Walsh et al., *Research Tool Patenting and Licensing*, *supra* note , at 299.

<sup>86</sup> Walsh et al., *Research Tool Patenting and Licensing*, *supra* note , at 302.

<sup>87</sup> Eliot Marshall, *NIH Cuts Deal on Use of OncoMouse*, 287 *Science* 567 (2000). Ultimately, the NIH negotiated with DuPont to ease these restrictions. See *infra* Part IV.A.I.

<sup>88</sup> See *Cetus To Exact Royalties from PCR Sales; Probe Absolves Convicted Rapist*, BIOTECH. NEWSWATCH, Sept. 5, 1988, at 7.

basic research. One reason that upstream patents have not severely inhibited basic research is because of the aggressive intervention of the NIH to enhance access to taxpayer-financed research tools, a practice illustrating consideration-based patent regulation. As will be further elaborated, the NIH played a crucial role in negotiating greater access to patented human embryonic stem cells as well as patented techniques for transferring genes into mammalian cells.<sup>89</sup> 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.<sup>90</sup>

The threat that patents may inhibit basic biomedical research is real, and much hangs in the balance. Basic biomedical science generates immense spillovers benefitting society at large.<sup>91</sup> Basic biomedical research occupies “Pasteur’s Quadrant:” while it strives for deep understanding, it is also intrinsically oriented towards achieving practical objectives.<sup>92</sup> Given the close proximity and overlap between what has traditionally been distinguished as basic and applied science, inhibitions of basic research can have enormous negative implications for technological advance.<sup>93</sup> For all of these reasons, many have decried the privatization of the scientific research commons.<sup>94</sup>

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.<sup>95</sup> Economic theory posits that exclusive rights are necessary to generate new inventions, and access constraints are simply the necessary tradeoff.<sup>96</sup> However, this tradeoff does not necessarily exist in all contexts. In the biomedical field, public institutions—notably the federal government and universities, but also state governments, non-profit organizations, and disease advocacy groups—fund and conduct the bulk of research that produces patented research tools.<sup>97</sup> While exclusive rights may be warranted to encourage further commercial development of these assets,<sup>98</sup> public support has already satisfied the incentive to invent many underlying tools. In the biomedical research context, the costs of access constraints to these patented technologies may far outweigh their benefits.

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

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<sup>89</sup> See *infra* Part IV.A.I.

<sup>90</sup> See Heller & Eisenberg, *supra* note , at 699.

<sup>91</sup> See Mark A. Lemley & Brett M. Frischmann, *Spillovers*, 100 Colum. L. Rev. 257, 257 (2007)

<sup>92</sup> D. Stokes, Pasteur’s Quadrant: Basic Science and Technological Innovation (1996); Nelson, *supra* note, at 455, 57; Francis Narin et al., *The Increasing Linkage Between U.S. Technology and Public Science*, 26 Research Policy 317, 317 (2000).

<sup>93</sup> See Nelson, *supra* note, at 456-57.

<sup>94</sup> See, e.g., Nelson, *supra* note , at 455; Andrews et al., *supra* note , at 1396.

<sup>95</sup> Cf. Rich, *supra* note , at 164.

<sup>96</sup> See Lemley, Patenting Nanotechnology, *supra* note , at 618 n. 81 (collecting authorities on this debate).

<sup>97</sup> See Rai & Eisenberg, *supra* note , at 300; see also Katherine J. Strandburg, Users as Innovators: Implications for Patent Doctrine, (Mar. 2007) (unpublished manuscript), available at <http://ssrn.com/abstract=969399>.

<sup>98</sup> Kieff, Property Rights and Property Rules, *supra* note , at .

The challenge of patents on biomedical research tools has elicited a number of actual and proposed “public law” responses.<sup>99</sup> By “public law” mechanisms, I refer to traditional modes of patent regulation arising from judicial interpretations, legislative enactments, and administrative rulemaking. 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 contractual agreements that establish *in personam* rights and obligations between individual parties.<sup>100</sup> 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,<sup>101</sup> but none offers a complete solution. 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

A doctrine aimed directly at allowing unlicensed use of patented inventions for noncommercial purposes is the common law experimental use exception.<sup>102</sup> Traditionally, the doctrine distinguished “philosophical,” noncommercial uses of patented inventions from commercial ones, exempting the former from infringement.<sup>103</sup> While theoretically the doctrine

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<sup>99</sup> For proposals dealing with gene patents alone, see Jordan Paradise et al., *Patents on Human Genes: An Analysis of Scope and Claims*, 307 Science 1566, 1567 (2005).

<sup>100</sup> 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 , at 777.

<sup>101</sup> See also Oskar Liivak, *Maintaining Competition in Copying: Narrowing the Scope of Gene Patents*, 41 U.C. DAVIS L. REV. 177 (2007); Maureen A. O’Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177 (2000).

<sup>102</sup> The doctrine has attracted voluminous academic commentary, much of it positive. See, e.g., Eisenberg, *Patents and the Progress of Science*, *supra* note ; Janice M. Mueller, *No “Dilettante Affair”: Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 Wash. L. Rev. 1 (2001); Rochelle Dreyfuss, *Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense Arrived?*, 46 Ariz. L. Rev. 457 (2004); Strandburg, *Experimental Use and the Patent Bargain*, *supra* note ; Jeffrey R. Armstrong, *Bayh-Dole Under Siege: The Challenge to Federal Patent Policy as a Result of Madey v. Duke University*, 30 J.C. & U.L. 619 (2004); Nelson, *supra* note , at 466. However, the doctrine has attracted negative commentary as well. See, e.g., Elizabeth A. Rowe, *The Experimental Use Exception to Patent Infringement: Do Universities Deserve Special Treatment?*, 57 Hastings L.J. 921 (2006); Richard E. Bee, *Experimental Use as an Act of Patent Infringement*, 39 J. Pat. Off. Soc’y 357 (1957); Jordan P. Karp, *Experimental Use as Patent Infringement: The Impropriety of a Broad Exception*, 100 Yale L.J. 2169 (1991); Michael S. Mireles, *An Examination of Patents, Licensing, Research Tools, and the Tragedy of the Anticommons in Biotechnology Innovation*, 38 U. Mich. J.L. Reform 141, 201-05, 211-16 (2004) [hereinafter Mireles, *Patents, Licensing, Research Tools*].

<sup>103</sup> *Whittemore v. Cutter*, 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600) (“[I]t could never have been the intention of the legislature to punish a man, who constructed such a[n allegedly infringing] machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.”); see *Sawin v. Guild*, 21 F. Cas. 554, 555 (C.C.D. Mass. 1813) (No. 12,391); *Poppenhuisen 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).

might have provided a safe harbor from patent infringement for non-profit university research, recent court decisions have largely foreclosed that possibility.<sup>104</sup>

Most prominently, in *Madey v. Duke University*, the Federal Circuit articulated a very narrow view of the experimental use exception.<sup>105</sup> 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.”<sup>106</sup> Duke’s “legitimate business” involved educating students and attracting research grants and faculty, and its use of 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.<sup>107</sup> Furthermore, the ruling also reveals the difficulties of defining “experimental” activities that should qualify for the exception.<sup>108</sup> While some commentators applaud a narrow research exception,<sup>109</sup> this narrowing exacerbates concerns about the viability of university research that relies on patented inventions as inputs.<sup>110</sup>

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

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<sup>104</sup> 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 .

<sup>105</sup> 307 F.3d 1351 (Fed. Cir. 2002).

<sup>106</sup> 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 .

<sup>107</sup> See *Strandburg*, *What Does the Public Get?*, *supra* note , at 84 (“[R]ecent decisions from the U.S. Court of Appeals for the Federal Circuit threaten to shrink the experimental-use exemption to extinction.”). See also *Applera Corp. v. MJ Research, Inc.*, 311 F. Supp. 2d 293, 296 (D. Conn. 2004) (affirming *Madey*’s “very narrow” and “strictly limited” interpretation of the experimental use exception).

Theoretically, state universities could invoke sovereign immunity to shield themselves from patent infringement. See *Florida Prepaid Postsecondary Education Expense Bd. v. College Savings Bank*, 527 U.S. 627 (1999); *Biomedical Patent Management Corp. v. State of California, Dept. of Health Services*, No. 2006-1515 (Fed. Cir. Oct. 23, 2007); Peter Lattman, *Critics Take Aim at California’s Patent Shield*, *Wall Street Journal Online*, Nov. 13, 2007, available at <http://blogs.wsj.com/law/2007/11/13/critics-take-aim-at-californias-patent-shield>.; see generally Gary Pulsinelli, *Freedom to Explore: Using the Eleventh Amendment to Liberate Researchers at State Universities from Liability for Intellectual Property Infringements*, 82 *Wash. L. Rev.* 275 (2007). However this defense would not apply to private universities and individual researchers at state universities could still be personally liable for infringement. See *Ex Parte Young*, 209 U.S. 123 (1908); Pulsinelli, *supra* note , at 312-14.

<sup>108</sup> Contractual approaches have sought to sidestep this thorny issue by generally exempting research conducted by non-profit organizations, even though this may arguably include commercially-relevant activities. While somewhat imprecise, this distinction is relatively crisp and implementable. Compared to statutes and doctrine, there may be less of a need for precise ex ante definitions in contracts, as individual parties can work out their differences over time. Cf. Robert E. Scott & George G. Triantis, *Incomplete Contracts and the Theory of Contract Design*, 56 *Case W. Res. L. Rev.* 187 (2005).

<sup>109</sup> See *Rowe*, *supra* note , at 923.

<sup>110</sup> See Brief for Association of American Medical Colleges, et al, as Amici Curiae in Support of Petitioner at 14, *Duke Univ. v. Madey*, 123 S. Ct. 2639 (2003) (No. 02-1007) (claiming that the narrowing of the experimental use exception will have a “chilling effect” on academic scientific research); Suz Redfearn, *The Madey Decision and Academic Research: Has the Sky Fallen?*, 1 *Preclinica* 230, 231 (Nov./Dec. 2003).

incentives of private companies to develop research tools primarily used by academic and non-profit entities. At no point in its doctrinal history has the common law 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 *statutory* experimental use exception, it is relatively narrow in scope. The 1984, Congress passed Hatch-Waxman Act, which expedited the process by which firms may introduce generic versions of patented drugs.<sup>111</sup> 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.”<sup>112</sup> However, the Act does not establish a true experimental use exception. First, the act’s safe harbor applies to a rather narrow range of research activities, essentially, those leading to submitting information to the FDA. Second, the Act exempts from infringement uses of patented materials that are decidedly *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 Section 271(a), holding that it applies to the use of patented materials in *preclinical* research reasonably related to an FDA submission.<sup>113</sup> Nevertheless, the Hatch-Waxman Act falls far short of creating a noncommercial research exception from patent infringement.

### C. The De Facto Experimental Use Exception

In addition to formal doctrines, a *de facto* experimental use exception also prevents many patentees and exclusive licensees from suing university researchers for infringement.<sup>114</sup> Pharmaceutical and biotechnology firms rationally forbear from suing university researchers for several reasons.<sup>115</sup> First, private firms that routinely seek licenses from universities are

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<sup>111</sup> Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended in scattered sections of 21 U.S.C. and 35 U.S.C.). The act responded to the Federal Circuit’s decision in *Roche Products Inc. v. Bolar Pharmaceuticals*, 733 F.2d 858 (Fed. Cir. 1984), which held that use of a patented pharmaceutical for investigation related to Food and Drug Administration (FDA) submission requirements did not qualify for the common law experimental use exception.<sup>111</sup> The holding effectively extended the period of market exclusivity enjoyed by patentees of FDA-approved drugs; generic competitors had to wait until expiration of the patent term before starting FDA testing, which could take several years. See Rebecca S. Eisenberg, *Patents, Product Exclusivity, and Information Dissemination: How Law Directs Biopharmaceutical Research and Development*, 72 *Fordham L. Rev.* 477, 482-86 (2003) [hereinafter Eisenberg, *Patents, Product Exclusivity, and Information Dissemination*]; Gluck, *supra* note , at 6-7.

<sup>112</sup> 35 U.S.C. § 271(e). To offset delays in FDA approval, the Hatch-Waxman Act also allows patent term extensions of up to five years. 35 U.S.C. § 156.

<sup>113</sup> *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005).

<sup>114</sup> Rai & Eisenberg, *supra* note 53, at 296 (“[P]atent holders practice an informal regime of price discrimination in favor of nonprofit researchers, primarily by not enforcing their patents against such researchers for non-commercial uses.”); see Walsh et al., *Research Tool Patenting and Licensing*, *supra* note , at 324-26; Pressman et al., *supra* note , at 35; Cristina Weschler, Note, *The Informal Experimental Use Exception: University Research after Madey v. Duke University*, 79 *N.Y.U. L. Rev.* 1536 (2004).

<sup>115</sup> Leon Rosenberg, *Perspectives from Different Sectors: Major Pharmaceutical Company*, in Nat’l Research Council, *INTELLECTUAL PROPERTY RIGHTS AND RESEARCH TOOLS IN MOLECULAR BIOLOGY* 61, 63 (1997), available at <http://books.nap.edu/html/property>.

understandably reluctant to antagonize the academic community with threats of suit. 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, private patentees may seek to free ride on the basic research conducted by universities by allowing them to experiment on patented assets without a license.<sup>116</sup> Third, such suits are clearly problematic from a public relations standpoint.<sup>117</sup>

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.<sup>118</sup> Additionally, evidence suggests that industry’s willingness to forbear from enforcing patents against university researchers is waning.<sup>119</sup> Furthermore, many of the most egregious instances of patent holdup have only been forestalled by the NIH’s proactive engagement, thus corroborating the model of consideration-based patent regulation described in this Article.<sup>120</sup> In an increasingly proprietary biomedical landscape, a de facto research exception does not provide a stable means to ensure the viability of noncommercial biomedical research.

#### D. Modifications to Patentable Subject Matter

Shifting from various experimental use exceptions, a more drastic approach to eliminating access constraints on research tools is to simply remove them from patentable subject matter.<sup>121</sup> For example, courts could extend the traditional bar against patenting “products of nature”<sup>122</sup> to resources such as gene fragments and extracted, purified human embryonic stem cells.<sup>123</sup> Alternatively, they could extend the doctrinal prohibition against

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<sup>116</sup> Ariad Pharmaceuticals is the exclusive licensee of a patent on NH-kB, a signaling protein. After the company sued Eli Lilly for patent 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 , at 30.

<sup>117</sup> Furthermore, 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 , at 1019.

<sup>118</sup> See *supra* notes and accompanying text.

<sup>119</sup> Nelson, *supra* note , at 467; see also National Research Council, *Reaping the Benefits of Genomic and Proteomic Research* (2006).

<sup>120</sup> See *infra* Part IV.A.1.

<sup>121</sup> See 35 U.S.C. § 101 (defining patentable subject matter as “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof”); see generally Lee, *Inverting the Logic of Scientific Discovery*, *supra* note , at 92-103; Eileen M. Kane, *Patent Ineligibility: Maintaining a Scientific Public Domain*, 80 *ST. JOHN’S L. REV.* 519 (2006).

<sup>122</sup> 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.

<sup>123</sup> Rai & Eisenberg, *supra* note , at 299. Of course, this would rarely affect “process” research tools, such as techniques for copying DNA fragments.



patenting natural laws, physical phenomena, and abstract ideas<sup>124</sup> to limit patents on research tools that are necessary to discover these elements.<sup>125</sup>

These proposals, however, raise difficulties in light of expansive doctrinal conceptions of patentable subject matter. In the seminal case of *Diamond v. Chakrabarty*, the Supreme Court drew from the legislative history of the 1952 Patent Act in invoking Congress’s intent that “anything under the sun that is made by man” is eligible for patenting.<sup>126</sup> Other cases have reinforced this expansive view of patentable subject matter.<sup>127</sup> Although recent Supreme Court<sup>128</sup> and Federal Circuit<sup>129</sup> pronouncements have signaled a potential narrowing of patentable subject matter, the exact extent of future modifications is unpredictable. While Congress is currently considering patent law reform,<sup>130</sup> curtailing patentable subject matter to eliminate research tool patents is not on the agenda.

Furthermore, summarily eliminating research tools from patentable subject matter would eviscerate private incentives to invent and develop such technologies.<sup>131</sup> In many contexts, private firms rely on exclusive rights when investing in creating new inventions. Additionally, even where exclusive rights are not necessary to motivate invention, they may be necessary to motivate further investment in developing and commercializing existing inventions.<sup>132</sup> This was the underlying logic of the Bayh-Dole Act, which allows recipients of federal funds to patent taxpayer-financed inventions.<sup>133</sup> A more refined approach would distinguish between noncommercial research use of an existing invention and commercial sale, providing exclusive

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<sup>124</sup> See *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

<sup>125</sup> See Lee, *Inverting the Logic of Scientific Discovery*, *supra* note .

<sup>126</sup> 447 U.S. 303 (1980).

<sup>127</sup> 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).

<sup>128</sup> See *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, \_\_\_ U.S. \_\_\_, 126 S. Ct. 2921, 2922 (2006) (per curiam) (Breyer, J., dissenting from the dismissal of certiorari) (“[S]ometimes *too much* patent protection can impede rather than ‘promote the Progress of Science and useful Arts’ . . .”).

<sup>129</sup> See *In re Petrus A.C.M. Nuijten*, 500 F.3d 1346 (Fed. Cir. 2007), en banc reh’g denied, 2008 WL 361044 (Fed. Cir. 2008) (denying a patent application claiming electronic signals); *In re Stephen W. Comiskey*, 499 F.3d 1365 (Fed. Cir. 2007) (denying a patent application claiming a method for arbitrating disputes). The Federal Circuit recently decided, *sua sponte*, to review the patentability of business methods in *In re Bilski*, a move which casts doubt on the court’s earlier endorsement of business method patent in *State Street*. *In re Bilski*, 2008 WL 417680 (Fed. Cir. 2008). Academics have roundly criticized the current breadth of patentable subject matter. See, e.g., Andrews et al., *supra* note , at 1396; Rochelle Cooper Dreyfuss, *Are Business Method Patents Bad for Business?*, 16 SANTA CLARA COMPUTER & HIGH TECH. L.J. 263 (2000); Alan L. Durham, “*Useful Arts*” in the Information Age, 1999 B.Y.U. L. REV. 1419 (1999); John R. Thomas, *The Patenting of the Liberal Professions*, 40 B.C. L. REV. 1139 (1999).

<sup>130</sup> See Patent Reform Act of 2006, S. 3818, 109th Cong. (2006); Patent Reform Act of 2005, H.R. 2795, 109th Cong. (2005); Steve Seidenberg, *Reinventing Patent Law*, ABA J., Feb. 2008, at 62-63.

<sup>131</sup> See *Integra Lifesciences I Ltd. v. Merck KGaA*, 331 F.2d 860, 878 (Fed. Cir. 2003) (Newman, J., dissenting); Federal Trade Comm’n, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, at ch. 4, at 36 (2003) (“Inventors of tools used by researchers need an income stream from those who use their inventions.”).

<sup>132</sup> See Kieff, *Property Rights and Property Rules*, *supra* note , at 703.

<sup>133</sup> See *infra* Part IV.A.2.

rights only for the latter. Summarily eliminating research tools from patentable subject matter precludes this use-specific distinction.<sup>134</sup>

#### E. Novelty, Utility, and Nonobviousness

The requirements that a patented invention must be novel, useful, and nonobvious may also prevent undue patenting of research tools.<sup>135</sup> For example, to the extent that a research tool would be obvious to one of ordinary skill in the art at the time it was invented, it would not be eligible for patenting.<sup>136</sup> The same, of course, goes for research tools that are not novel. In particular, the requirement that patentable inventions must be useful has indeed curbed patents on research tools.<sup>137</sup> While utility has traditionally served as a rather nominal requirement, courts have denied patents on “upstream” discoveries where the patentee has not demonstrated a requisite specific utility.<sup>138</sup> Along these lines, in 2001 the Patent and Trademark Office issued guidelines requiring a demonstrated specific and substantial utility for all patented inventions.<sup>139</sup> These guidelines have made it more difficult to patent expressed sequence tags (ESTs) that encode proteins of no known biological activity.<sup>140</sup> It is unclear, however, whether these guidelines have curtailed patenting of other types of research tools.

#### F. Compulsory Licenses

Yet another mechanism for enhancing access to patented biomedical research tools is compulsory licensing.<sup>141</sup> Under a compulsory licensing regime, 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.<sup>142</sup> Unlike eliminating patents on research tools, compulsory licenses maintain incentives to invent because the patentee receives some compensation. Some

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<sup>134</sup> A narrower approach would specifically exempt non-profit researchers from *remedies* arising from infringing such patented inventions. Analogously, the Patent Act exempts health care professionals from infringement remedies arising from their unlicensed use of patented medical and surgical techniques. 35 U.S.C. § 287(c); see *Pallin v. Singer*, 1995 WL 608365, 36 U.S.P.Q.2d 1050 (D. Vt. 1050 1995); Chris J. Katopis, *Patients v. Patents?: Policy Implications of Recent Patent Legislation*, 71 St. John’s L. Rev. 329 (1997). However, there have been no congressional attempts to recreate this exception for basic researchers. In addition, such a measure may unduly compromise incentives to invent for private companies that develop research tools and license them to noncommercial researchers.

<sup>135</sup> See 35 U.S.C. §§ 101-103.

<sup>136</sup> In this regard, public interest groups recently challenged the validity of human embryonic stem cell patents on nonobviousness grounds. See Andrew Pollack, *3 Patents on Stem Cells Are Revoked in Initial Review*, N.Y. TIMES, Apr. 3, 2007, at C2. See *KSR Int’l Co. v. Teleflex Inc.*, \_\_\_ U.S. \_\_\_, 127 S. Ct. 1727, 1746 (2007).

<sup>137</sup> Nelson, *supra* note, at 466; see Golden, *supra* note, at 182.

<sup>138</sup> See, e.g., *Brenner v. Manson*, 383 U.S. 519, 534 (1966).

<sup>139</sup> Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001); ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, *PATENT LAW AND POLICY: CASES AND MATERIALS* 238-40 (4th ed. 2007); Golden, *supra* note, at 129.

<sup>140</sup> *In re Fisher*, 421 F.3d 1365 (Fed. Cir. 2005).

<sup>141</sup> While the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement allows compulsory licensing, such licensing is much more common in other countries. See Art. 31, Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establish the World Trade Organization, Annex IC, Results of the Uruguay Round, 1869 U.N.T.S. 299, 33 I.L.M. 1143 (1994); Jaffe, *supra* note, at 536, 551.

<sup>142</sup> F.M. Scherer & Jayashree Watal, *Post-TRIPS Options for Access to Patented Medicines in Developing Countries*, J. INT’L ECON. L. 913, 914 (2002).

have suggested that publicly funded research should be subject to compulsory licenses.<sup>143</sup> While the Bayh-Dole Act, discussed below, authorizes specific compulsory licenses for taxpayer-funded inventions, all patented inventions are susceptible to compulsory licensing pursuant to 1) 28 U.S.C. § 1498 and 2) antitrust consent decrees.<sup>144</sup> Section 1498 provides that patentees may seek damages, but not an injunction, for the federal government’s unlicensed use of patented inventions. Effectively, it allows the federal government to practice any patented invention without a license as long as it provides adequate compensation to the patentee. However, the government has invoked § 1498 very rarely,<sup>145</sup> and it is unlikely to do so to open access to patented biomedical research tools. While antitrust consent decrees have been a much more common,<sup>146</sup> they have not traditionally been motivated by the objective of widening access to research tools to promote scientific activity.

### G. Remedies Analysis

Another mechanism for tempering exclusive rights on patented research tools involves the law of patent infringement remedies. In *eBay Inc. v. MercExchange, L.L.C.*, the Supreme Court recently rejected the Federal Circuit’s “general rule” of granting injunctions upon a finding of patent infringement.<sup>147</sup> Instead, it held that courts must apply a traditional four-factor equitable test to determine the appropriateness of an injunction.<sup>148</sup> 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.<sup>149</sup> Applying this proposal, courts could protect patents on foundational research tools used in basic biomedical research with damages rather than an injunction.

It is too early to tell if courts will embrace a broad view of the *eBay* mandate consistent with this proposal. In the short time following *eBay*, courts have most frequently protected patents with liability rules in the “patent troll” context, denying injunctions to firms that assert

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<sup>143</sup> Ron A. Bouchard, *Balancing Public and Private Interest*, in the Commercialization of Publicly Funded Medical Research: Is There A Role For Compulsory Government Royalty Fees?, 13 B.U. J. Sci. & Tech. L. 120, 125-26 (2007); see also Gary Pulsinelli, *Share and Share Alike: Increasing Access to Government-Funded Inventions Under the Bayh-Dole Act*, 7 Minn. J.L. Sci. & Tech. 393, 396 (2006) (offering a variant on this proposal).

<sup>144</sup> Colleen Chien, *Cheap Drugs at What Price To Innovation: Does the Compulsory Licensing of Pharmaceutical Hurt Innovation?*, 18 Berkeley Tech. L.J. 853, 867 (2003); Sean M. O’Connor, *Intellectual Property Rights and Stem Cell Research: Who Owns the Medical Breakthroughs?*, 39 New Eng. L. Rev. 665, 709-11 (2005) (characterizing § 1498 as a “formalized takings provision”).

<sup>145</sup> Recently, the federal government’s proposal to compulsorily license the manufacture of Cipro under § 1498 in the wake of terrorist threats involving anthrax drove down the price of that patented drug by 50%. Chien, *supra* note, at 868.

<sup>146</sup> Chien, *supra* note, at 868.

<sup>147</sup> 547 U.S. 388, 391 (2006).

<sup>148</sup> 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.*

<sup>149</sup> See Lee, *The Evolution of Intellectual Infrastructure*, *supra* note; see Guido Calabresi & A. Douglas Melamed, *Property Rules, Liability Rules, and Inalienability: One View of the Cathedral*, 85 HARV. L. REV. 1089, 1092 (1972).

but do not practice patents.<sup>150</sup> Even if courts ultimately decide to protect 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. The relatively small welfare losses from injunctions on each of those patents, taken individually, may not warrant a departure from property rule protection.

#### H. Summary

While valuable, public law attempts to temper the excesses of 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 these technologies. 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 it is too early to evaluate the impact of recent doctrinal changes. Given the inadequacy of public law mechanisms to address the excesses of patents,<sup>151</sup> 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.<sup>152</sup> In particular, the perceived excesses of intellectual property rights have long spurred market actors to mitigate them through private arrangements. For example, firms in copyright and patent industries frequently face a “tangled, twisted mass” of intellectual property rights that impedes productivity.<sup>153</sup> As Professor Robert Merges has influentially described, Collective Rights Organizations (CROs) often emerge to address these impediments. 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.<sup>154</sup> Similarly, collective copyright licensing organizations such as ASCAP and BMI allow industry players to “contract into”

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<sup>150</sup> Andrew Beckerman-Rodau, *The Aftermath of eBay v. MercExchange*, 126 S. Ct. 1837 (2006); *A Review of the Subsequent Judicial Decisions*, J. Pat. & Trademark Off. Soc’y 607, 632, 657 (2007); Benjamin H. Diessel, Note, *Trolling for Trolls: The Pitfalls of the Emerging Market Competition Requirement for Permanent Injunctions in Patent Cases Post-eBay*, 106 Mich. L. Rev. 305, 312-15 (2007).

<sup>151</sup> See Nelson, *supra* note, at 466 (“I am not optimistic about how much of the problem can be dealt with by patent law.”).

<sup>152</sup> See generally ROBERT ELLICKSON, *ORDER WITHOUT LAW* (1991); ELINOR OSTROM, *GOVERNING THE COMMONS* (1990).

<sup>153</sup> Robert P. Merges, *Contracting into Liability Rules: Intellectual Property Rights and Collective Rights Organizations*, 84 CAL. L. REV. 1293, 1295 (1996) [hereinafter Merges, *Liability Rules*].

<sup>154</sup> Merges, *Liability Rules*, *supra* note, at 1340-58.

liability rules in an aggregate fashion, thus creating an easily-accessible pool of licenses.<sup>155</sup> In the biomedical research realm, some have argued for private collective action to resolve anticommons problems.<sup>156</sup>

At the most drastic level, industry players have addressed increasing proprietization through another type of private ordering: simply relegating materials to the public domain. For example, the recent trend by biotechnology companies to patent single nucleotide polymorphisms (SNPs), which are useful as genetic disease markers, raised concerns that such patents could block useful research.<sup>157</sup> In response, pharmaceutical companies partnered with the Wellcome Trust, a U.K.-based non-profit, to create the SNP Consortium.<sup>158</sup> This coordinated effort identifies SNPs and places all resulting information in the public domain.<sup>159</sup> 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.<sup>160</sup> Merck's initiative prevents patenting of these essential resources and has substantially contributed to easing potential anticommons threats.<sup>161</sup>

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 GPL ("General Public License"), which allows downstream users to make and distribute verbatim and modified versions of source code<sup>162</sup> and requires users to grant a license to anyone who comes into possession of a copy.<sup>163</sup> The license is considered "viral" because it "infects" all downstream iterations of code based on source code originally governed by the GPL.<sup>164</sup> Commentators laud the open source licensing approach as enabling collaborative "peer production" that may be nimbler, faster, and more robust than traditional market-based firm structures.<sup>165</sup> IBM, for example, has engaged in substantial "property pre-empting" investments by supporting open source software.<sup>166</sup> Crucially, while the GPL enforces norms of open access, it is fundamentally predicated on the right to exclude inherent in copyright.<sup>167</sup>

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<sup>155</sup> Merges, *Liability Rules*, *supra* note , at 1328-40.

<sup>156</sup> Karl Bergmann & Gregory D. Graff, *The Global Stem Cell Patent Landscape: Implications for Efficient Technology Transfer and Commercial Development*, 25 *Nature Biotech.* 419, 422 (2007) (suggesting an "intellectual property clearinghouse mechanism" to facilitate bulk licensing of stem cell patents).

<sup>157</sup> Rai & Eisenberg, *supra* note , at 298.

<sup>158</sup> See Nicholas Wade, 10 Drug Makers Join in Drive to Find Diseases' Genetic Roots, *N.Y. Times*, Apr. 15, 1999, at ; Michael Morgan, The SNP Consortium, in National Research Council, *Proceedings of the Symposium on the Role of Scientific and Technical Data and Information the Public Domain* (2003).

<sup>159</sup> Rai & Eisenberg, *supra* note , at 298; Merges, *A New Dynamism in the Public Domain*, *supra* note , at 189-90.

<sup>160</sup> See Merges, *A New Dynamism in the Public Domain*, *supra* note , at 188.

<sup>161</sup> Merges, *A New Dynamism in the Public Domain*, *supra* note , at 188.

<sup>162</sup> GNU General Public License Version 3, at §§ 4, 5 (June 29, 2007) [hereinafter GPL], available at <http://www.gnu.org/licenses/gpl.txt>.

<sup>163</sup> GPL, *supra* note , at § 5.

<sup>164</sup> See generally Greg R. Vetter, "Infectious" Open Source Software: *Spreading Incentives or Promoting Resistance?*, 36 *Rutgers L.J.* 53 (2004) (discussing principles of viral licensing in the context of GPL version 2).

<sup>165</sup> See Benkler, *Coase's Penguin*, *supra* note , at 376-77, 415-22, 436-38; Dan M. Kahan, *The Logic of Reciprocity: Trust, Collective Action, and Law*, 102 *Mich. L. Rev.* 71, 93-98 (2003); but see Vetter, *supra* note (questioning the GPL's impact on software creation and distribution).

<sup>166</sup> See Merges, *A New Dynamism in the Public Domain*, *supra* note , at 192-93. IBM's motives, however, are far from altruistic. See *id.*

<sup>167</sup> Vetter, "Infectious" Open Source Software, *supra* note , at 84; Boyle, *supra* note , 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.<sup>168</sup> 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.<sup>169</sup> As Professor Pamela Samuelson notes, “Open source, CC [(“Creative Commons”)], and similar licensed materials are best understood as a contractually constructed information commons.”<sup>170</sup> 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.<sup>171</sup> This Article extends similar principles to patented biomedical inventions.

Of course, the intersection of private ordering and intellectual property rights is not always salutary. Private ordering has raised concerns that “private legislation” can undermine the policy objectives of federal intellectual property law.<sup>172</sup> This arises, for example, in the proliferation of “shrinkwrap” licenses that allow content owners to assert, through contract, a higher degree of control over information than permitted under traditional patent and copyright law.<sup>173</sup> 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.<sup>174</sup>

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 law regulation had not been able to achieve. However, this need not be the case, 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 *private* entities: while public institutions play facilitative, coordinating roles, for-profit institutions exercising market power are the primary drivers of private ordering. However, public institutions are

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<sup>168</sup> Creative Commons, at <http://creativecommons.org/>; Merges, A New Dynamism in the Public Domain, *supra* note , at 183-84.

<sup>169</sup> 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 that “run with the land”).

<sup>170</sup> Samuelson, Enriching Discourse, *supra* note , at 800.

<sup>171</sup> Reichman & Uhlir, *supra* note .

<sup>172</sup> See generally Charles R. McManis, *The Privatization (or “Shrink-Wrapping”) of American Copyright Law*, 87 Cal. L. Rev. 173 (1999); Eric Schlachter, *The Intellectual Property Renaissance in Cyberspace: Why Copyright Law Could be Unimportant on the Internet*, 12 Berkeley Tech. L.J. 15, 38049 (1997); Apik Minassian, *The Death of Copyright: Enforceability of Shrinkwrap Licensing Agreements*, 45 UCLA L. Rev. 569, 601-02 (1997).

<sup>173</sup> See, e.g., ProCD v. Zeidenberg, 86 F.3d 1447 (1996); J.H. Reichman & Jonathan A. Franklin, *Privately Legislated Intellectual Property Rights: Reconciling Freedom of Contract with Public Good Uses of Information*, 147 U. Pa. L. Rev. 875 (1999).

<sup>174</sup> Reichman & Franklin, *supra* note , at 939-51.

market participants, too.<sup>175</sup> As such, they can also leverage the mechanisms of private ordering to advance their institutional norms and 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<sup>176</sup> in contractual relationships with downstream patentees. Current debates on upstream-downstream dynamics in biomedical patenting have focused on potential productivity losses arising from upstream patents.<sup>177</sup> 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 (or at least aspire)<sup>178</sup> to knowledge-sharing norms that contravene the exclusivity inherent in patents.<sup>179</sup> This Article extends these considerations to the institutional level.

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 access and distribution 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 expression of access norms in biomedical patenting. In addition to defining this possibility, the next Part will explore how it 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 often involves 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 leveraging their contributions to biomedical research to require, in a quid pro quo fashion, recipients of those contributions to refrain from asserting patents in ways that inhibit noncommercial biomedical research. This approach does not involve enacting broad legislation to change the general nature of patent rights. Instead, public institutions are tying valuable consideration to *in personam* rights and obligations between themselves and patentees rather than modifying the *in rem* nature of patent rights in general.

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<sup>175</sup> Cf. Evelyn Alicia Lewis, *When Entrepreneurs of Commercial Nonprofits Divorce: Is It Anybody's Business?*, 73 N.C. L. Rev. 1761, 1765-74 (1995) (exploring the significant market power of some non-profit organizations).

<sup>176</sup> See Rai & Eisenberg, *supra* note , at 289.

<sup>177</sup> See *supra*, Part I.A.

<sup>178</sup> F. Scott Kieff, *Facilitating Scientific Research: Intellectual Property and the Norms of Science—A Response to Rai and Eisenberg*, 95 Nw. U. L. Rev. 691 (2001) [hereinafter Kieff, *Facilitating Scientific Research*].

<sup>179</sup> Eisenberg, *Proprietary Rights and the Norms of Science*, *supra* note , at 182; Rai, *Regulating Scientific Research*, *supra* note ; Kahan, *supra* note , at 90-93; Robert K. Merton, *The Sociology of Science* 275 (Norman W. Storer ed., 1973); Warren O. Hagstrom, *The Scientific Community* (1965); Bernard Barber, *Science and the Social Order* (1953).

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 access conditions on downstream partners. Part IV.A considers the NIH’s attempts to leverage its enormous funding of biomedical research as well as 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 funding must share patented discoveries liberally with non-profit research institutions. Part IV.C considers the immense role of universities in conducting basic biomedical research and examines licensing practices ensuring wide access to patented research tools for noncommercial research purposes. 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, a public institution’s significant “upstream” contributions to the development of a patented invention provide it with 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 recreate it through contract. More broadly, this collective effort reveals that contributions of money, patent rights, and materials provide “normative portals” for public institutions to express “non-profit” norms in the patent system.

#### A. The Federal Government

The federal government provides enormous support for basic biomedical research in this country and is leveraging its contributions to discourage grant recipients from asserting resulting patents to impede noncommercial research.<sup>180</sup> 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.<sup>181</sup> In 2003, the NIH, the “primary focal point of federally sponsored biomedical research,”<sup>182</sup>

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<sup>180</sup> Reichman & Uhlir, *supra* note , 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.”).

<sup>181</sup> See Golden, *supra* note , at 136; see generally Harvey Brooks, *National Science Policy and Technological Innovation*, in *The Positive Sum Strategy: Harnessing Technology for Economic Growth* 119 (Ralph Landau & Nathan Rosenberg eds., 1986) (providing a historical overview of federal science policy). The federal government also supports research and development through tax subsidies. I.R.C. § 174 (1994); see generally Peter S. Arno & Michael H. Davis, *Why Don’t We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally Funded Research*, 75 *Tul. L. Rev.* 631, 638 (2001).



provided \$26.4 billion for biomedical research, or 28% of the national total.<sup>183</sup> Similarly, in FY 2004, the NIH's \$28 billion budget comprised about one third of national biomedical research spending.<sup>184</sup> While funding less aggregate biomedical research than private industry, the federal government actually funds more on *basic* research, as opposed to applied research and development, than all private sources combined.<sup>185</sup> In 2004, 55% of NIH funds for research and development went to basic research.<sup>186</sup> The NIH takes a decidedly “upstream” approach to its funding mission. 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.”<sup>187</sup> This basic research, moreover, produces many research tools critical to further inquiry.

In addition to direct funding, the NIH also significantly subsidizes basic research by allowing grantees to patent taxpayer-financed inventions pursuant to the Bayh-Dole Act.<sup>188</sup> Prior to the Bayh-Dole Act, federal agencies possessed no uniform policy regarding the ownership of patent rights arising from taxpayer-funded ventures.<sup>189</sup> Some agencies took title to resulting inventions while other agencies granted title to outside contractors and only retained a license for their own use.<sup>190</sup> Concerns grew that government-owned patents were stifling innovation because firms would not invest in developing existing inventions into commercial goods without themselves having exclusive rights over the inventions.<sup>191</sup> In order to put government-funded inventions to good use, and amid concerns over lagging U.S. economic

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<sup>182</sup> William H. Frist, *Federal Funding for Biomedical Research: Commitment and Benefits*, 287 JAMA 1722, 1724 (2002).

<sup>183</sup> 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.*

<sup>184</sup> Elias A. Zerhouni, *US Biomedical Research: Basic, Translational, and Clinical Science*, 204 JAMA 1352, 1352 (2005).

<sup>185</sup> See Golden, *supra* note , at 139; Ronald L. Meeks, National Science Foundation, InfoBrief: Federal Agencies Supported R&D Grown Over the Period of FY 1994-2004, NSF 07-302 (revised), June 2007, at 1.

<sup>186</sup> Moses III et al., *supra* note , at 1338 table 4; see

<sup>187</sup> NIH, Report to Congress on Affordability of Inventions and Products, July 2004, at 3 [hereinafter NIH, *Affordability of Inventions and Products*]. Gregory D. Graff et al., *The Public-Private Structure of Intellectual Property Ownership in Agricultural Biotechnology*, 21 NATURE BIOTECH. 989, 989 (2003); see Zerhouni, *supra* note , at 1355.

<sup>188</sup> Pub. L. No. 96-517, Sec. 6(a), 94 Stat. 3015, 3019-27 (1980) (codified as amended at 35 U.S.C. §§ 200-211). See generally, Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 Va. L. Rev. 1663, 1691-1709 (1996) [hereinafter Eisenberg, *Public Research and Private Development*]; Arno & Davis, *supra* note , at 646-67.

<sup>189</sup> For a history of the Bayh-Dole Act and related legislation dealing with technology transfer, see Eisenberg, *Public Research and Private Development*, *supra* note , at 1671-95; Ashley J. Stevens, *The Enactment of Bayh-Dole*, 29 J. TECH. TRANSFER 93, 93 (2004).

<sup>190</sup> Eisenberg, *Public Research and Private Development*, *supra* note , at 1677; see S. Rep. No. 96-480, at 2 (1979) (identifying at least 24 different patent policies among federal agencies).

<sup>191</sup> In the 1970s, prior to Bayh-Dole, NASA had a commercialization rate of less than 1% for inventions under its free use policy, but 18-20% for inventions where contractors controlled intellectual property rights. Aaron S. Kesselheim & Jerry Avorn, *University-based Science and Biotechnology Products*, 293 JAMA 850, 851 (2005).

competitiveness relative to Europe and Japan,<sup>192</sup> Congress passed the Bayh-Dole Act in 1980. The Act allowed and encouraged small businesses and non-profit organizations—including universities—to elect to patent the results of government-sponsored research provided that they satisfy certain statutorily defined conditions.<sup>193</sup> In a related vein, also in 1980, Congress passed the Stevenson-Wylder Technology Innovation Act, which required federal laboratories to take a more active role in transferring technology to private industry.<sup>194</sup>

The Bayh-Dole Act represents a significant federal subsidy for research and development.<sup>195</sup> The act has led to an explosion of university patenting and has generated enormous income for some recipients of government funding.<sup>196</sup> 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.”<sup>197</sup> 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.<sup>198</sup> Nevertheless, under the current quid pro quo of government contracting, grant recipients stand to benefit substantially from the option to patent 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.”<sup>199</sup> 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,<sup>200</sup> the agency does not seek to maximize short-term profits. Vannevar Bush, one of the original architects of U.S. research policy under President Franklin D. Roosevelt, envisioned the federal government taking an active role in creating a

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<sup>192</sup> Timothy L. Faley & Michael Sharer, *Technology Transfer and Innovation: Reexamining and Broadening the Perspective of the Transfer of Discoveries Resulting from Government-Sponsored Research*, 3 Comp. Tech. Transfer & Soc’y 109, 113 (2005); Clifton Leaf, *The Law of Unintended Consequences*, Fortune, Sept. 19, 2005, at .

<sup>193</sup> 35 U.S.C. §202. While originally the Bayh-Dole Act only applied to non-profit institutions and small businesses, President Reagan extended the policy to large business contractors in 1984 and Congress enacted this extension in 1984. See Eisenberg, Public Research and Private Development, *supra* note , at 1694; Memorandum to the Heads of Executive Departments and Agencies: Government Patent Policy, Pub. Papers 248 (Feb. 18, 1983); S. Rep. No. 98-662, at 2 (1984), reprinted in 1984 U.S.C.A.N.N. 5799, 5800; Trademark Clarification Act of 1984, § 501(13), 35 U.S.C. § 210(c).

<sup>194</sup> Pub. L. 96-480, 94 Stat. 2311 (1980) (codified as amended at 15 U.S.C. §§ 3701-3717).

<sup>195</sup> See Michael S. Mireles, Jr., *States as Innovation System Laboratories: California, Patents, and Stem Cell Technology*, 28 Cardozo L. Rev. 1133, 1147-49 (2006) [hereinafter Mireles, States as Innovation System Laboratories];

<sup>196</sup> See *infra* Part IV.C.

<sup>197</sup> The Economist, *Innovation’s Golden Goose*, Dec. 14, 2002, at 365.

<sup>198</sup> See Eisenberg, Public Research and Private Development, *supra* note , at 1666; H.R. Rep. No. 96-1307, pt. 1 at 29-32, reprinted in 1980 U.S.C.C.A.C. 6487, 6487-91 (statement of Rep. Jack Brooks); see also Mireles, States as Innovation System Laboratories, *supra* note , at 1149-52; Sage, *supra* note , at 1741.

<sup>199</sup> About NIH, available at <http://www.nih.gov/about/index.html#mission>.

<sup>200</sup> About NIH, available at <http://www.nih.gov/about/index.html#mission>; see Faley & Sharer, *supra* note , at 112; Narin et al., *supra* note , at 317.

scientific “reservoir of knowledge.”<sup>201</sup> 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.<sup>202</sup> 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.<sup>203</sup>

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 itself, “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.”<sup>204</sup> Furthermore, the Act seeks “to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise *without unduly encumbering future research and discovery.*”<sup>205</sup> Indeed, the possibility that taxpayer-financed patents could stymie valuable basic research seems antithetical to the goals of 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.”<sup>206</sup>

The Bayh-Dole Act ensures these access and distribution objectives through several statutory provisions. First, under 35 U.S.C. § 202(a)(ii), a federal funding agency can restrict patenting by a grantee contractor in “exceptional circumstances” when the agency determines that withholding title to the invention “will better promote the policy and goals” of the act.<sup>207</sup> 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.<sup>208</sup> 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.<sup>209</sup> Thus, in exchange for

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<sup>201</sup> Vannevar Bush, *Science: The Endless Frontier*, available at <http://www.nsf.gov/about/history/vbush1945.htm>.; Faley & Sharer, *supra* note , at 111.

<sup>202</sup> See National Institutes of Health, *Review Criteria for and Rating of Unsolicited Research Grant and Other Applications* (June 27, 1997), at <http://grants.nih.gov/grants/guide/notice-files/not97-010.html>.

<sup>203</sup> As an example of these norms, in 1994 the NIH voluntarily withdrew patent applications on expressed sequent 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). See also Reichman & Uhler, *supra* note , at 332 .

<sup>204</sup> 35 U.S.C. § 200.

<sup>205</sup> 35 U.S.C. § 200 (emphasis added).

<sup>206</sup> 35 U.S.C. § 200.

<sup>207</sup> 35 U.S.C. § 202(a)(ii).

<sup>208</sup> 35 U.S.C. § 202(c)(4).

<sup>209</sup> 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;

providing patent rights to taxpayer-funded inventions to grantees, funding agencies like the NIH retain formal claims on how those inventions can be used. Significantly, these rights operate in a viral manner and apply not only to the government contractor, such as a university, that patents the invention, but to licensees of that patent as well.<sup>210</sup> By regulation, patentees electing to take title under the act must state the following on any patent applications and issued patents: “This invention was made with government support under [contract name] awarded by [federal agency]. The government has certain rights in the invention.”<sup>211</sup>

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

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.<sup>212</sup> Indeed, the Bayh-Dole Act has been useful in this regard; the threat of invoking these 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”).<sup>213</sup> These Principles and Guidelines reflect the NIH’s commitment to open science by specifically seeking to ensure wide dissemination of research resources developed with NIH funds.<sup>214</sup> Notably, the Principle and Guidelines distinguish between “internal use by non-profit institutions” and “commercial development and sale or provision of services,” which may require some degree of exclusivity.<sup>215</sup> The guidelines recommend transferring patented research tools to non-profits on terms no more onerous than the Uniform Biological Material Transfer Agreement (UBMTA),<sup>216</sup> a standardized process for sharing biological materials developed by the NIH.<sup>217</sup> Furthermore, they recommend transferring NIH-funded research tools to for-profit entities “with the fewest

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- (3) action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or
  - (4) action is necessary because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204.

Id.

<sup>210</sup> See Jaffe, *supra* note , at 533 (“[T]he rules governing the patentability of federally supported research essentially control university patenting.”).

<sup>211</sup> 37 C.F.R. § 410.14(f)(4).

<sup>212</sup> For a partial list arranged chronologically, see Ferguson, *supra* note , at 111s.

<sup>213</sup> 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 , at 32.

<sup>214</sup> 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.”).

<sup>215</sup> NIH, Principles and Guidelines, 64 Fed. Reg. at 72,093.

<sup>216</sup> 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].

<sup>217</sup> NIH, Principles and Guidelines, 64 Fed. Reg. at 72,094.

encumbrances possible.”<sup>218</sup> Interestingly, these Principles and Guidelines reflect a shift away from viewing patents as simple rights to exclude towards reconstituting patents as complex governance regimes of selective access and exclusivity.<sup>219</sup>

These Principles and Guidelines also seek to implement the Bayh-Dole Act’s<sup>220</sup> goal of maximizing utilization of new tools by the research community.<sup>221</sup> 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.”<sup>222</sup> 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.”<sup>223</sup> While exclusive licenses may be appropriate for additional commercial development, they should ultimately aim for widespread dissemination of a resulting product.<sup>224</sup>

While the Bayh-Dole Act constrains the NIH’s ability to explicitly enforce these Principles and Guidelines,<sup>225</sup> the NIH’s funding power ensures that they have “real teeth.”<sup>226</sup> The NIH explicitly considers compliance with the Principles and Guidelines in awarding grants.<sup>227</sup> Although the NIH may not *generally* regulate the patenting practices of federal grantees,<sup>228</sup> the NIH has incorporated these Principles and Guidelines as criteria in awarding individual grants.<sup>229</sup> The possibility of denying funding is clearly present, and operates as a strong incentive to comply.<sup>230</sup> While commentators caution that the NIH may be exceeding its authority under the Bayh-Dole Act in “enforcing” these guidelines,<sup>231</sup> the NIH suggests that widespread noncompliance with these policies may spur regulatory or statutory intervention.<sup>232</sup>

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<sup>218</sup> NIH, Principles and Guidelines, 64 Fed. Reg. at 72,094

<sup>219</sup> See Smith, *supra* note .

<sup>220</sup> NIH, Principles and Guidelines, 64 Fed. Reg. at 72,092.

<sup>221</sup> Ferguson, *supra* note , at 111S.

<sup>222</sup> NIH, Principles and Guidelines, 64 Fed. Reg. at 72,093.

<sup>223</sup> NIH, Principles and Guidelines, 64 Fed. Reg. at 72,093.

<sup>224</sup> NIH, Principles and Guidelines, 64 Fed. Reg. at 72,093.

<sup>225</sup> Rai & Eisenberg, *supra* note , at 293.

<sup>226</sup> Mauricio A. Flores, Taking the Profit Out of Biomedical Research Tools, 17 Nature Biotech. 819, 820 (1999).

<sup>227</sup> Pressman et al., *supra* note , at 32.

<sup>228</sup> Rai & Eisenberg, *supra* note , 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>

<sup>229</sup> Flores, *supra* note , at 820; David Malakoff, *NIH Roils Academe with Advice on Licensing DNA Patents*, 303 Science 1757, 58 (2004).

<sup>230</sup> Flores, *supra* note , at 820.

<sup>231</sup> Rai & Eisenberg, *supra* note , at 308-09.

<sup>232</sup> NIH, Principles and Guidelines, 64 Fed. Reg. at 72,090; Ferguson, *supra* note , at 112S; cf. National Institutes of Health, National Human Genome Research Institute, NHGRI Policy Regarding Intellectual Property of Human Genomic Sequence, Apr. 9, 1996, at <http://www.genome.gov/10000926> (stating that the NIH would invoke the “exceptional circumstances” provision of the Bayh-Dole Act to restrict patenting on the results of the Human Genome Project) [hereinafter NHGRI, Policy Regarding Intellectual Property of Human Genomic Sequence].

The reach of the NIH's influence is considerable given that it administers about thirty thousand outstanding grants to individual principal investigators.<sup>233</sup> Universities routinely advise their researchers on drafting grant proposals that comply with NIH policy guidance.<sup>234</sup> Furthermore, the NIH expects that institutions receiving both federal and private research support will make private sponsors aware of the NIH's expectations for research tool availability.<sup>235</sup> Through the "carrot" of enormous financial support, the NIH is helping to ensure that grantees do not assert patents to impede biomedical science.

Other NIH policies also encourage the widespread availability of taxpayer-funded research resources. In 2004, the NIH issued policy guidelines for sharing model organisms for biomedical research.<sup>236</sup> In 2005, the NIH issued "Best Practices" guidelines for licensing genomic inventions.<sup>237</sup> 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."<sup>238</sup> These guidelines parallel practices at the NIH's own Office of Technology Transfer and recommend that recipients of NIH funding strongly consider broad, nonexclusive licensing of genomic inventions. Significantly, the guidelines recognize the appropriateness of exclusive licensing when necessary to facilitate post-invention commercialization.<sup>239</sup> 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.<sup>240</sup> While this mechanism does not implicate patented research tools, it demonstrates the NIH's ability to leverage funding to compel sharing of resources it considers essential to research.

In addition to issuing guidelines, the NIH has actively negotiated enhanced access to specific taxpayer-financed, patented research tools. In the late 1990s, the University of Wisconsin's patents on extracted and purified human embryonic stem cells<sup>241</sup> raised concerns that exclusive rights could inhibit scientific investigations using these basic research tools.<sup>242</sup> To address these concerns, in 2001 the Public Health Service (PHS),<sup>243</sup> entered into a Memorandum of Understanding (MOU) with the WiCell Research Institute, a University of Wisconsin-affiliated non-profit organization holding licenses to the stem cell patents.<sup>244</sup> Under the MOU,

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<sup>233</sup> Golden, *supra* note , at 150.

<sup>234</sup> See, e.g., The University of Chicago, Guidelines for Grant and Contract Management, available at <http://researchadmin.uchicago.edu/guidelines/300/312.shtml>.

<sup>235</sup> Ferguson, *supra* note , at 111S

<sup>236</sup> NIH, NIH Policy on Sharing of Model Organisms for Biomedical Research, NOT-OD-04-042, May 7, 2004, available at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html>.

<sup>237</sup> NIH, Best Practices for the Licensing of Genomic Inventions: Final Notice, 70 Fed. Reg. 18413, 18,415 (April 11, 2005).

<sup>238</sup> NIH, NIH Grants Policy Statement 115 (2003).

<sup>239</sup> Pressman et al., *supra* note , at 32.

<sup>240</sup> National Institutes of Health, Final NIH Statement on Sharing Research Data, Feb. 26, 2003, available at <http://grants.nih.gov/grants/guide/notice-files/not-od-03-032.html>; NIH Data Sharing Policy and Implementation Guidance (March 5, 2003), at [http://grants.nih.gov/grants/policy/data\\_sharing/data\\_sharing\\_guidance.htm](http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm).

<sup>241</sup> U.S. Patent No. 5,843,780 (filed Jan. 18, 1996); U.S. Patent No. 6,200,806 (filed June 26, 1998); see Lee, Inverting the Logic of Scientific Discovery, *supra* note , at 89-92.

<sup>242</sup> See generally Hazuka, *supra* note .

<sup>243</sup> The PHS is the umbrella agency housing the NIH.

<sup>244</sup> Memorandum of Understanding Between WiCell Research Institute, Inc. and Public Health Service, U.S. Department of Health and Human Services 5 (Sept. 5, 2001), available at <http://ott.od.nih.gov/pdfs/WiCellMOUhuman.pdf> [hereinafter *WiCell MOU*].

WiCell agreed to provide a research license for Wisconsin Patent Rights as well as actual cell lines 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.”<sup>245</sup> The MOU does not only benefit NIH-funded scientists, but further requires WiCell to provide licenses and actual cell lines to all non-profit organizations on similar terms.<sup>246</sup>

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 obtained a patent on processes and products related to inserting genes in mammalian cells, which comprise fundamental research tools.<sup>247</sup> Axel’s research was funded in part by the NIH, but Columbia’s patent application preceded the Bayh-Dole Act by several months.<sup>248</sup> Accordingly, pursuant to the pre-Bayh-Dole regime, the NIH assigned the patent to Columbia upon condition that the university must license it widely and nonexclusively<sup>249</sup> and that it would not charge “unreasonable” royalties to licensees.<sup>250</sup>

At the far end of the spectrum, the NIH has also invoked the “exceptional circumstances” provision of the Bayh-Dole Act to discourage patenting of key research resources. For example, the NIH leveraged its financing of the Human Genome Project to ensure that grant recipients did not patent large blocks of sequenced DNA.<sup>251</sup> As part of a Request for Applications (RFA), the National Human Genome Research Institute (“NHGRI”) required applicants to agree to rapidly release human genome data to public databases as a condition of receiving funds.<sup>252</sup> Furthermore, NHGRI explicitly discouraged grantees from patenting raw human genomic DNA sequences,<sup>253</sup> which it believed lacked the specific utility to warrant patentability.<sup>254</sup> NHGRI stated that if grantees did in fact patent DNA sequences, it would consider invoking the exceptional circumstances provision of the Bayh-Dole Act<sup>255</sup> to foreclose such patenting.<sup>256</sup>

The NIH explicitly invoked the “exceptional circumstances” provision of the Bayh-Dole Act in a taxpayer-financed initiative to sequence the mouse genome, develop new model

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<sup>245</sup> *WiCell MOU*, *supra* note . The funding situation was a bit unique because the federal ban on financing human embryonic stem cell research limited NIH’s contributions. Some of the research was funded by Geron, a private biotechnology company, which received several commercial licenses for the patented human embryonic stem cells.

<sup>246</sup> *WiCell MOU*, *supra* note .

<sup>247</sup> U.S. Patent No. 4,399,216; Ken Howard, *Biotechs Sue Columbia over Fourth Axel Patent*, 21 *Nature Biotechnology* 955, 955 (2003).

<sup>248</sup> Bernard Wysocki Jr., *Columbia’s Pursuit of Patent Riches Angers Companies*, *Wall St. J.*, Dec. 21, 2004, at A1.

<sup>249</sup> Wysocki, Jr., *supra* note , at A1.

<sup>250</sup> Wysocki, Jr., *supra* note , at A1.

<sup>251</sup> See Gregory A. Petsko, *Who Owns the Data?*, 6 *Genome Biology* 107.1, 107.1 (2005); see Human Genome Project Information at [http://www.ornl.gov/sci/techresources/Human\\_Genome/home.shtml](http://www.ornl.gov/sci/techresources/Human_Genome/home.shtml).

<sup>252</sup> NHGRI, Policy Regarding Intellectual Property of Human Genomic Sequence, *supra* note .

<sup>253</sup> Marshall, *Genome Researchers Take the Pledge*, *supra* note , at .

<sup>254</sup> NHGRI, Policy Regarding Intellectual Property of Human Genomic Sequence, *supra* note .

<sup>255</sup> See *infra* Part IV.A.2.b.

<sup>256</sup> NHGRI, Policy Regarding Intellectual Property of Human Genomic Sequence, *supra* note .

transgenic animals, and characterize these animals' phenotypes.<sup>257</sup> The NIH stated it would rely on this provision to prevent project grantees from patenting their results.<sup>258</sup> 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.<sup>259</sup>

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 United States Court of Federal Claims.<sup>260</sup> As Professors Rai and Eisenberg observe, relaxing these administrative burdens could enhance the effectiveness of the exceptional circumstances provision.<sup>261</sup> 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.<sup>262</sup> Again, as Professors Rai and Eisenberg argue, a chief difficulty in exercising march-in rights is that such rights can only take effect after elaborate administrative proceedings and exhaustion of court appeals.<sup>263</sup> Reforming this process could enhance the NIH's ability to effectively utilize march-in rights to compel wide licensing of federally-funded research tools.<sup>264</sup>

While these examples illustrate the NIH's leveraging of *extramural* funding to encourage wide access to patented research tools, the NIH has adopted similar policies for its *intramural* research. For many years, the NIH's own Intramural Research Tool Distribution Policy has required NIH scientists to make their research results widely available to the scientific community. In its own policies, 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.<sup>265</sup> The NIH observes that the success of this internal program could also extend to all federally funded research.<sup>266</sup>

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<sup>257</sup> See generally NIH, Trans-NIH Mouse Initiatives, at <http://www.nih.gov/science/models/mouse/>; Steven O. Moldin et al., *Trans-NIH Neuroscience Initiatives on Mouse Phenotyping and Mutagenesis*, 12 *Mammalian Genome* 575 (2001).

<sup>258</sup> Eliot Marshall, *A Deluge of Patents Creates Hassles for Research*, 288 *Science* 255, (2000); NIH, Mouse Mutagenesis and Phenotype: Developmental Defects, RFA: HD-99-007, March 31, 1999, available at <http://grants.nih.gov/grants/guide/rfa-files/RFA-HD-99-007.html> (“NIH expects to make a Determination of Exceptional Circumstances (DEC) to eliminate the potential for patents on mutant mice, embryos, and sperm.”).

<sup>259</sup> Moldin, *supra* note, at 580.

<sup>260</sup> Rai & Eisenberg, *supra* note, at 293; see 35 U.S.C. § 203(2); *see also* 35 U.S.C. § 202(b)(4); 37 C.F.R. § 401.4.

<sup>261</sup> Rai & Eisenberg, *supra* note, at 310.

<sup>262</sup> Office of the Director, National Institutes of Health, Determination in the Case of Petition of CellPro, Inc., (Aug. 1, 1997), available at [http://www.nih.gov/icd/od/foia/cellpro/pdfs/foia\\_cellpro39.pdf](http://www.nih.gov/icd/od/foia/cellpro/pdfs/foia_cellpro39.pdf); Office of the Director, National Institutes of Health, In the Case of Norvir (July 2, 2004), available at <http://www.essentialinventions.org/legal/norvir/norvir-29jan04petition.pdf>; Office of the Director, National Institutes of Health, In the Case of Xatalan, Manufactured by Pfizer, Inc., Sept. 17, 2004; *see* Barbara M. McGarey and Annette C. Levey, *Patents, Products, and Public Health: An Analysis of the CellPro March-In Petition*, 14 *BERKELEY TECH. L. J.* 1095 (1999); Mireles, *supra* note, at 1156-57; O'Connor, *supra* note, at 700-03.

<sup>263</sup> Rai & Eisenberg, *supra* note, at 294; 35 U.S.C. § 203(2); 37 C.F.R. § 401.6.

<sup>264</sup> Rai & Eisenberg, *supra* note, at .

<sup>265</sup> Public Health Service, Patent License Agreement – *Exclusive 5*, available at <http://ott.od.nih.gov/docs/PHS%20Patent%20License-Exclusive-model%20102005.DOC>.



c. 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 been able to establish. 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 wide availability of patented research tools.<sup>267</sup> The NIH has exploited its funding power to express these norms and policy objectives in transactions with grant recipients. The Bayh-Dole Act also represents a vehicle for advancing non-profit norms. The rights retained by the NIH under that statute help advance the policy objective of maximizing the productive use of taxpayer-funded inventions. Here, money and patent rights represent “normative portals” for the NIH to promote widespread use of privately-patented technologies for research purposes.

Procedurally, these efforts reflect consideration-based patent regulation rather than a traditional public law model for advancing patent policy. Although the NIH is a public agency, it is creating *in personam* obligations with individual grantees. The NIH embeds expectations of access to research tools in quid pro quos with grantees who receive significant financial support; the NIH’s Principles and Guidelines are only relevant to recipients of federal grants, 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” and is taking an entrepreneurial approach to address the excesses of patent exclusivity.<sup>268</sup>

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 particular bargain whereby contractors may take title to taxpayer-funded inventions. Through this mutual exchange, government agencies limit the ordinary rights conferred by the Patent Act.

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The NIH has even negotiated greater access to *privately-developed* research tools. For example, the NIH negotiated with DuPont to widen access to its patented *Cre-loxP* and *OncoMouse* technologies for noncommercial research purposes. See generally Eliot Marshall, *Sharing Reagents: NIH, DuPont Declare Truce in Mouse War*, 281 *Science* 1261, (1998); Eliot Marshall, *NIH Cuts Deal on Use of OncoMouse*, 287 *Science* 567, 567 (2000); NIH, NIH, Jackson Laboratory and DuPont Pharmaceutical Sign *Cre-Lox* Technology Use Agreement, Aug. 21, 1998, available at <http://www.nih.gov/news/pr/aug98/od-21.htm>; NIH, NIH and E.I. DuPont Sign *OncoMouse* Agreement, Jan. 19, 2000, available at <http://www.nih.gov/news/pr/jan2000/od-19.htm>.

<sup>266</sup> Ferguson, *supra* note , at 110S

<sup>267</sup> Ferguson, *supra* note , at 110S.

<sup>268</sup> Golden, *supra* note , at 176.

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.<sup>269</sup>

## 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, leveraging its support of basic scientific research to promote access to patented research tools.

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

While state governments have historically been rather marginal funders of 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.<sup>270</sup> However, numerous states have recently begun substantial initiatives to fund human embryonic stem cell research.<sup>271</sup> On August 9, 2001, President George W. Bush announced that federal funds for human embryonic stem cell research would be limited to cell lines whose derivation was initiated prior to 9:00 pm E.D.T. on that date.<sup>272</sup> This generated widespread concern that limitations on federal funds would imperil this significant research.<sup>273</sup> Accordingly, 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.<sup>274</sup> Notwithstanding recent discoveries that adult stem cells can be reprogrammed to behave like embryonic stem cells,<sup>275</sup>

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<sup>269</sup> Rai & Eisenberg, *supra* note , at .

<sup>270</sup> Moses III et al., *supra* note , at 1335. Significantly, these figures do not directly capture funds from tobacco settlements or California's stem cell initiative. Moses III et al., *supra* note , at 1334; see Mireles, States as Innovation System Laboratories, *supra* note , at 1135 n.3 (collecting state statutes related to funding and subsidizing basic research).

<sup>271</sup> Cf. Moses III et al., *supra* note , at 1338.

<sup>272</sup> President George W. Bush, President Discusses Stem Cell Research (Aug. 9, 2001), <http://www.whitehouse.gov/news/releases/2001/08/20010809-2.html>; NIH, NIH Statement on the President's Stem Cell Address (Aug. 9, 2001), at <http://www.nih.gov/news/pr/aug2001/od-09.htm>; NIH, Federal Policy, at <http://stemcells.nih.gov/policy/>.

<sup>273</sup> See, e.g., Jennifer L. Enmon, Note, *Stem Cell Research: Is the Law Preventing Progress?*, 2002 UTAH L. REV. 621, 647 (2002). President Bush's statement noted that 60 suitable cell lines were already in existence. Bush, *supra* note . However, the methods to derive these early lines were technically demanding and often produced imperfections. Liza Gross, *Stem Cell Promise, Interrupted: How Long Do US Researchers Have to Wait?*, 5 PLoS Biology 6, 7 (2007). Furthermore, these stem cell lines were grown on mouse fibroblasts, which increases the risk of rejection by human immune systems. *Id.* at 7; see Joanna K. Sax, *The States "Race" with the Federal Government for Stem Cell Research*, 15 Annals Health L. 1, 18(2006). As of March 2007, there were 21 cell lines listed in the NIH Human Embryonic Stem Cell Registry. NIH, Frequently Asked Questions (FAQs), at <http://stemcells.nih.gov/info/faqs.asp>.

<sup>274</sup> See Joe Palca, *States Take Lead in Funding Stem-Cell Research*, NPR, Apr. 1, 2007, at <http://www.npr.org/templates/story/story.php?storyId=9244363>; see generally National Conference of State Legislatures, Stem Cell Research, at <http://ncsl.org/programs/health/genetics/embfet.htm>; Lori Gruen & Laura Grabel, *Concise Review: Scientific and Ethical Roadblocks to Human Embryonic Stem Cell Therapy*, 24 Stem Cells 2162 (2006); Susan Okie, *Stem-Cell Research—Signposts and Roadblocks*, 353 N. Engl. J. Med. 1 (2005).

<sup>275</sup> See Nicholas Wade, *Biologists Make Skin Cells Work Like Stem Cells*, N.Y. Times, June 7, 2007, at .

many researchers still feel that embryonic stem cells, which are the primary targets of these state initiatives, remain the “gold standard” for stem cell research.<sup>276</sup>

This Subpart focuses on California’s stem cell initiative because: 1) it vastly exceeds the size of other state initiatives;<sup>277</sup> 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 have a significant impact on 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.<sup>278</sup> To administer the grants, Proposition 71 established the California Institute of Regenerative Medicine (“CIRM”),<sup>279</sup> a state agency governed by a 29-member Independent Citizens Oversight Committee (“ICOC”) comprised of representatives from academia, government, business, and disease advocacy groups.<sup>280</sup>

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

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.”<sup>281</sup> Proposition 71 identifies several additional objectives, including improving California’s health care system, reducing health care costs, and generating revenue from sponsored research.<sup>282</sup> 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.<sup>283</sup>

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<sup>276</sup> 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. It is therefore far from certain that federal funding for induced stem cell research will completely displace state-funded human embryonic stem cell research. Furthermore, Proposition 71 allows CIRM to fund research on adult stem cells, over which its intellectual property policies would still apply. Cal. Health & Safety Code § 125290.60(c)(1)(c)-(d).

<sup>277</sup> See National Conference of State Legislatures, *supra* note .

<sup>278</sup> The ballot initiative passed 59 percent to 41 percent. Ceci Connolly, *Calif. Stem Cell Initiative Could Backfire Nationally*, Wash. Post, Nov. 14, 2004, at A15. See O’Connor, *supra* note , at 674-79; Molly Silfen, Note, *How Will California’s Funding of Stem Cell Research Impact Innovation? Recommendations for an Intellectual Property Policy*, 18 Harv. J.L. & Tech. 459, 468-71 (2005); Connie Bruck, *Hollywood Science: Should a Ballot Initiative Determine the Fate of Stem-Cell Research*, New Yorker, Oct. 18 2004, at . Interestingly, venture capitalists provided half the money necessary to pass the bill. Cynthia M. Ho, *Do Patents Promote the Progress of Justice? Reflections on Varied Visions of Justice*, 36 Loy. U. Chi. L.J., 469, 473 (2005).

<sup>279</sup> California Secretary of State, Text of Proposed Laws – Proposition 71, in California Official Voter Information Guide 147, 147 (2004), <http://www.cirm.ca.gov/pdf/prop71.pdf> [hereinafter Proposition 71].

<sup>280</sup> Proposition 71, *supra* note , at 147.

<sup>281</sup> Proposition 71, *supra* note , at 147.

<sup>282</sup> Proposition 71, *supra* note , at 147.

<sup>283</sup> Proposition 71, *supra* note , at 149.

Relative to the NIH’s funding of basic biomedical research, CIRM’s mandate is less explicitly “altruistic”: the State of California has a financial stake in resulting 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 non-profit<sup>284</sup> and for-profit grantees.<sup>285</sup> More recently, CIRM has codified these policies in regulations, to which we will now turn.<sup>286</sup>

### 3. Leveraging State Money to Enhance Access to Patented Research Tools

CIRM is addressing potential patent holdup by explicitly leveraging its funding of biomedical research to insist on wide access to state-funded patented biomedical research tools. Following the recommendations of the California Council on Science and Technology,<sup>287</sup> CIRM has adopted a Bayh-Dole model allowing grant recipients to patent resulting inventions.<sup>288</sup> However, CIRM goes much further than the Bayh-Dole Act in explicitly limiting the patent rights of grant recipients to ensure that such patents do not impede biomedical research.

In exchange for receiving state funds, 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 for sharing research tools, 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.<sup>289</sup> Furthermore, non-profit grantees must agree to make all such inventions readily accessible on reasonable terms to California research institutions for noncommercial purposes.<sup>290</sup> CIRM regulations further promote the wide availability of funded inventions by stating that non-profit “[g]rantee organizations shall negotiate non-exclusive licenses whenever possible.”<sup>291</sup>

In addition, CIRM also mandates disseminating “biomedical materials”<sup>292</sup> developed by non-profit grantees that are described in academic publications. Non-profit grantees must share such materials on reasonable terms<sup>293</sup> within 60 days of a request to use them for research

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<sup>284</sup> CIRM, NON-PROFIT POLICY, *supra* note .

<sup>285</sup> CIRM, FOR-PROFIT POLICY, *supra* note .

<sup>286</sup> Given the recent nature of these codifications, these regulations are subject to change. However, it is unlikely that they will deviate significantly from the core provisions described here.

<sup>287</sup> See Mireles, *supra* note , at 1181-86.

<sup>288</sup> CIRM, Non-Profit Policy, *supra* note , at 2; CIRM, For-Profit Policy, *supra* note , at 4, 29.

<sup>289</sup> 17 Cal. Code Regs. § 100306(a); CIRM, Non-Profit Policy, *supra* note , at 18; see Mireles, *supra* note , at 1190, 1199-1200.

<sup>290</sup> 17 Cal. Code Regs. § 100306(a); CIRM, NON-PROFIT POLICY, *supra* note , at 18, 37.

<sup>291</sup> 17 Cal. Code Regs. § 100306(b).

<sup>292</sup> CIRM’s definition of “biomedical materials” is largely coextensive with biomedical research tools and covers [e]ntities of biomedical relevance . . . including but not limited to unique research resources such as synthetic compounds, organisms, cell lines, viruses, cell products, cloned DNA, as well as DNA sequences, mapping information, crystallographic coordinates, and spectroscopic data. Specific examples include specialized and/or genetically defined cells, including normal and diseased human cells, monoclonal antibodies, hybridoma cell lines, microbial cells and products, viruses and viral products, recombinant nucleic acid molecules, DNA probes, nucleic acid and protein sequences, certain types of animals including transgenic mice and other property such as computer programs.

17 Cal Code Regs. § 10031 (d).

<sup>293</sup> CIRM, Non-Profit Policy, *supra* note , at 16.

purposes.<sup>294</sup> Finally, CIRM maintains march-in rights to compulsorily license any CIRM-funded invention based on certain codified criteria.<sup>295</sup> March-in rights are available, for example, “[t]o meet requirements of public use” of CIRM-funded inventions.<sup>296</sup> Notably, however, CIRM’s march-in rights lack the cumbersome administrative review provisions of the Bayh-Dole Act.<sup>297</sup> Ultimately, in the quid pro quo of accepting state funds, grantees must also accept limitations on their patent rights.<sup>298</sup>

While CIRM maintains different policies for for-profit grantees, they also promote widely disseminating CIRM-funded biomedical 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.”<sup>299</sup> If a for-profit grantee developed an asset that did not need further refinement for use as a research tool, then CIRM could in theory invoke this provision to limit exclusive licensing of that asset only for *commercial sale* of products related to that tool while requiring nonexclusive licensing of the tool for basic research purposes.

CIRM’s requirement of widely sharing biomedical resources described in publications also applies to for-profit grantees, although somewhat differently. 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.<sup>300</sup> Materials are to be shared without cost or at cost.<sup>301</sup> However, exceptions exist for for-profit entities.<sup>302</sup> For example, such sharing is not required if “a sharing request is in direct conflict with the business of the Grantee.”<sup>303</sup> Finally, CIRM maintains march-in rights for inventions developed by for-profit entities with state funds.<sup>304</sup> Again, CIRM may exercise these rights if, among other reasons, “the Grantee or its exclusive licensee has failed to satisfy requirements for public use.”<sup>305</sup>

#### 4. Analysis

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<sup>294</sup> CIRM, NON-PROFIT POLICY, *supra* note , at 28-31; 17 Cal. Code. Reg. § 100304 ; see Mireles, *supra* note , at 1188-89.

<sup>295</sup> CIRM, NON-PROFIT POLICY, *supra* note , at 2, 22; 17 Cal. Code. Reg. § 100310 (2007).

<sup>296</sup> 17 Cal. Code Regs. § 100310.

<sup>297</sup> See Mireles, *supra* note , at 1191

<sup>298</sup> 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 , at 32, 35.

<sup>299</sup> 17 Cal. Code Regs. § 100405(c).

<sup>300</sup> CIRM, NON-PROFIT POLICY, *supra* note , at 28-31; CIRM, FOR-PROFIT POLICY, *supra* note , at 38; 17 Cal. Code. Reg. § 100304 (2007); 17 Cal. Code Reg. § 100404 (2008); See Mireles, *supra* note , at 1188-89.

<sup>301</sup> 17 Cal. Code Regs. § 100404(a); CIRM, For-Profit Policy, *supra* note , at 38.

<sup>302</sup> 17 Cal. Code Regs. § 100404(c); CIRM, FOR-PROFIT POLICY, *supra* note , at 38.

<sup>303</sup> 17 Cal. Code Regs. § 100404(c)(2).

<sup>304</sup> 17 Cal. Code Regs. § 100410.

<sup>305</sup> 17 Cal. Code Regs. § 100410(b)(3).

To a degree greater than the NIH, the state of California is taking an entrepreneurial approach to preventing patent holdup by explicitly requiring broad access to state-funded, 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 intellectual property 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,”<sup>306</sup> and virtually identical language applies to for-profit grantees.<sup>307</sup> Clearly, California could not regulate licensing practices as general legislation applicable to all patented inventions in that state; federal patent law would preempt such statutes.<sup>308</sup> However, as a market participant adopting the model of private ordering, CIRM has much greater flexibility to place conditions on its money to ensure that grantees do not assert patent rights to impede research.

CIRM’s intellectual property policies reveal several of the promises of consideration-based patent regulation. Again, 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 some 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 access to patented research tools to research 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 not benefit the interests of the national scientific community as a whole.<sup>309</sup>

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<sup>306</sup> 17 Cal. Code Regs. § 100300.

<sup>307</sup> 17 Cal. Code Regs. § 100400.

<sup>308</sup> See generally, *Bonito Boats Inc. v. Thunder Craft Boats, Inc.* 489 U.S. 141, 164-68 (1989); *Compco Corp. v. Day-Brite Lighting Inc.*, 376 U.S. 234, 237 (1964); *Sears, Roebuck & Co v. Stiffel Co.*, 376 U.S. 225, 228-31 (1964); Mark A. Lemley, *Beyond Preemption, The Law and Policy of Intellectual Property Licensing*, 87 Cal. L. Rev. 111, 138-39 (1999); Keith Aoki, *Balancing Act: Reflections on Justice O’Connor’s Intellectual Property Jurisprudence*, 44 Hous. L. Rev. 965, 976-80 (2007).

<sup>309</sup> See O’Connor, *supra* note , at 679; Sax, *supra* note , at 30-31; Cf. Rebecca S. Eisenberg & Arti K. Rai, *Harnessing and Sharing the Benefits of State-Sponsored Research: Intellectual Property Rights and Data Sharing in California’s Stem Cell Initiative*, 21 Berkeley Tech. L.J. 1187, 1198 (2006).

### C. Universities

Unlike funding agencies like the NIH and CIRM, universities are particularly critical to the contractual creation of a noncommercial research exception 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.<sup>310</sup> This Subpart first provides an overview of university contributions to basic biomedical science as well as the rise of academic patenting to show the significant leverage that universities enjoy in this area. It then discusses the complicated normative position of universities regarding patents on biomedical research tools: while universities stand to profit from such patents, traditional commitments to openly share basic research materials still persist. Finally, it turns to intellectual property policies in place at universities that enhance the availability of patented research tools for foundational scientific investigation.

#### 1. University Contributions to Basic Biomedical Research

Universities play a predominant role in conducting basic biomedical research.<sup>311</sup> In 2002, universities and colleges spent \$19.6 billion on biomedical research.<sup>312</sup> 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.<sup>313</sup> Unlike commercial firms, which tend to focus on applied research and development, universities particularly focus on *basic* research.<sup>314</sup> As a result of the close nexus of basic biomedical research and tangible applications, university research has generated a significant number of research tools,<sup>315</sup> including: recombinant DNA technology; extracted, purified human embryonic stem cells; and genetically-modified disease models.<sup>316</sup>

Universities are not only generating these discoveries, but obtaining patents on them. University patenting has exploded in the past three decades.<sup>317</sup> A number of factors have contributed to this phenomenon, including: the Bayh-Dole Act; doctrinal reforms expanding the

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<sup>310</sup> Nelson, *supra* note at 467.

<sup>311</sup> Amanda L. Brewster et al., *Facilitating Humanitarian Access to Pharmaceutical and Agricultural Innovation*, in *Handbook of Best Practices*, *supra* note , at 52.

<sup>312</sup> Moses III et al., *supra* note , at 1337. In some sense, universities are pass-through entities for federal grants: federal expenditures accounted for 64% of the research support provided by universities. *Id.*

<sup>313</sup> NIH, NIH Budget, at <http://www.nih.gov/about/budget.htm>.

<sup>314</sup> In 2004, \$5.479 billion of \$7.932 billion (69.1%) of non-federal money spent by universities on research and development went to *basic* research. National Patterns of R&D Resources: 2006 Data Update, Sept. 2007, at 26.

<sup>315</sup> Cf. Lemley, Are Universities Patent Trolls?, *supra* note , at 614.

<sup>316</sup> See Annetine C. Gelijns & Samuel O. Thier, *Medical Innovation and Institutional Interdependence: Rethinking University-Industry Connections*, 287 JAMA 72, 74 (2007).

<sup>317</sup> See generally Walter W. Powell & Jason Owen-Smith, *Universities and the Market for Intellectual Property in the Life Sciences*, 17 J. Pol'y Analysis & Management 253 (1998); Lita Nelsen, *The Rise of Intellectual Property Protection in the American University*, 279 Science (1998). Of course, university patenting did not begin with the Bayh-Dole Act. See Charles Weiner, *Patenting and Academic Research: Historical Case Studies*, 12 Science, Tech., & Human Values 50 (1987).

scope of patentable subject matter;<sup>318</sup> advances in molecular biology revealing a relatively clear path from “basic” discoveries to commercial products;<sup>319</sup> and market pressures on universities.<sup>320</sup> 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.<sup>321</sup> By 2002, universities were awarded more than 3,000 patents a year, with licensing revenues exceeding \$1.2 billion.<sup>322</sup> The number of patents held and the number of licenses arranged by universities has more than doubled between 1991 and 2005.<sup>323</sup> In 2006 alone, firms introduced 697 new products based on active university licenses.<sup>324</sup>

University patenting is particularly prevalent in the biopharmaceutical field.<sup>325</sup> University research in genetics and molecular biology spawned the biotechnology industry;<sup>326</sup> in that sector alone, universities hold approximately 18% of all patents.<sup>327</sup> 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.<sup>328</sup> As noted, university patents are more likely to cover building blocks critical to innovation, including biomedical research tools, than particular downstream applications of a technology.<sup>329</sup>

Universities thus hold assets of immense value and enjoy considerable leverage when transferring patented technologies to external parties for commercial development. While knowledge transfer between academic and private-sector institutions is not a one-way street,<sup>330</sup> basic investigations at universities, usually funded through taxpayer dollars, often produce key insights that private companies then seek commercialize.<sup>331</sup> 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

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<sup>318</sup> See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

<sup>319</sup> Eisenberg, Patents and Data-sharing in Public Science, *supra* note , at 1014.

<sup>320</sup> See generally Derek Bok, *Universities in the Marketplace: The Commercialization of Higher Education* (2003).

<sup>321</sup> Jerry G. Thursby & Marie C. Thursby, *University Licensing and the Bayh-Dole Act*, 310 *Science* 1052, 1052 (2003).

<sup>322</sup> Association of University Technology Managers, AUTM Licensing Survey, FY 2002 Survey Summary, available at [www.autm.net/events/File/Surveys/02\\_Abridged\\_Survey.pdf](http://www.autm.net/events/File/Surveys/02_Abridged_Survey.pdf).

<sup>323</sup> Association of University Technology Managers, *AUTM Licensing Survey: FY 2005* (2007).

<sup>324</sup> Association of University Technology Managers, AUTM U.S. Licensing Activity Survey: FY 2006, at 5 (2007).

<sup>325</sup> Powell & Owen-Smith, *supra* note , at 257; Gelijns & Thier, *supra* note , at 73; Jaffe, *supra* note , at 541; Eisenberg, Patents, Product Exclusivity, and Information Dissemination, *supra* note , at 479.

<sup>326</sup> Gelijns & Thier, *supra* note , 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).

<sup>327</sup> David E. Adelman & Kathryn L. DeAngelis, *Patent Metrics: The Mismeasurement of Innovation in the Biotech Patent Debate*, 85 *Tex. L. Rev.* 1677, 1687 & n.44 (2007).

<sup>328</sup> Gelijns & Thier, *supra* note , at 74.

<sup>329</sup> Lemley, *Patenting Nanotechnology*, *supra* note , at 616.

<sup>330</sup> Golden, *supra* note , at 119; Gelijns & Thier, *supra* note , at 76; Faley & Sharer, *supra* note , at 118; Powell & Owens-Smith, *supra* note , at 266.

<sup>331</sup> Kesselheim & Avorn, *supra* note , at 851; cf. Narin et al., *supra* note , at 318.



While universities are traditionally seen as bastions of open science,<sup>332</sup> recent increases in university patenting have raised anxieties that commercial interests may be eroding traditional academic norms.<sup>333</sup> As a general matter, the increasing commercialization of universities has raised concerns over: financial interests unduly influencing research agendas,<sup>334</sup> increased secrecy and publication delays,<sup>335</sup> manipulation of results,<sup>336</sup> decreases in academic productivity,<sup>337</sup> conflicts of interest between universities and their faculties,<sup>338</sup> weakening of the tenure system and academic freedom,<sup>339</sup> the erosion of public confidence in university science,<sup>340</sup> and even reduced dissemination of university research findings throughout the developing world.<sup>341</sup> Complicating the rise of university patenting has been the independent, through related, rise in university-industry partnerships.<sup>342</sup> These partnerships often allow industry partners to obtain patent rights arising from industry-sponsored, university-conducted research.<sup>343</sup>

Most salient for our purposes, university patenting and profit motives may be eroding traditional academic norms of open science. Commentators observe that university-generated

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<sup>332</sup> Historically, universities had particularly strong norms against patenting inventions in the biomedical arena. See Lemley, Patenting Nanotechnology, *supra* note , at 610; Sally Smith Hughes, *Making Dollars out of DNA: The First Major Patent in Biotechnology and the Commercialization of Molecular Biology, 1974–1980*, 92 *ISIS* 541 (2001).

<sup>333</sup> See generally Bok, *supra* note ; see also Jennifer Washburn, University, Inc.: The Corporate Corruption of Higher Education (2005); Gelijns & Thier, *supra* note , 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 .

<sup>334</sup> Eyal Press & Jennifer Washburn, *Kept University: Commercially Sponsored Research Is Putting at Risk the Paramount Value of Higher Standards – Disinterested Inquiry*, *The Atlantic Monthly*, March 2000; Powell & Owen-Smith, *supra* note at 270; Pierre Azouley et al., The Impact of Academic Patenting on the Rate, Quality, and Direction of (Public) Research, (NBER Working Paper No. 11917, 2006), available at <http://www.nber.org/papers/w11917>; Brett M. Frischmann, *Commercializing University Research Systems in Economic Perspective: A View From the Demand Side*, in 16 *University Entrepreneurship and Technology Transfer: Process, Design, and Intellectual Property*, *supra* note , at 155, 176-78.

<sup>335</sup> Bok, *supra* note , at 64-76; Press & Washburn, *supra* note .; 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).

<sup>336</sup> Press & Washburn, *supra* note ; Mildred Cho,

<sup>337</sup> David Blumenthal et al., *Participation of Life-Science Faculty in Research Relationships in Industry*, 335 *New Eng. J. M.* 1734, 1738 (1996).

<sup>338</sup> David J. Trigg, *Patenting the Sun: Enclosing the Scientific Commons and Transforming the University – Ethical Concerns*, 63 *Drug Development Research* 139, 143-44 (2005).

<sup>339</sup> Risa L. Lieberwitz, *The Marketing of Higher Education: The Price of the University’s Soul*, 89 *Cornell L. Rev.* 76, 793-98 (2004) (book review).

<sup>340</sup> Trigg, *supra* note , at 144-45.

<sup>341</sup> Trigg, *supra* note , at 145.

<sup>342</sup> See, e.g., Press & Washburn, *supra* note , at ; Jennifer Washburn, *Big Oil Buys Berkeley: The BP-UC Berkeley Research Deal Pushes Academic Integrity Aside for Profit*, *L.A. Times*, Marc 24, 2007, at ; Kevin Buckley, *New University-Industry Collaborations*, at <http://blog.biocommercialization.com/2008/01/24/new-university-industry-collaborations.aspx>.

<sup>343</sup> Eliot Marshall, *NIH Cuts Deal on Use of OncoMouse*, 287 *Science* 567 (2000) (describing an agreement between DuPont and Harvard University).

knowledge that would have previously entered the public domain is now being subject to intellectual property constraints.<sup>344</sup> Professors Rai and Eisenberg argue that the proliferation of university patenting can exacerbate anticommons problems, thus inhibiting effective use of patented research tools.<sup>345</sup> 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.<sup>346</sup> Indeed, several high-profile cases reveal universities’ aggressive approach to enforcing their patents.<sup>347</sup>

While some argue that profit motives are distorting academic norms, it is worth noting that university patents rarely generate significant revenues.<sup>348</sup> As of 2003, university licenses produced over \$1 billion a year in revenue.<sup>349</sup> Though significant, “Patent revenues account for a trivial fraction of overall university research budgets, while public research funding remains of critical importance.”<sup>350</sup> In one survey, median net licensing income for research institutions was only \$1.13 million per year.<sup>351</sup> Of all university patent licenses in 2000, only 43% earned royalties, and 0.56% earned more than \$1 million.<sup>352</sup> Among U.S. institutions, the ratio of licensing income to privately-sponsored research was 5% or less in 2005.<sup>353</sup> There is a high degree of variability in revenues obtained from university licensing, which exhibits a “winner-take-all” phenomenon where a few institutions and a few inventions earn most of the money.<sup>354</sup> For example, the nine-campus University of California’s net licensing income of \$91 million far exceeds the average revenue for a university system.<sup>355</sup> Furthermore, five patented inventions account for about 95% of all licensing revenues at Columbia University.<sup>356</sup> 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.<sup>357</sup> At an individual and group level, the scientific community has long been

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<sup>344</sup> Triggler, *supra* note , at 143.

<sup>345</sup> Rai & Eisenberg, *supra* note , at 295-303; see also Graff et al., *supra* note , at 995.

<sup>346</sup> Lemley, Are Universities Patent Trolls?, *supra* note , at 619. Lemley concludes that characterization as a troll should be determined by behavior, not by institutional identity.

<sup>347</sup> See, e.g., Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559 (Fec. Cir. 1997); Eolas Technologies v. Microsoft, 399 F.3d 1325 (Fed. Cir. 2005).

<sup>348</sup> Chokshi & Rajkumar, *supra* note , at 1936; Gregory K. Sobolski et al., *Technology Licensing, Lessons From the U.S. Experience*, 294 JAMA 3137, 3137 (2005).

<sup>349</sup> Thursby & Thursby, *supra* note , at 1052.

<sup>350</sup> Eisenberg, Public Research and Private Development, *supra* note , at 1726.

<sup>351</sup> Sobolski et al, *supra* note , at 3137.

<sup>352</sup> Thursby & Thursby, *supra* note , at 1052.

<sup>353</sup> Sobolski et al, *Technology Licensing*, 294 JAMA 3137-40 (2005).

<sup>354</sup> Sobolski et al., *supra* note , at 3137; see, e.g., David Baltimore, *On Over-Weighting the Bottom Line*, 301 Science 1050, 1050 (2003) (book review); Leaf, *supra* note , at .

<sup>355</sup> Sobolski et al., *supra* note , at 3138.

<sup>356</sup> Gelijns & Thier, *supra* note , at 75.

<sup>357</sup> See Baltimore, *supra* note , at 1050; Nelsen, *supra* note , 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 , at 114.

characterized by norms emphasizing openly sharing knowledge and ideas.<sup>358</sup> These “public sector values” have been cultivated by the taxpayer-funded research system encompassing university and government laboratories.<sup>359</sup> University knowledge production is motivated by a host of non-financial rewards, and is built on freely exchanging ideas and information.<sup>360</sup> While some caution that patents have eroded this communal culture,<sup>361</sup> others point out that informal sharing norms persist even within an increasingly proprietary environment.<sup>362</sup>

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.<sup>363</sup> At a broad level, universities are still committed to widely and promptly disseminating research results.<sup>364</sup> 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.<sup>365</sup> Harvard University’s intellectual property policy is representative in this fashion when it acknowledges the university’s “primary commitment” to the public interest.<sup>366</sup> For its part, the Association of University Technology Managers (AUTM) observes that most of its members “would define success through the criterion of public benefit.”<sup>367</sup> While the commercialization of universities is

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<sup>358</sup> See, e.g., Merton, *supra* note , at 275; Hagstrom, *supra* note , ; Barber, *supra* note , ; but see Kieff, *Facilitating Scientific Research*, *supra* note (suggesting that actual behavior may deviate substantially from these “aspirational” norms).

<sup>359</sup> Golden, *supra* note , at 153.

<sup>360</sup> See Kahan, *supra* note , at 90-93.

<sup>361</sup> Eisenberg, *Proprietary Rights and the Norms of Science*, *supra* note , at 182; Rai, *Regulating Scientific Research*, *supra* note .

<sup>362</sup> Robert P. Merges, *Property Rights Theory and the Commons: The Case of Scientific Research*, SOC. PHIL. & POL’Y, Summer 1996, at 145, 150 [hereinafter Merges, *Property Rights Theory and the Commons*]; cf. J.M. Balkin, *Cultural Software: A Theory of Ideology* (1998) (discussing a theory of cultural transmission based on memes).

<sup>363</sup> Cf. Merges, *Property Rights Theory and the Commons*, *supra* note , at 150.

<sup>364</sup> Thursby & Thursby, *supra* note , at 1052; Eisenberg, *Patents and Data-sharing in Public Science*, *supra* note , at 1013 (2006). University mission statements are often replete with noble aspirations of creating and disseminating knowledge in the public interest. Choski & Rajkumar, *supra* note , at 1936. See also Robert E. Litan et al., *Commercializing University Inventions: A Better Way* (Apr. 2007) (working paper, Nat’l Bureau of Econ. Research), available at [http://www.kauffman.org/pdf/NBER\\_0407.pdf](http://www.kauffman.org/pdf/NBER_0407.pdf).

<sup>365</sup> See, e.g., Brewster et al., *supra* note , at 49, 51 (collecting intellectual property policies of the top four universities in terms of patent activity).

<sup>366</sup> Harvard University, *Statement of Policy In Regard to Intellectual Property*, Feb. 4, 1998, available at <http://otd.harvard.edu/resources/policies/patent/PatentPolicy.pdf>; see also Yale University, *Yale University Patent Policy*, Feb. 1998, available at <http://www.yale.edu/ocr/pfg/policies/patents.html> (“The objective of the University is to assure the development of its technology in furtherance of its own educational mission and for the benefit of society in general.”); UC Davis, *Office of Research, Licensing and Confidentiality*, available at <http://www.innovationaccess.ucdavis.edu/home.cfm?id=ovc,23,1728,1718,1719,1725> (“Agreements with external parties shall support the ability of the University to make available for the public benefit in a diligent and timely manner any resulting innovations and works of authorship.”).

<sup>367</sup> AUTM, *FY 2006 Survey*, *supra* note , 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. Richard C. Atkinson et al., *Intellectual Property Rights: Public Sector Collaboration for Agricultural IP Management*, 301 *Science* 174 (2003).

a real phenomenon, these norms suggest that universities can and do take a wider view of patenting than revenue maximization.<sup>368</sup>

#### 4. University Licensing Policies Favoring Access to Patented Research Tools

Indeed, universities are leveraging their ownership of patents on research tools to ensure, in contractual transactions with third parties, a robust research commons in biomedicine. Unlike government funding agencies such as the NIH and CIRM, universities have a much more direct role to play in creating such a commons because they actually own a significant number of patents and can contractually determine how they are used.

##### a. Reserved Research Exemptions for Licensed Inventions

Increasingly, universities are carving out research exceptions for themselves and other nonprofit organizations as a condition of licensing patented technologies to outside parties.<sup>369</sup> 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.”<sup>370</sup> In essence, when universities license—even exclusively license—technologies to external parties, they generally retain the right to use that invention for noncommercial research purposes. 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.<sup>371</sup> 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.”<sup>372</sup>

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.”<sup>373</sup> Similar language appears in numerous technology transfer agreements from universities around the country.<sup>374</sup> Notably, these clauses directly respond to the Federal Circuit’s narrow conception of

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<sup>368</sup> See Lemley, *Are Universities Patent Trolls?*, *supra* note , 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.”).

<sup>369</sup> See Yochai Benkler, *Commons-Based Strategies and the Problems of Patents*, *supra* note , at 1110-11; Brewster et al., *supra* note , at 56.

<sup>370</sup> Pressman et al., *supra* note , at 35.

<sup>371</sup> See, e.g., Pressman et al., *supra* note , at 35 (drawing examples from Harvard University, UCSD, UCLA, and UCSF, and UC Berkeley).

<sup>372</sup> Pressman et al., *supra* note , at 35.

<sup>373</sup> Alan B. Bennett, *Reservation of Rights for Humanitarian Uses*, in Krattinger et al. eds., *supra* note , at 42.Ch%2002%2001%20Bennett%20Retention%20of%20Rights.pdf. For additional examples, see *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](http://news-service.stanford.edu/news/2007/march7/gifs/whitepaper.pdf) [hereinafter, *In the Public Interest*].

<sup>374</sup> See, e.g., Stanford University, *Exclusive Agreement 2*, *available at* <http://otl.stanford.edu/industry/resources/exclusive.pdf>; Wisconsin Alumni Research Foundation, *Standard Non-Exclusive License Agreement 1, 9*, *available at* [http://www.warf.org/uploads/media/20031002132027680\\_Std\\_non\\_exclusive\\_license\\_agrmt.pdf](http://www.warf.org/uploads/media/20031002132027680_Std_non_exclusive_license_agrmt.pdf); Baylor College of

the experimental use exception articulated in *Madey v. Duke University*.<sup>375</sup> Many of these clauses define the research exception by explicitly listing the types of activities that the *Madey* court 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.<sup>376</sup> The guidelines include this example provision:

*INSTITUTION reserves the rights, for itself and others, to*

- (i) make and use, solely for NON-COMMERCIAL RESEARCH PURPOSES, the subject matter described and claimed in PATENT RIGHTS and covered by PROPERTY RIGHTS and*
- (ii) provide to OTHERS the BIOLOGICAL MATERIALS; each solely for NON-COMMERCIAL RESEACH PURPOSES.*<sup>377</sup>

Again, the guidelines define “non-commercial research purposes” with explicit reference to *Madey*.<sup>378</sup> The Stanford consortium also notes that reserving a research exemption corresponds with the NIH’s recommendations for best practices for licensing genomic inventions.<sup>379</sup>

#### b. Exclusive Versus Nonexclusive Licensing

Universities are also exploiting their ownership of patents to enhance the wide availability of research tools by favoring nonexclusive licensing of such technologies.<sup>380</sup> 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.<sup>381</sup> This appears to be a win-win situation in which widespread licensing of the gene splicing technology also helped it become the single most profitable invention licensed by these two universities.<sup>382</sup>

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Medicine, Exclusive License Agreement – Research Product 3, available at [http://www.bcm.edu/blg/docs/lic\\_research.dot](http://www.bcm.edu/blg/docs/lic_research.dot).

<sup>375</sup> Bennett, *supra* note , at 42; In the Public Interest, *supra* note , at 11.

<sup>376</sup> In the Public Interest, *supra* note , at 2.

<sup>377</sup> In the Public Interest, *supra* note ,at 10.

<sup>378</sup> In the Public Interest, *supra* note ,at 11; see also Bennett, *supra* note , at 42 (discussing university research exceptions as a response to *Madey v. Duke University*).

<sup>379</sup> NIH, Best Practices for the Licensing of Genomic Inventions: Final Notice, 70 Fed. Reg. at 18,415 (April 11, 2005).

<sup>380</sup> Wide, nonexclusive licensing of research tools maximizes their availability and best promotes basic scientific investigations. See Lemley, Are Universities Patent Trolls?, *supra* note , at 612; Lemley, Patenting Nanotechnology, *supra* note , at 627.

<sup>381</sup> See Lee, The Evolution of Intellectual Infrastructure, *supra* note , at 93-94.

<sup>382</sup> Mowery & Ziedonis, *supra* note , at 194; Smith Hughes, *supra* note , at 542. As noted, Columbia University also nonexclusively licensed the Axel patents related to gene insertion in mammalian cells, but only did so upon direct compulsion by the NIH. See *supra* Part IV.A.1.

The issue of exclusive or nonexclusive licensing of research tools is complicated by the fact that the same resource—such as a patented human embryonic stem cell—may both facilitate academic research and represent a precursor to a commercial product requiring further investment and development; in the latter situation, exclusive licensing may be necessary to provide requisite incentives to innovate.<sup>383</sup> While the majority of university licenses continue to be exclusive,<sup>384</sup> universities are beginning to adopt policies drawing these distinctions and favoring nonexclusive licensing of fully functional research tools for noncommercial research purposes.<sup>385</sup>

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.<sup>386</sup> The guidelines state that:

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.<sup>387</sup>

Accordingly, the guidelines distinguish between licensing *use* and licensing *sale* of assets such as research reagents, kits, or devices. Following the guidelines, a university should insist that “the license is exclusive for the sale, but not use, of such products and services.”<sup>388</sup> In this manner, members of the scientific community may still use the patented technology for research purposes,<sup>389</sup> but they may not *sell* the technology, thus maintaining the commercial incentives of the exclusive licensee.

Evidence suggests that universities are already following these policies.<sup>390</sup> A survey of university technology transfer offices revealed a preference for nonexclusively licensing most DNA research tools.<sup>391</sup> Furthermore, respondents noted that the same patent could be licensed differently for research use versus commercial use.<sup>392</sup> 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 cost of commercialization associated with developing these products.<sup>393</sup> However, universities are less likely to patent (and more likely to nonexclusively license) DNA sequences

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<sup>383</sup> Jaffe, *supra* note , at 552; but see Golden *supra* note , at .

<sup>384</sup> Lemley, Are Universities Patent Trolls?, *supra* note , at 617.

<sup>385</sup> See Lemley, Patenting Nanotechnology, *supra* note , at 628 (suggesting utilizing the Bayh-Dole Act to restrict the ability of university to exclusively license basic building block patents).

<sup>386</sup> *In the Public Interest*, *supra* note , at 5.

<sup>387</sup> *In the Public Interest*, *supra* note , at 3.

<sup>388</sup> *In the Public Interest*, *supra* note , at 5.

<sup>389</sup> *In the Public Interest*, *supra* note , at 5.

<sup>390</sup> See Golden, *supra* note , at 143 (“[G]overnment laboratories and universities have favored widespread granting of non-exclusive licenses, particularly for their more fundamental inventions.”).

<sup>391</sup> Pressman et al., *supra* note , at 34-35.

<sup>392</sup> Pressman et al., *supra* note , at 35.

<sup>393</sup> Pressman et al., *supra* note , at 33.

that are markers only, as the immediate utility of such inventions is unclear and the development costs associated with them are relatively small.<sup>394</sup>

#### 4. Analysis

As opposed to simply providing funding for basic biomedical research, universities can play a much more direct route in the contractual creation of a noncommercial research commons because they own a substantial number of patents. Given the dominant role that universities play in conducting basic research and obtaining patents, the potential impact of broad-based adoption of these policies is enormous. A concerted effort by universities to use reservation of rights clauses would effectively create a noncommercial research exception to patent infringement.

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 non-profit research universities as commercial entities with business objectives that included raising revenues.<sup>395</sup> 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 influence on university culture, it is fair to say that universities are a different sort of patentee than most commercial firms.<sup>396</sup> The traditional goal of universities has been to serve the public interest with education and research, not to maximize profits.<sup>397</sup> 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.<sup>398</sup>

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.”<sup>399</sup> Of course, sharing norms may also be self-serving; universities reserving broad research exceptions ensure that patent holdup will not impede research 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

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<sup>394</sup> Pressman et al., *supra* note , at 33-34.

<sup>395</sup> *Madey v. Duke University*, 307 F.3d 1351 (Fed. Cir. 2002).

<sup>396</sup> Even this is a controversial assertion for some. For example, Columbia University has attracted significant criticism for its attempts to effectively extend the life of the Axel patents on techniques for inserting genes in cells. See, e.g., Wysocki, Jr., *supra* note , at A1; Howard, *supra* note ; Ownership At Too High a Price, 21 *Nature Biotechnology* 953, 953 (2003).

<sup>397</sup> Baltimore, *supra* note , at 1050; see *In the Public Interest*, *supra* note , 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.”).

<sup>398</sup> Eisenberg, *Public Research and Private Development*, *supra* note , at 1701.

<sup>399</sup> Gelijns & Thier, *supra* note , at 77.

how that role affects patent policies.”<sup>400</sup> Public scrutiny and moral suasion can help reinforce science-friendly licensing at universities.<sup>401</sup> Perhaps aided by the realization that windfall licensing profits are highly unlikely, university technology transfer offices can take a broader view of their role in technology transfer.<sup>402</sup> While some are skeptical that universities would voluntarily adopt open licensing practices that may lower revenues,<sup>403</sup> to varying extents, institutions are already doing so.

Notably, the mechanism by which universities are articulating these norms and constructing a research commons is contracts. Universities are advancing the objectives of basic research by reserving research rights for themselves and other non-profit institutions, even for “exclusively” licensed inventions. 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 revenue have strong incentives to grant exclusive licenses.<sup>404</sup> 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.<sup>405</sup> Distinguishing among various technologies, licensees, and uses is crucial for ideal exploitation of biomedical inventions.<sup>406</sup> This may be a challenging task for technology transfer offices that on average employ four professionals.<sup>407</sup>

#### D. Non-Profit Funding Organizations

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<sup>400</sup> Lemley, *Are Universities Patent Trolls?*, *supra* note, at 627.

<sup>401</sup> Jaffe, *supra* note, at 552.

<sup>402</sup> Mark Lemley, quoted in *Witnesses Say Universities Too Rigid In Licensing Patent Rights Under Bayh-Dole*, July 18, 2007, available at <http://www.law.stanford.edu/news/details/1043/>.

<sup>403</sup> Nelson, *supra* note at, 469.

<sup>404</sup> Lemley, *Are Universities Patent Trolls?*, *supra* note, at 616; see Faley & Sharer, *supra* note, at 125.

<sup>405</sup> Rai & Eisenberg, *supra* note, at 305.

<sup>406</sup> Bennett, *supra* note, at 42; Thursby & Thursby, *supra* note, at 1052; Yale University, *supra* note; see Pressman et al., *supra* note, at 37.

<sup>407</sup> Lorelei Ritchie de Larena, *The Price of Progress: Are Universities Adding to the Cost?*, 43 *Hous. L. Rev.* 1373, 1387, 1412 (2007).



Non-profit organizations are also leveraging their financial support for biomedical research to insist that grant recipients refrain from asserting patent rights to impede basic research. Though relatively small compared to federal and commercial sources, private-non-profits provide significant funding for biomedical research.<sup>408</sup> In 2003, not-profit organizations provided \$2.5 billion to support such research,<sup>409</sup> and they are expected to grow in importance as funding sources.<sup>410</sup> Furthermore, *what* they fund is oftentimes more important than *how much* they fund. Foundations fill gaps by funding research that is scientifically speculative and politically risky or unpopular and where commercial value is low or not readily apparent.<sup>411</sup> This “gap filling” function extends to funding new and interdisciplinary research that may not receive NIH support.<sup>412</sup> For example, the Howard Hughes Medical Institute (HHMI) describes its culture as prizing “bold thinking and scientific risk taking.”<sup>413</sup> Interestingly, the high tech boom of the 1990s produced a new generation of “venture philanthropists” who are particularly committed to strategic risk-taking.<sup>414</sup> 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”<sup>415</sup> that contributed \$599 million to research in 2007.<sup>416</sup> 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.”<sup>417</sup> Consistent with other public institutions, funding provides non-profit organizations with claims on how grant recipients may use resulting patented inventions.

HHMI maintains several policies aimed at providing 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

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<sup>408</sup> Foundations established by nineteenth-century industrialists played a major role in funding biomedical research in the early twentieth century, and 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).

<sup>409</sup> Moses III et al., *supra* note , 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).

<sup>410</sup> Moses III et al., *supra* note , at 1338-39; Jeffrey Mervis, *U.S. Science Adviser Tells Researchers to Look Elsewhere*, 316 *Science* 817, 817 (2007).

<sup>411</sup> Moses III et al., *supra* note , at 1339; Field et al., *supra* note , at 227.

<sup>412</sup> Moses III et al., *supra* note , at 1338.

<sup>413</sup> 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.”).

<sup>414</sup> Trisha Guru, *Biomedical Philanthropy*, *Silicon Valley Style*, 410 *Nature* 140, 140-43 (2001).

<sup>415</sup> Balaram, *supra* note , at 538.

<sup>416</sup> Howard Hughes Medical Institute, 2007 Annual Report 78 (2007). This figure does not include outlays for plant construction, science education, and international research scholars.

<sup>417</sup> Howard Hughes Medical Institute, Science Policies, Intellectual Property Policy (SC-600) 1, available at <http://www.hhmi.org/about/research/sc600.pdf> [hereinafter HHMI, Intellectual Property Policy].

research at its Janelia Farm Research Campus. HHMI claims an ownership interest in any invention where at least one inventor is an HHMI employee.<sup>418</sup> 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.<sup>419</sup> HHMI's policy on research tools is consistent with NIH guidelines,<sup>420</sup> 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.”<sup>421</sup> HHMI also favors liberal transfers of patented materials for research purposes. HHMI is a signatory of the NIH's Uniform Biological Materials Transfer Agreement (UMBTA),<sup>422</sup> and it encourages the use of a simplified one-page agreement to facilitate material transfers to non-profit organizations.<sup>423</sup> Given the reach of HHMI funding throughout the biomedical research world, this contractually-created research exception is quite substantial.

As with CIRM, HHMI has also issued policies specific to materials, data, and software described in academic publications.<sup>424</sup> For example, upon publication of HHMI-funded work, laboratory heads are “expected” to make materials, data, databases, and software freely available for research use.<sup>425</sup> 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.<sup>426</sup> HHMI expects grant recipients to provide requested materials, data, or software to third parties within 60 days of receiving a request.<sup>427</sup>

Leveraging its provision of 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—again, usually a university—and generally allows it to take the lead in technology transfer decisions.<sup>428</sup> However, host institutions have an “obligation to include certain provisions for HHMI's benefit in each license.”<sup>429</sup> Notably, this includes HHMI's

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<sup>418</sup> Howard Hughes Medical Institute, Intellectual Property and HHMI Employees: A Guide for Host Institutions 3, available at <http://www.hhmi.org/pdf/host-guide.pdf> [hereinafter HHMI, *Intellectual Property Guide for Host Institutions*]. HHMI employees agree as a condition of their employment that they will assign their rights in all inventions made in the course of HHMI employment to HHMI. *Id.* at 4.

<sup>419</sup> HHMI, *Intellectual Property Guide for Host Institutions*, *supra* note , at 7; Howard Hughes Medical Institute, Research Tools (SC-310), at 1, available at [http://www.hhmi.org/about/research/sc\\_310.pdf](http://www.hhmi.org/about/research/sc_310.pdf). [hereinafter HHMI, Research Tools].

<sup>420</sup> NIH, Principles and Guidelines, 64 Fed. Reg. at 72,092 n.1.

<sup>421</sup> HHMI, Research Tools, *supra* note , at 1.

<sup>422</sup> Howard Hughes Medical Institute, Materials Transfers (SC-330), available at <http://www.hhmi.org/about/research/sc330.pdf>.

<sup>423</sup> HHMI, Materials Transfers, *supra* note , at 1.

<sup>424</sup> HHMI, Sharing of Publication-Related Materials, Data and Software, *supra* note . As with the NIH, HHMI also required grant recipients contributing to the Human Genome Project to place their data in a public database. Petsko, *supra* note , at 107.1.

<sup>425</sup> Howard Hughes Medical Institute, Sharing of Publication-Related Materials, Data and Software (SC-300), at 1, May 15, 2007, available at [http://www.hhmi.org/about/research/sc\\_300.pdf](http://www.hhmi.org/about/research/sc_300.pdf) [hereinafter HHMI, Sharing of Publication-Related Materials, Data and Software].

<sup>426</sup> HHMI, Sharing of Publication-Related Materials, Data and Software, *supra* note , at 2.

<sup>427</sup> HHMI, Sharing of Publication-Related Materials, Data and Software, *supra* note , at 2-3.

<sup>428</sup> HHMI, Intellectual Property Policy, *supra* note , at 3.

<sup>429</sup> HHMI, Intellectual Property Guide for Host Institutions, *supra* note , at 6.

irrevocable license to use any subject property for research purposes.<sup>430</sup> 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.<sup>431</sup> This underscores HHMI’s commitment to preserving a free zone of research uses for patented inventions that do not impinge upon 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.<sup>432</sup> 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 research community.<sup>433</sup>

Similar policies apply to HHMI’s intramural research. HHMI policies on sharing of research tools and published materials govern licensing of inventions developed at the Janelia Farm Research Campus.<sup>434</sup> This includes the preference for nonexclusive licensing of research tools as well as the reservation of a research use exception in all licenses with downstream partners.

## 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 basic 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 both formal and informal 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 likely well-equipped to draw meaningful distinctions between research use and commercial sale of patented assets. However, HHMI’s efforts to enhance access to biomedical research tools exhibits 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. Also, while HHMI is a substantial player, the provisions upon which it insists are coextensive only with the reach of its grants. Widening the scope of reserved research rights could better advance the objective of open science, but may make HHMI funding less attractive to recipients.

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<sup>430</sup> HHMI, Intellectual Property Policy, *supra* note , at 3.

<sup>431</sup> HHMI, *Intellectual Property Guide for Host Institutions*, *supra* note , at 6.

<sup>432</sup> HHMI, *Intellectual Property Guide for Host Institutions*, *supra* note , at 9. HHMI, Research Tools, *supra* note .

<sup>433</sup> HHMI, Research Tools, *supra* note , 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. See Howard Hughes Medical Institute, Intellectual Property and Licensing Policies, Licensing by Host Institutions to Companies (SC-610), available at <http://www.hhmi.org/about/research/sc610.pdf>.

<sup>434</sup> HHMI, Intellectual Property Policy, *supra* note , at 4.

## 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,<sup>435</sup> they sometimes offer another upstream contribution as well: unique 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.<sup>436</sup> 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,<sup>437</sup> demonstrates the vital upstream support that donors of biological materials can provide in biomedical research.<sup>438</sup> 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.<sup>439</sup> 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-afflicted families.<sup>440</sup> 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.<sup>441</sup> In 1998, MCH began licensing a Canavan screening test, but charged a royalty of \$12.50 per test and

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<sup>435</sup> See Shannon F. Terry et al., *Advocacy Groups as Research Organizations: The PXE International Example*, 8 *Nature Reviews: Genetics* 157, 158-59 (2007).

<sup>436</sup> See generally, Carlos Novas, *The Political Economy of Hope: Patients' Organizations, Science, and Biovalue*, 1 *BioSocieties* 289, 293 (2006). Commentators have observed that AIDS activists provided the template for this model for proactive participation of patient groups in biomedical research. *Id.* at 292. See also Cori Hayden, *Taking as Giving: Bioscience, Exchange, and the Politics of Benefit-sharing*, 37/5 *Social Studies of Science*, 729, 738-39 (2007).

<sup>437</sup> National Institutes of Neurological Disorders and Stroke, *What is Canavan Disease?*, at <http://www.ninds.nih.gov/disorders/canavan/canavan.htm>.

<sup>438</sup> See Donna M. Gitter, *Ownership of Human Tissue: A Proposal for Federal Recognition of Human Research Participants' Property Rights in Their Biological Material*, 61 *Wash. & Lee L. Rev* 257, 325-330 (2004); Radhika Rao, *Genes and Spleens: Property, Contract, or Privacy Rights in the Human Body*, *Journal of Law, Medicine & Ethics*, Symposium, Genetics and Group Rights, 371, 372-74 (2007); Sabrina Safrin, *Chain Reaction: How Property Begets Property*, 82 *Notre Dame L. Rev.* 1917, 1933-34 (2007).

<sup>439</sup> Eliot Marshall, *Families Sue Hospital, Scientist for Control of Canavan Gene*, 290 *Science* 1041, 1062 (2000) [hereinafter Marshall, *Families Sue Hospital*].

<sup>440</sup> Novas, *supra* note , at 299; Marshall, *Families Sue Hospital*, *supra* note , at 1062; Canavan Foundation, *Canavan Foundation Joins Lawsuit against Miami Children's Hospital*, *supra* note .

<sup>441</sup> Novas, *supra* note , at 299.

limited the total number of tests that laboratories could perform.<sup>442</sup> 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.<sup>443</sup> 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.<sup>444</sup> The donors believed that any resulting genetic tests would be available on an affordable basis "and that [the] research would remain in the public domain."<sup>445</sup> The court dismissed all of the plaintiffs' claims except their claim for unjust enrichment.<sup>446</sup> That issue was never resolved on the merits, however, as the parties entered into a confidential settlement. Notably, the settlement provided for continued royalty-based testing by licensed laboratories, but royalty-free use by institutions, doctors, and scientists engaged in "pure" research.<sup>447</sup>

As the Canavan gene controversy illustrates, disease advocacy groups can make vital contributions to basic biomedical research. Matalon's work simply could not have proceeded without the tissue samples that Greenberg and his associates provided. In addition to making vital contributions to research, members of the patient community subscribe to norms that focus overwhelmingly on developing cures and facilitating further scientific investigation, not on exclusivity and maximizing profits.<sup>448</sup> 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.<sup>449</sup> In 1994, Patrick and Sharon Terry's two children were diagnosed with PXE, a rare genetic disorder that affects connective tissue.<sup>450</sup> Shortly thereafter, the Terrys "began to scheme about what we

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<sup>442</sup> MCH ultimately planned to license the test to a large commercial lab that would dominate the market. Rao, *supra* note , at 373.

<sup>443</sup> Marshall, *Families Sue Hospital*, *supra* note , at 1062; Canavan Foundation Joins Lawsuit against Miami Children's Hospital, Oct. 30, 2000, at [http://www.canavanfoundation.org/news/10-00\\_miamihospital.php](http://www.canavanfoundation.org/news/10-00_miamihospital.php).

<sup>444</sup> 264 F. Supp. 2d 1064 (S.D. Fla. 2003); see Gitter, *supra* note , at 331-38; see Marshall, *Families Sue Hospital*, *supra* note , at 1062; Rao, *supra* note , at 373.

<sup>445</sup> *Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 208 F. Supp. 2d 918, 921 (N.D. Ill. 2002). The court subsequently transferred the case to the Southern District of Florida.

<sup>446</sup> 264 F. Supp. at 1066.

<sup>447</sup> Canavan Foundation, Joint Press Release (Sept. 29, 2003), available at [http://www.canavanfoundation.org/news/09-03\\_miami.php](http://www.canavanfoundation.org/news/09-03_miami.php); Novas, *supra* note , at 301.

<sup>448</sup> Cf. Terry et al., *supra* note , at 158 (2007).

<sup>449</sup> See Gitter, *supra* note , at 315-24; Paul Smaglik, *Tissue Donors Use Their Influence in Deal Over Gene Patent Terms*, 407 *Nature* 821, 821 (2000); Safrin, *supra* note , at 1934-35; Gina Kolata, *Sharing of Profits is Debated As the Value of Tissue Rises*, *N.Y. Times*, May 15, 2000, at .

<sup>450</sup> Eliot Marshall, *Patient Advocate Named Co-Inventor On Patent for the PXE Disease Gene*, 305 *Science* 1857, 1225 (2004) [hereinafter Marshall, *Patient Advocate*].

would do if we were managing research on this disease.”<sup>451</sup> In 1995, the Terrys founded PXE International, which was dedicated to funding research and providing support services to afflicted patients.<sup>452</sup> Shortly after its establishment, PXE International created 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 the non-profit would retain ownership rights in any patent applications arising from research based on access to its registry.<sup>453</sup> This arrangement allowed PXE International to share in any revenue, ensure broadly available and affordable genetic tests, and influence future licensing.<sup>454</sup> By establishing the terms under which scientists could access the registry, the registry has served as a “significant relay of power” through which PXE International has been able to coordinate and influence scientific activities.<sup>455</sup>

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.<sup>456</sup> In an unusual move, Sharon Terry was listed as a co-inventor on the patent application for the gene, along with four university researchers.<sup>457</sup> As per standard practice, the University of Hawaii held 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.<sup>458</sup> 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.<sup>459</sup>

Significantly, through exercising control over the patented PXE gene, PXE International has ensured that scientists have access to the gene for research purposes.<sup>460</sup> PXE International has licensed the gene to 19 laboratories and eight biotechnology companies.<sup>461</sup> Such widespread licensing is consistent with PXE International’s aim to maximize “patient-centric opportunities.”<sup>462</sup> 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

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<sup>451</sup> 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.” Allen *supra* note , quoting Shannon Terry.

<sup>452</sup> In the course of three years, the Terrys raised \$500,000 for research. Arthur Allen, *Who Owns My Disease?*, MotherJones.com, Nov/Dec 2001.

<sup>453</sup> Gitter, *supra* note , at 317; Matt Fleischer, *Patent Thyself*, American Lawyer, June 21, 2001, at 87.

<sup>454</sup> Gitter, *supra* note , at 317; Fleischer, *supra* note , at 87; Rao, *supra* note , at 375.

<sup>455</sup> Novas, *supra* note , at 296.

<sup>456</sup> The gene is known alternatively as ABCC6 or MRP6.

<sup>457</sup> Marshall, *Patient Advocate*, *supra* note , at 1226.

<sup>458</sup> Gitter, *supra* note , at 318.

<sup>459</sup> Gitter, *supra* note , at 318.

<sup>460</sup> Novas, *supra* note , at 297.

<sup>461</sup> Novas, *supra* note , at 297.

<sup>462</sup> A similar strategy has been used by the Alpha-1 Foundation, a Florida non-profit representing Alpha-1 antitrypsin deficiency sufferers. Bovenberg, *supra* note , at 931; Merz et al., *supra* note , at 966.

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 non-profit organizations 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.<sup>463</sup> This promises to be a growing trend.<sup>464</sup>

The contribution of disease advocacy groups to basic biomedical research allows them to express norms privileging access to resulting discoveries.<sup>465</sup> As opposed to downstream patentees such as MCH and the University of Hawaii, disease advocates do not generally aim for strict exclusivity over patented assets. According to Shannon Terry, her co-ownership of the PXE gene patent ensures that PXE International is now “driving the boat;”<sup>466</sup> she considers herself and her organization “stewards” of the gene.<sup>467</sup> Norms matter a great deal to how these organizations utilize patents. In the basic research context, they are invoking patent rights to assert an ongoing right to *include*.

In a variety of ways, contracts are driving these efforts<sup>468</sup> 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 necessary bodily materials to ensure that MCH would not assert its patent to inhibit research on the gene. More formally, PXE International explicitly conditioned access to its tissue registry on receiving some say in how resulting intellectual property could 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 attract NIH funding or large-scale university research. From the perspective of institutional competence, motivated disease groups may be well-positioned to discriminate 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

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<sup>463</sup> Novas, *supra* note , at 297.

<sup>464</sup> Gitter, *supra* note , at 318. Other patients groups such as Cure Autism Now and the Juvenile Diabetes Research Foundation International have 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 specific advocacy groups. PXE International, <http://www.pxe.org/english/View.asp?x=1683>.

<sup>465</sup> Novas, *supra* note , at 303.

<sup>466</sup> Marshall, *Patient Advocate*, *supra* note , at 1226.

<sup>467</sup> Terry, *supra* note , at 170.

<sup>468</sup> Cf. Gitter, *supra* note , at 315.

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.”<sup>469</sup> 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,<sup>470</sup> it is conceivable that PXE International’s interest in the gene may only extend to its namesake disease, thus leaving other conditions unexplored.<sup>471</sup> Additionally, tissue donors negotiating quid pro quos with researchers raise unique biomedical ethical concerns beyond the scope of this Article.<sup>472</sup> This behavior substantially challenges the notion of the gift as the founding gesture of participation in biomedical research.<sup>473</sup> Such “compensation” may conflict with the prohibition against “undue inducement”<sup>474</sup> and may discourage truly “altruistic” donations by patients whose tissues are necessary to conduct research.<sup>475</sup>

## **Part V. A Critical Assessment of the Contractual Creation of a Biomedical Research Commons**

Public institutions are taking matters into their own hands to address potential patent holdup in biomedical research. The early portions of this Article examined the role of patents in inhibiting biomedical research as well as the limitations and uncertainties of public law initiatives to address this challenge. The most recent Part examined an emerging development among public institutions—the use of private law mechanisms to create, through the quid pro quo model of contracts, a research commons for publicly-supported, privately-patented biomedical technologies. This Part critically assesses this trend. In so doing, it explores the promises and perils of consideration-based patent regulation more generally.

### **A. Opportunities and Benefits**

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<sup>469</sup> Jon F. Merz et al., *Protecting Subjects’ Interests in Genetic Research*, 70(4) *American Journal of Human Genetics*, 965, 969 (2002).

<sup>470</sup> Novas, *supra* note , at 297; Rao, *supra* note , at 378; cf. Gitter, *supra* note , at 323; Bovenberg, *supra* note , at 932.

<sup>471</sup> 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 , at 100.

<sup>472</sup> The Human Genome Organisation has cautiously endorsed benefit-sharing for participants in biomedical research. The Human Genome Organisation, *Statement on Benefit-Sharing*, Apr. 9, 2000, available at [http://cellbank.nibio.go.jp/information/ethics/kiban01/downloadEN/HUGOStatement\\_on\\_Benefit\\_Sharing.htm](http://cellbank.nibio.go.jp/information/ethics/kiban01/downloadEN/HUGOStatement_on_Benefit_Sharing.htm). (“[A] benefit is not identical with profit in the monetary or economic sense. Determining a benefit depends on needs, values, priorities and cultural expectations.”).

<sup>473</sup> Hayden, *supra* note , at 740.

<sup>474</sup> Hayden, *supra* note , at 739. The Council of Europe decreed in 1990 that financial benefit for research in general should be considered an “inducement” that “compromises free consent.” Bartha Knoppers, *Status, Sale, and Patenting of Human Genetic Material: An International Survey*, 22(1) *Nature Genetics* 23, 24 (1999).

<sup>475</sup> Fleischer, *supra* note , at 87.



The primary advantage of a contractual approach to exempting noncommercial research from patent infringement is that it is actually occurring. As explored in Part II, public law initiatives to address this problem, such large-scale reforms to formally codify an experimental use exception, are difficult to implement and likely to embroil numerous political interests. On the contrary, tying access conditions to valuable consideration in individual contracts is an implementable approach that is less likely to disrupt settled expectations than traditional top-down regulation. 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 structure” of the biomedical research sector. Subject to exceptions, institutions that dominate upstream support for basic 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<sup>476</sup>—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.<sup>477</sup> 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. As noted, 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 acting in a funding capacity, the NIH can exercise significant leverage over individual grant recipients to require concessions far and above the Patent Act baseline. As others have noted, streamlining the procedural and administrative requirements of the Bayh-Dole Act could provide the NIH with even greater flexibility in this regard.<sup>478</sup> The greater freedom to operate afforded by consideration-based patent regulation 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.<sup>479</sup> However, by acting in a funding capacity rather than a “legislative” capacity, CIRM is free to impose just that restriction on its grantees.

As opposed to general legislation, the *in personam* nature of this approach also allows for precise, highly contextualized policy interventions. Access and exclusivity both play important roles in the optimal exploitation of biomedical resources, which often requires distinguishing basic research use from commercial development and sale. As distinctions and complexity increase, information costs rise and patents begin to function less like simple rights to exclude

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<sup>476</sup> Merz, *supra* note , at .

<sup>477</sup> Interestingly, activists, academics, shareholders, and consumers are increasingly making those requests and firms are heeding them. 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).

<sup>478</sup> Rai & Eisenberg, *supra* note .

<sup>479</sup> See *supra* note .

and more like governance regimes.<sup>480</sup> Ex ante, general legislation may lack the granularity to address individualized 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 types of 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 Limitations

Of course, consideration-based patent regulation in general, and the contractual creation of a research commons in particular, must be attentive to several challenges and limitations. 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 safe harbors in their funding and licensing arrangements. Furthermore, the Bayh-Dole Act limits the ability of the NIH to directly establish a research exception for all federally-funded, grantee-patented biomedical inventions. The result is a patchwork arrangement rather than a general noncommercial research exception for publicly-developed research tools. Concerted private ordering can rarely achieve the same scope as modifying the *in rem* nature of property rights.

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 development and commercialization of taxpayer-funded inventions. Excessive strings on money, patent rights, or materials could stifle these exchanges.<sup>481</sup> However, carefully drafted *noncommercial research* exceptions can ensure that exclusivity for sale of refined inventions still exists 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.<sup>482</sup>

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 carve out appropriate exceptions from patent infringement for these inventions.<sup>483</sup> As entities like CIRM gain more experience in monitoring grants, their ability to make these distinction will increase. Furthermore, collective organizations like the

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<sup>480</sup> See Smith, *supra* note , at.

<sup>481</sup> Cf. Constance Holden, *Universities Find Too Many Strings Attached to Foundation’s Offer*, 312 Science 1127 (2006).

<sup>482</sup> 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 , at 309-10.

<sup>483</sup> In particular, Professors Rai & Eisenberg have argued that the NIH is better positioned than universities to determine licensing schemes for patented biomedical inventions. Rai & Eisenberg, *supra* note .

Stanford consortium and the Association of University Technology Managers can provide technical assistance to university technology transfer offices to enhance their capacity to 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 are written to 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.<sup>484</sup> 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.<sup>485</sup> This criticism is particularly salient to universities, some of which espouse the ideals of open science while vigorously enforcing their patents.<sup>486</sup> 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.<sup>487</sup> 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 norms and policies, university leadership may need to consider changing the incentive structures and performance metrics for these offices. In a broad sense, the contractual construction of a research commons requires some institutions to forgo financial remuneration in order to express non-profit oriented norms in the marketplace.

## **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 via consideration-based patent regulation holds several wider implications for patent law. Most importantly, it reveals that money, labor, materials, and patent rights represent “normative portals” by which upstream institutions may influence the disposition of inventions by downstream, profit-maximizing patentees. 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 that the patent system might better serve. Consideration-based patent regulation by upstream institutions is a

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<sup>484</sup> Novas, *supra* note , at 297; Rao, *supra* note , at 378; Cf. Gitter, *supra* note , at 323; Bovenberg, *supra* note , at 932.

<sup>485</sup> Cf. Oona Hathaway, *Do Human Rights Treaties Make a Difference?*, 111 Yale L. J. 935 (2002) (arguing that some countries enjoy the expressive benefits of ratifying human rights treaties without actually complying with them).

<sup>486</sup> See, e.g., Ken Howard, *Biotechs Sue Columbia over Fourth Axel Patent*, 21 Nature Biotechnology 955 (2003).

<sup>487</sup> See 17 Cal. Code Reg. §100308 (applying to non-profit grantees); Proposed 17 Cal. Code Reg. §100408 (applying to for-profit grantees).

means for enhancing “normative plurality” within patent law.<sup>488</sup> This Article has focused on the norm of open science, but there are examples where public institutions are leveraging upstream research support to insist that resulting patented inventions promote other ends, such as distributive justice and widespread commercialization.<sup>489</sup> Of course, the dynamics of these efforts may differ considerably from the present effort to create a basic biomedical 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 unduly undermine incentives to innovate.<sup>490</sup>

Procedurally, consideration-based patent regulation represents a significant shift from property to contract as a means for regulating patent practice. The nature of consideration-based patent regulation is very different from traditional judicial, legislative, and administrative regulation. This model relies on the *quid pro quo* of mutual exchange rather than on top-down regulation to promote public policy goals. In this sense, consideration-based patent regulation is much less coercive than centralized patent reform that may disturb settled expectations.

This shift from property to contract provides a new perspective on how the patent system achieves its policy objectives. At a primary level, patents serve the utilitarian objective of technological progress through their property-like character. In the conventional view, exclusive property rights spur invention, disclosure, and commercialization, and promote efficient allocation of resources.<sup>491</sup> However, at a secondary level, certain policy objectives are best advanced by selectively curbing these exclusive rights through a contractually-enforced right to *include*.

Consideration-based patent regulation also challenges prevailing characterizations of participants in the patent system, thus illustrating the importance of institutional norms. A fundamental premise of the U.S. patent system is that parties investing in invention and development seek to maximize profits. While this is a reasonable assumption for many players, it can be grossly inaccurate for others. Many institutions contributing enormous amounts of money, labor, and materials to research and development leading to patented inventions do so with only secondary regard for financial gain.<sup>492</sup> This is particularly true of parties involved in the early stages of invention: federal, state, and non-profit agencies that fund scientific research; universities that conduct basic research, and advocacy groups that contribute necessary tissue samples. Supplementing traditional economic accounts emphasizing efficiency and transaction

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<sup>488</sup> Of course, whether or not normative plurality *within* patent law is desirable is itself a controversial normative question. A rival approach would, for example, allow strict patents on government financed inventions, increase taxes on these patentees, and utilize these revenues to subsidize noncommercial researchers who want to license these inventions. While not attempting to resolve the question of which approach is superior, this Article points out that consideration-based patent regulation avoids the redundancy of taxpayers having to finance licenses for taxpayer-financed inventions.

<sup>489</sup> See *supra* note .

<sup>490</sup> See NIH, A Plan to Ensure Taxpayer’s Interests are Protected, *supra* note , at \*10; Thomas A. Hemphill, Economic Considerations in Cooperative Research and Development Agreements (CRADA): The Case of Taxol, NIH, and Technology Transfer, 28 *Tech. in Soc’y* 321, 328-29 (2006); William A. Sage, *Funding Fairness: Public Health Investment, Proprietary Rights and Access to Health Care Technology*, 82 *Va. L. Rev.* 1737, 1742 (1996).

<sup>491</sup> See Eisenberg, Patents and the Progress of Science, *supra* note , at ; Oddi, *supra* note ; Kitch, *supra* note .

<sup>492</sup> See Katherine Strandburg, Users as Innovators: Implications for Patent Doctrine, available at <http://ssrn.com/abstract=969399>.

costs, the role of institutional norms in creating a research commons underscores an important reason why the initial allocation of property rights (or of legal claims on those rights) matters a great deal.

Further upsetting institutional stereotypes, this model casts public institutions as dynamic, entrepreneurial market actors. In recent years, much useful commentary has focused on a new “dynamism in the public domain.”<sup>493</sup> In the typical narrative, market actors resort to private ordering to temper the excesses of intellectual property rights. Overwhelmingly, private companies are the drivers of these initiatives, with public institutions playing a coordinating, facilitative role. However, consideration-based patent regulation reveals that public institutions, wielding enormous market power, can drive private ordering that advances broad policy objectives. In particular, the federal government is not only a “market maker” in that it grants patents; it is a significant 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” that are available to address the excesses of patent exclusivity.<sup>494</sup> Federal and state governments, acting in a funding rather than a legislative role, as well as universities, non-profit funding organizations, and disease advocacy groups, are actively enhancing the availability of patented biomedical inventions critical for scientific research. Self-recognition as policy actors may spur public institutions to expand existing practices liberalizing access to research technologies. 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.<sup>495</sup> 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.<sup>496</sup> Open source software is a frequently-cite 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.<sup>497</sup> 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.<sup>498</sup> 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.”<sup>499</sup> Taxpayers, universities, non-profit organizations, and tissue donors who contribute much to

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<sup>493</sup> See Merges, A New Dynamism in the Public Domain, *supra* note .

<sup>494</sup> See Burk & Lemley, *supra* note .

<sup>495</sup> Lemley, Are Universities Patent Trolls?, *supra* note , at 611.

<sup>496</sup> See generally Benkler, Coase’s Penguin, *supra* note ; Yochai Benkler, The Wealth of Networks (2006).

<sup>497</sup> See Sunder, *supra* note .

<sup>498</sup> James Boyle, Shames, Software, Spleens (1996).

<sup>499</sup> Kesselheim & Avorn, *supra* note , at 850.

biomedical research should be able to expect something in return.<sup>500</sup> Consideration-based patent regulation provides a path by which contracts can preserve what intellectual property would otherwise take away. Conditioning the support of public institutions on assurances that resulting patents will not disrupt fundamental research is one way to acknowledge their vital upstream contributions and to democratize the rewards of patent protection.

## Conclusion

While exclusive rights help promote technological progress, overly strict exclusivity can undermine this goal. In particular, patents on the technological inputs to biomedical research can inhibit basic scientific inquiry as well as 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. While significant in its own right, this trend represents but one application of the general phenomenon of consideration-based patent regulation.

In particular, this Article argues that public institutions—understood broadly to include 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 biomedical research. 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 materials on requirements that recipients do not use resulting intellectual property to inhibit biomedical research. In all of these instances, public institutions are leveraging upstream research support to advance norms of open scientific research in an increasingly proprietary landscape.

At a substantive level, this investigation highlights the enduring importance of institutional norms in the patent system. Within the “normative structure” of the biomedical research sector, institutions that play the most critical role in supporting upstream research are also generally committed to wide dissemination of these technologies for research purposes. 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

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<sup>500</sup> Jon F. Merz et al., Protecting Subjects’ Interests in Genetic Research, 70(4) American Journal of Human Genetics, 965, 969 (2002).

policy objectives through the faster, nimbler, and more palatable medium of individualized quid pro quo exchanges.

In addition to providing working solutions to the problem of patent holdup, consideration-based patent regulation holds several broader implications for patent law. Most notably, it provides a means by which upstream institutions can inject non-profit norms into a patent system often criticized for preoccupation with exclusivity and profit maximization. Furthermore, consideration-based patent regulation moves beyond the realm of the federal government to reveal a wider universe of institutional actors that are actively advancing patent-related public policy objectives. Finally, consideration-based patent regulation provides upstream contributors with a greater role in determining how patented inventions are used, thus democratizing the management and rewards of the patent system.