

## PATENT EXPERIMENTALISM

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*M*ANY scholars have wrestled with what I call the “first-order question” in patent law: What policies should we adopt to promote innovation? This Article grapples with the second-order question: What policies should we adopt to promote innovation about promoting innovation? I argue that empirical progress in patent law depends on greater policy diversity (rather than the current emphasis on uniformity), but unconstrained “laboratories of experimentation” are suboptimal due to the spillovers from local policies. Instead, patent policy makers should adopt a third way between uniformity and local control: centralized promotion of policy variation. The optimal approach to such policy experimentation depends on the context. Randomized policy experiments should be used more often, both in the field (for example, testing prizes in a random selection of pharmaceutical classes) and in the lab (for example, testing how varying disclosure affects performance in implementing software patents). But many nuanced, dynamic issues—such as the patent-eligibility of new technologies in heterogeneous jurisdictions—are better approached not through fixed experiments, but rather through an adaptive “experimentalist” governance regime. Local actors—patent examiners, judges, or even individual countries—should be granted broad discretion to meet centrally defined framework goals, with the requirement of defending their decisions through robust peer review. Even where controlled experiments are infeasible, experimentalist policies could elicit local knowledge, generate varied observational data, and encourage more robust theory development about the mechanisms by which innovation policies work. This pluralistic, evidence-based approach to patent policy can be

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*guided by recent trends in personalized and evidence-based medicine, and the resulting framework for legal experimentation has implications for policy learning beyond patent law.*

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#### INTRODUCTION

Despite well over a century of intense interest, we lack answers to fundamental empirical questions in patent law.<sup>1</sup> Do patents provide a net innovation incentive? Are other incentives—such as prizes, grants, or

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<sup>1</sup> See Adam B. Jaffe, *The U.S. Patent System in Transition: Policy Innovation and the Innovation Process*, 29 Res. Pol'y 531, 531 (2000); Fritz Machlup & Edith Penrose, *The Patent Controversy in the Nineteenth Century*, 10 J. Econ. Hist. 1, 1–2 (1950).

research tax incentives—superior?<sup>2</sup> If innovation is funded with these alternative mechanisms, should patents also be allowed on the resulting inventions?<sup>3</sup> If patents are allowed, which inventions deserve patents, how broad should the scope of those patents be, how much disclosure should be required, and how should those patents be examined? And how should policies evolve with changing technologies?<sup>4</sup>

The dominant push in patent law, however, has been toward uniformity. Interpretation of U.S. patent law has been centralized in the U.S. Court of Appeals for the Federal Circuit,<sup>5</sup> patent cases have begun to be funneled to certain district court judges,<sup>6</sup> and state law innovation regimes are limited by preemption doctrine.<sup>7</sup> The discretion of other countries to experiment with innovation policy has been limited by the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”) and other international agreements,<sup>8</sup> and the U.S. patent system has been informally exported by sending Federal Circuit judges

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<sup>2</sup> See generally Daniel J. Hemel & Lisa Larrimore Ouellette, *Beyond the Patents-Prizes Debate*, 92 *Tex. L. Rev.* 303, 303 (2013) (developing a new taxonomy of innovation incentives).

<sup>3</sup> Cf. Mark A. Lemley, *Are Universities Patent Trolls?*, 18 *Fordham Intell. Prop. Media & Ent. L.J.* 611, 619–25 (2008) (describing the debate over university patenting).

<sup>4</sup> Cf. Yochai Benkler, *The Wealth of Networks: How Social Production Transforms Markets and Freedom* 461–62 (2006) (arguing that the shift to a networked global information economy increased the inefficiency of IP rights).

<sup>5</sup> See Rochelle Cooper Dreyfuss, *In Search of Institutional Identity: The Federal Circuit Comes of Age*, 23 *Berkeley Tech. L.J.* 787, 788 (2008).

<sup>6</sup> See Robert Gunther & Omar Khan, *Patent Pilot Program, One Year Later*, *N.Y. L.J.*, Jan. 7, 2013, at S6.

<sup>7</sup> See *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 156–57 (1989); Jeanne C. Fromer, *The Intellectual Property Clause’s Preemptive Effect*, in *Intellectual Property and the Common Law* 265, 265–66 (Shyamkrishna Balganesh ed., 2013).

<sup>8</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS]; see *Rotec Indus. v. Mitsubishi Corp.*, 215 F.3d 1246, 1253 (Fed. Cir. 2000) (“[W]e must recognize one of [TRIPS’s] declared purposes: harmonizing worldwide patent law.”); Peter K. Yu, *The International Enclosure Movement*, 82 *Ind. L.J.* 827, 832 (2007) (“[T]he one-size-fits-all templates [in TRIPS and other] agreements have drastically reduced the policy space available to less developed countries.”). Administrative harmonization in the Patent Cooperation Treaty also drives substantive harmonization. See Amy Kapczynski, *Harmonization and Its Discontents: A Case Study of TRIPS Implementation in India’s Pharmaceutical Sector*, 97 *Calif. L. Rev.* 1571, 1625–26 (2009). And the European Union is creating a unified patent system. Unitary Patent & Unified Patent Court, European Patent Office, <http://www.epo.org/law-practice/unitary.html> (last visited July 12, 2013).

to teach foreign patent judges<sup>9</sup> and by training foreign patent examiners through the U.S. Patent and Trademark Office (“PTO”).<sup>10</sup> Over the past thirty years, U.S. policy makers have generally strengthened and harmonized patent protection.

This emphasis on uniformity is unfortunate in light of the vast uncertainties about patents. Locking the world into uniformly strong patent protection simply makes it more difficult to address these questions because empirical progress depends on policy variation.<sup>11</sup> Furthermore, optimal innovation policy likely varies across heterogeneous jurisdictions.<sup>12</sup> U.S. patent policy should focus not on uniformity, but rather on improving innovation incentives through an evidence-based approach that depends on policy diversity. This Article addresses this second-order question of how to address patent law’s uncertainties through policy experiments: How do we promote innovation in promoting innovation?

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<sup>9</sup> See Randall R. Rader, *The State of Patent Litigation*, 21 Fed. Cir. B.J. 331, 331 (2011) (stating that the author was asked “to encourage the Chinese judiciary” to strengthen IP enforcement); Lisa Larrimore Ouellette, *The Federal Circuit & International Patent Law*, Written Description (Feb. 13, 2013, 1:59 PM), <http://writtendescription.blogspot.com/2013/02/international-patents.html>.

<sup>10</sup> See U.S. Patent & Trademark Office, U.S. Dep’t of Commerce, *Performance and Accountability Report: Fiscal Year 2011*, at 32 (2011), <http://www.uspto.gov/about/stratplan/ar/2011/USPTOFY2011PAR.pdf> (stating that the PTO’s Global Intellectual Property Academy trained over 5500 attendees from 138 countries in the 2011 fiscal year); Kapczynski, *supra* note 8, at 1622–27; see also Tom Fox, *Talking Leadership with the Patent and Trademark Office’s Teresa Stanek Rea*, Wash. Post (July 11, 2013), <http://www.washingtonpost.com/blogs/on-leadership/wp/2013/07/11/talking-leadership-with-the-patent-and-trademark-offices-teresa-stanek-rea> (“[W]e’re hoping that other countries will also modify their substantive patent laws to more closely align them with . . . our best practices.”).

<sup>11</sup> Cf. David S. Abrams, *Did TRIPS Spur Innovation? An Analysis of Patent Duration and Incentives to Innovate*, 157 U. Pa. L. Rev. 1613, 1624 (2009) (“Empirical research on the incentive effects of patent duration is quite difficult due to the scarcity of policy variation.”).

<sup>12</sup> For example, corruption levels vary between countries, see *Corruption Perceptions Index 2011*, Transparency Int’l, <http://www.transparency.org/cpi2012/results> (last visited July 12, 2013), and incentives that depend on government decision makers acting in the public interest (such as grants and prizes) seem less likely to be effective in high-corruption countries. Optimal policy also likely varies across technologies, as numerous scholars have argued. See Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 Va. L. Rev. 1575, 1577 (2003); Michael W. Carroll, *One for All: The Problem of Uniformity Cost in Intellectual Property Law*, 55 Am. U. L. Rev. 845, 846–47 (2006); Benjamin N. Roin, *The Case for Tailoring Patent Awards Based on Time-to-Market*, 61 UCLA L. Rev. 672, 676 (2014).

The role of so-called laboratories of experimentation has long been viewed as a benefit of federalism,<sup>13</sup> and yet central coordination of patent law is valued due to business costs and the externalities of innovation—jurisdictions do not internalize all the benefits of their innovation laws. But the debate between centralized uniformity and local control overlooks a third option: *promotion of policy variation by central planners*. Recent scholarship has articulated clearer visions for these systematic experiments, ranging from policy randomization<sup>14</sup> to “experimentalist” systems in which local experimentation is guided by central goals and robust feedback.<sup>15</sup> And yet there has been little discussion of when each approach to policy variation should be used.<sup>16</sup>

The patent system is a useful lens for analyzing these different approaches because the special challenges of patent experimentation magnify their strengths and weaknesses. First, measuring success is hard. The welfare benefit of innovation is difficult to quantify, leading to the substitution of imperfect proxies.<sup>17</sup> Second, policy uncertainty is particularly salient in patent law, where the relevant decisions are often made by multinational companies with long time horizons.<sup>18</sup> Where the costs of nonuniformity are high, experimentation may not be cost-justified. And third, patents have pronounced transjurisdictional effects. Local patent laws have global effects on both knowledge users (who benefit from the resulting knowledge even if they do not share the costs of supra-competitive pricing) and knowledge producers (who benefit

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<sup>13</sup> Cf. Akhil Reed Amar, Five Views of Federalism: “Converse-1983” in Context, 47 Vand. L. Rev. 1229, 1233–35 (1994) (dating the metaphor to *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting)).

<sup>14</sup> See Michael Abramowicz et al., Randomizing Law, 159 U. Pa. L. Rev. 929, 933 (2011); *infra* notes 114–16.

<sup>15</sup> See, e.g., Michael C. Dorf & Charles F. Sabel, A Constitution of Democratic Experimentalism, 98 Colum. L. Rev. 267, 287–88 (1998); Charles F. Sabel & William H. Simon, Minimalism and Experimentalism in the Administrative State, 100 Geo. L.J. 53, 55 (2011); see also *infra* notes 164–70.

<sup>16</sup> See Abramowicz et al., *supra* note 14, at 931 n.2 (criticizing “the most prominent” account of policy experimentation, Dorf & Sabel, *supra* note 15, for “mentioning randomization . . . only once,” but also not comparing the two approaches themselves).

<sup>17</sup> Metrics become even more challenging when we consider non-efficiency values, and quantitative studies will need to be complemented by qualitative and theoretical work.

<sup>18</sup> But note that research is always unpredictable; for example, about eighty percent of drugs that begin clinical trials will fail. See F.M. Scherer, The Pharmaceutical Industry—Prices and Progress, 351 New Eng. J. Med. 927, 928 (2004). Also, disuniformity is different from uncertainty.

from foreign patents under the entrenched norm of nondiscrimination<sup>19</sup>). These effects will dampen the impact of a policy change based on the size of that jurisdiction's market, although the problem is not insurmountable because innovators still focus more on their home market even in today's global economy.<sup>20</sup>

I will analyze how existing empirical work has addressed these challenges in Part I. To illustrate the diversity of methodological approaches and the extent of empirical uncertainty, I will focus on one of the most important (and, to outsiders, surprising) open questions: Do patents even promote innovation? Although various studies, both qualitative and quantitative, have made progress on this question, none provides a clear answer. But I will also argue that the heated debate over this question is misdirected: The key question is not whether the current patent system promotes innovation on average, holding all other innovation-related policies constant. Rather, the question for patent scholars should be: How can we improve patent laws in light of the complex array of innovation laws and institutions with which they interact (including research and development ("R&D") tax credits, government grants and prizes, regulations, contract law, immigration, education, antitrust, social norms, and more) to increase social welfare (including not only innovation and efficiency, but also non-efficiency values such as equity, autonomy, and privacy)?<sup>21</sup> Progress on this question can be made through both large, substantive changes (such as altering the strength of patent protection) and changes at the margins (such as improving the efficiency of patent examination and adjudication), and this Article suggests both kinds of experiments. But we will make more empirical progress by studying not *whether* patents

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<sup>19</sup> Since the nineteenth century, many countries have had to offer foreigners the same patent protections as their own nationals. Paris Convention for the Protection of Industrial Property of March 20, 1883 art. 2, July 14, 1967, 21 U.S.T. 1583, 1631, 828 U.N.T.S. 305, 313. TRIPS incorporated and reiterated this requirement. TRIPS, *supra* note 8, arts. 2–4.

<sup>20</sup> See *infra* notes 73–77 and accompanying text.

<sup>21</sup> Despite the dominant focus on how patents can best incentivize innovation, a number of scholars have argued for a broader conception of welfare. See, e.g., Madhavi Sunder, *From Goods to the Good Life: Intellectual Property and Global Justice* 31–32 (2012). Other scholars have recognized that innovation is affected by a host of laws and institutions. See, e.g., Kauffman Task Force on Law, Innovation & Growth, *Rules for Growth: Promoting Innovation and Growth Through Legal Reform* 4–6 (2011). But the interaction of patents with other innovation policies has been insufficiently explored. See, e.g., Hemel & Ouellette, *supra* note 2, at 306–07 (describing the scant literature comparing R&D tax credits and patents as innovation incentives).

currently work on average, but *why* they do (or do not) work in more specific contexts, as well as what it actually means for patent laws to increase welfare.

Before turning to this Article's core arguments about how to make empirical progress with different issues in patent law in Parts II and III, I note that most of this analysis brackets questions of political feasibility. Before worrying about how political economy constraints might impede optimal innovation policy, it is first necessary to determine an optimal innovation policy. But I take as a given the basic global legal structure, including national sovereignty and U.S. constitutional law. The intended audience for and implementer of most of these ideas is a well-motivated member of Congress. Some of my suggestions may be more likely than others, but they are at least all policies that Congress could realistically pursue.

Part II will describe how randomized experiments should be used to address certain empirical questions in patent law. Section II.A will argue that laboratory experiments should be more widely used for initial tests of radical ideas. Section II.B will then propose that randomization of actual patent policies in the field should be performed to compare well-defined policy options whose adoption depends on their average effect on something observable, as long as the policies can be randomly assigned to different units such that there are minimal spillovers between groups. For example, one could randomly select a sample of pharmaceutical categories to be eligible for a trial of the opt-in Health Impact Fund medical prize scheme, and then compare R&D spending, health impacts, and costs.<sup>22</sup> And proposals for new rights, such as "commercialization patents,"<sup>23</sup> could initially be tested on a randomized basis. One could also randomly assign patent examiners to different incentive structures and then audit a sample of their cases.

However, as Section II.C will explain, randomization would be ineffective for many nuanced, dynamic questions of patent law. For example, by the time a random trial of the patentability of human genes across countries<sup>24</sup> reached a significant conclusion about the average

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<sup>22</sup> See *infra* note 127 and accompanying text.

<sup>23</sup> Ted Sichelman, *Commercializing Patents*, 62 *Stan. L. Rev.* 341, 345 (2010).

<sup>24</sup> This assumes that a sensible category of unpatentable genes could be defined. Compare *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2111 (2013) (distinguishing between "naturally occurring" DNA and "synthetically created" cDNA), with Noam Prywes, *The Supreme Court's Sketchy Science*, *Slate* (June 14, 2013, 12:15 PM),

effect on genetic research (assuming transjurisdictional effects could be accounted for), the state of genetic research would have changed so that the result would have low “external validity,” that is, it could not be generalized to conditions outside the experiment. Innovation conditions may also be sufficiently heterogeneous (both in terms of inherent differences and differences in non-patent innovation policies) that the average treatment effect has little bearing on an individual country’s optimal policy. The required trial duration would also make such experiments very costly, both financially and politically.

Part III will then propose that the regulated local autonomy of “experimentalist” governance—whether exercised by patent examiners, judges, or individual states or countries—may be a more effective framework for some of these more nuanced issues. Unlike randomized field or laboratory experiments, which are discrete projects to identify the best of a few static policy options in a particular context, experimentalism is an adaptive, evidence-based method of governance. Actors at all levels of the patent system should make choices based on a framework goal of promoting innovation (and with awareness of non-patent innovation policies), but local actors’ autonomy should be constrained through robust peer review, evaluation by collaboratively defined metrics, and a duty to explain their choices based on existing theory and evidence.

While the externalities of innovation make international coordination desirable (to prevent freeriding), there is no good reason to coordinate around patent law rather than R&D tax credits, grants, prizes, or some combination of incentives. Allowing countries to experiment beyond the constraints of TRIPS—and requiring deviations to be justified by pro-innovation rationales supported by theory and available data—may lead to further improvements in our understanding of innovation policy.<sup>25</sup> The European Commission has taken steps in this experimentalist direction with its Open Method of Coordination, which combines an objective of R&D investment of three percent of GDP with peer reviews

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[http://www.slate.com/articles/health\\_and\\_science/science/2013/06/supreme\\_court\\_patent\\_case\\_science\\_the\\_justices\\_misunderstand\\_molecular\\_biology.html](http://www.slate.com/articles/health_and_science/science/2013/06/supreme_court_patent_case_science_the_justices_misunderstand_molecular_biology.html) (criticizing this distinction).

<sup>25</sup> Cf. Graeme B. Dinwoodie & Rochelle C. Dreyfuss, *A Neofederalist Vision of TRIPS: The Resilience of the International Intellectual Property Regime* 14–16 (2012) (arguing that TRIPS should not be viewed as a supranational code); Kapczynski, *supra* note 8, at 1574–75 (describing strategies to counteract the harmonizing effect of TRIPS).



and country comparisons along various metrics.<sup>26</sup> Although imperfect in implementation, this example shows that international experimentalism may be feasible. Experimentalism might also be valuable at smaller scales: Patent litigation might be improved by encouraging district courts to use their discretion to experiment and by dividing appellate patent jurisdiction in a way that avoids forum shopping (along with congressional encouragement to create circuit splits where an alternative rule appears promising),<sup>27</sup> and applying experimentalist principles to patent examination might lead to improved methods of locating “prior art” (the earlier references against which an application is compared, which are critical for evaluating patentability).

To be sure, when randomized field experiments are feasible, their evidence is more credible than that resulting from experimentalism, and in some cases the best approach may be to apply experimentalist techniques, such as peer review, in a randomized fashion. But where randomization is infeasible, experimentalism alone can still lead to empirical progress. It will produce varied observational data to test theoretical and structural models, it may be possible to analyze some policies as so-called natural experiments,<sup>28</sup> and the experimentalist structure will encourage richer development of qualitative evidence such as case studies and interviews.<sup>29</sup> And experimentalism’s most important strengths may be its ability to improve the *inputs* (what policies should be tested?) and the *metrics* (what does it mean for a policy to “work”?) for innovating with innovation policy. Given the complexity of innovation policy space, the limited existing data from varied policies, and the differing views on what increases welfare, the best approach

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<sup>26</sup> See *infra* notes 198–210 and accompanying text.

<sup>27</sup> Cf. Jeanne C. Fromer, *District Courts as Patent Laboratories*, 1 U.C. Irvine L. Rev. 307, 322 (2011) (arguing that district courts “can be improved so as to turn them into reliable patent laboratories”); Craig Allen Nard & John F. Duffy, *Rethinking Patent Law’s Uniformity Principle*, 101 Nw. U. L. Rev. 1619, 1625 (2007) (“[I]n addition to the Federal Circuit, at least one extant circuit court should be allowed to hear district court appeals relating to patent law.”); Xuan-Thao Nguyen, *Dynamic Federalism and Patent Law Reform*, 85 Ind. L.J. 449, 451–52 (2010) (describing “local patent reform” through the district courts).

<sup>28</sup> See, e.g., Abrams, *supra* note 11, at 1614; Josh Lerner, *The Empirical Impact of Intellectual Property Rights on Innovation: Puzzles and Clues*, 99 Am. Econ. Rev. 343, 343 (2009).

<sup>29</sup> For an overview of how rigorous qualitative work can be conducted using the same logic of causal inference that underlies quantitative methods, see Gary King et al., *Designing Social Inquiry: Scientific Inference in Qualitative Research* 76, 82–84 (1994).

when randomization is infeasible may be to encourage better theory development and greater policy variation through an experimentalist method that generates local buy-in, elicits local information, and promotes local values. Sometimes the best “experiment” is simply to explore what policy options are even possible.<sup>30</sup>

In sum, I argue for a pluralistic approach, in which the optimal approach to policy variation depends on the context. Randomized laboratory experiments are best for inexpensive initial tests of new ideas. Randomized field experiments should be used when evaluating well-defined policy options with measurable outcomes that are expected to be relatively stable across time and across jurisdictions, and when spillovers between assignments can be minimized. And experimentalism is valuable for generating buy-in from local units, for promoting local innovation with policy design, for eliciting local knowledge about the applicability of different policies to heterogeneous conditions, and for encouraging more robust theory development about the mechanisms by which innovation policies work.

Of course, implementing this approach to policy experimentation will not be easy, and Part IV will explore considerations such as institutional choice and international political economy. Some of this Article’s suggestions would be relatively straightforward to implement; for example, the PTO has been open to testing new policies, so PTO leadership might be interested in more systematically reducing the administrative and error costs of examination through the approach advocated here. But for many of the more substantive policy changes, it is less clear which institutions should coordinate these experiments, or how policy makers’ natural risk aversion could be overcome. I do not claim to have answers to these problems, but I suggest that experimentalism itself may be a promising structure for choosing among experimental approaches to different issues. And policy makers implementing a more evidence-based patent regime might also borrow from the trend toward personalized and evidence-based medicine, which blends “graded” evidence with local clinical expertise and a focus on

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<sup>30</sup> Cf. Chris Ansell, What Is a “Democratic Experiment”?, 9 *Contemp. Pragmatism* 159, 164, 172 (2012) (arguing that “if we want to treat experimentalism as a particular political and epistemic methodology, but do not want to be held to the gold standard of randomized controlled experiments, then one alternative is the framework offered by design science,” under which “the goal of experimentation is to identify the range of variables affecting outcomes of interest”).

understanding the mechanisms by which different treatments affect diverse patients.

Many questions in patent law are hard to answer, but that does not mean that we cannot make progress through this pluralistic and pragmatic approach. Although some of the biggest questions will be difficult to resolve even with optimally designed experiments, global policy standardization will make it impossible to resolve even the smallest uncertainties. Policy makers should thus embrace a new focus on patent experimentalism.

### I. EMPIRICAL UNCERTAINTY IN PATENT LAW

The benefits and costs of the patent system cannot be resolved theoretically. Knowledge is non-rivalrous and generally non-excludable, so it will be undersupplied absent state action such as increasing excludability through patents.<sup>31</sup> And it is clear that innovation responds to incentives,<sup>32</sup> and patents are one type of incentive. But patents have costs: In addition to creating deadweight loss and restricting access,<sup>33</sup> patents might overinduce innovation,<sup>34</sup> discourage subsequent innovation,<sup>35</sup> raise transaction costs,<sup>36</sup> or direct R&D away from beneficial but unpatentable inventions.<sup>37</sup> Other theoretical benefits of patents are similarly ambiguous: Patents encourage disclosure, but this disclosure may not be worth the cost,<sup>38</sup> patents facilitate firm entry, but they also lock in monopolies;<sup>39</sup> patents induce investment in later-stage

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<sup>31</sup> See Joseph Stiglitz, Knowledge as a Global Public Good, *in* International Intellectual Property in an Integrated World Economy 93, 93 (Frederick M. Abbott et al. eds., 2007).

<sup>32</sup> See Liam Brunt et al., Inducement Prizes and Innovation, 60 *J. Indus. Econ.* 657, 657 (2012); David Popp, Induced Innovation and Energy Prices, 92 *Am. Econ. Rev.* 160, 161 (2002).

<sup>33</sup> See F. Scott Kieff et al., *Principles of Patent Law* 57–65 (4th ed. 2008).

<sup>34</sup> See Yoram Barzel, Optimal Timing of Innovations, 50 *Rev. Econ. & Stat.* 348, 348 (1968).

<sup>35</sup> See Suzanne Scotchmer, Standing on the Shoulders of Giants: Cumulative Research and the Patent Law, *J. Econ. Persp.*, Winter 1991, at 29, 37–38.

<sup>36</sup> See Michael A. Heller & Rebecca S. Eisenberg, Can Patents Deter Innovation? The Anticommons in Biomedical Research, 280 *Science* 698, 698 (1998).

<sup>37</sup> See Amy Kapczynski & Talha Syed, The Continuum of Excludability and the Limits of Patents, 122 *Yale L.J.* 1900, 1942 (2013); Benjamin N. Roin, Unpatentable Drugs and the Standards of Patentability, 87 *Tex. L. Rev.* 503, 504–05 (2009).

<sup>38</sup> See Lisa Larrimore Ouellette, Do Patents Disclose Useful Information?, 25 *Harv. J.L. & Tech.* 545, 587 (2012).

<sup>39</sup> See Bronwyn H. Hall, Patents and Patent Policy, 23 *Oxford Rev. Econ. Pol'y* 568, 572 tbl.1 (2007).

commercialization, but many inventions are commercialized absent exclusive rights.<sup>40</sup> For developing countries, patents might increase foreign direct investment, but they might also harm domestic imitators and decrease consumer welfare.<sup>41</sup> The extent of these benefits and costs cannot be resolved without empirical inquiry.<sup>42</sup>

In the 1950s, economists Edith Penrose and Fritz Machlup concluded that the existing empirical evidence was insufficient to establish whether patent laws enhanced social welfare.<sup>43</sup> Professor George Priest and Judge Richard Posner have offered similar laments.<sup>44</sup> Professor Mark Lemley has stated that these concerns “ring[] false today” due to an “outpouring of empirical economic work.”<sup>45</sup> But none of these studies resolves whether patents have a net positive effect on innovation, much less their net welfare effect, or whether alternative innovation incentives such as grants, prizes, and tax credits are inferior.<sup>46</sup> This Part briefly

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<sup>40</sup> See generally Roberto Mazzoleni & Richard R. Nelson, *Economic Theories About the Benefits and Costs of Patents*, 32 *J. Econ. Issues* 1031, 1041 (1998) (discussing how “[a] simple head start on commercialization” can yield high enough profits to induce development without patents).

<sup>41</sup> See Lee Branstetter & Kamal Saggi, *Intellectual Property Rights, Foreign Direct Investment and Industrial Development*, 121 *Econ. J.* 1161, 1188 (2011).

<sup>42</sup> Of course, for those who believe patents are a natural right, these utilitarian concerns are irrelevant. See generally Adam Mossoff, *Who Cares What Thomas Jefferson Thought About Patents? Reevaluating the Patent “Privilege” in Historical Context*, 92 *Cornell L. Rev.* 953, 982–83 (2007) (arguing that early American courts and commentators justified patents within natural rights theory). But while “rights-based theories do influence debates about intellectual property theory in general, the consensus among those studying the American patent system is to focus on utilitarian approaches.” F. Scott Kieff, *Property Rights and Property Rules for Commercializing Inventions*, 85 *Minn. L. Rev.* 697, 697–98 (2001).

<sup>43</sup> Staff of Subcomm. on Patents, Trademarks & Copyrights of the S. Comm. on the Judiciary, 85th Cong., *An Economic Review of the Patent System*, Study No. 15, at 79–80 (Comm. Print 1958) (prepared by Professor Fritz Machlup); Edith Tilton Penrose, *The Economics of the International Patent System* 40 (1951) (“If national patent laws did not exist, it would be difficult to make a conclusive case for introducing them; but the fact that they do exist shifts the burden of proof and it is equally difficult to make a really conclusive case for abolishing them.”).

<sup>44</sup> Richard A. Posner, *Intellectual Property: The Law and Economics Approach*, 19 *J. Econ. Persp.* 57, 59 (2005); George L. Priest, *What Economists Can Tell Lawyers About Intellectual Property: Comment on Cheung*, 8 *Res. L. & Econ.* 19, 21 (1986).

<sup>45</sup> Mark A. Lemley, *Property, Intellectual Property, and Free Riding*, 83 *Tex. L. Rev.* 1031, 1065 n.137 (2005); see Dan L. Burk & Mark A. Lemley, *The Patent Crisis and How the Courts Can Solve It* 38 (2009).

<sup>46</sup> Some argue that there is “weak or no evidence that strengthening patent regimes increases innovation.” Michele Boldrin & David K. Levine, *Against Intellectual Monopoly* 192 (2008); see Michele Boldrin & David K. Levine, *The Case Against Patents*, 27 *J. Econ. Persp.* 3, 3 (2013). Others counter that research “has amply established a causal link between

reviews what has been learned about the extent to which patents promote innovation. My goal is not to comprehensively review all studies of patents' welfare effects, but rather to illustrate the diverse sources of evidence and the difficulty of reaching a clear answer on this one question.

*A. Direct Measurements of Costs and Benefits*

The conceptually easiest approach to evaluating the patent system is to directly estimate its costs and benefits. For example, Professor Josh Lerner estimated patent legal costs in 1991 to be \$1 billion (in 1991 dollars), which he called “a substantial amount relative to the \$3.7 billion spent by U.S. firms on basic research in 1991.”<sup>47</sup> Annual patent legal costs today are closer to \$5 billion for prosecution and \$2.5 billion for litigation.<sup>48</sup> But comparing these figures with basic research spending is misleading, both because there is no reason to exclude applied R&D—which brings U.S. R&D spending to over \$400 billion per year<sup>49</sup>—and because it is unclear how R&D spending compares to the value of patents. The private value of patented technology will generally be greater than its R&D cost (or else the research would not have been pursued), but patents are not the only means of appropriating that private value, so the added value of a patent must be distinguished from the value of the underlying technology.<sup>50</sup>

James Bessen and colleagues address these problems by estimating patents' value from renewal rates and stock-market value, and estimating costs based on event studies of lost market value in patent

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the development of intellectual property and the growth of our national economy.” Kieff, *supra* note 42, at 699 n.4. Most reviews fall in the middle. See, e.g., James Bessen & Michael J. Meurer, *Patent Failure: How Judges, Bureaucrats, and Lawyers Put Innovators at Risk* 93 (2008) (stating that “evidence *is* inconclusive” on whether patents’ “total net effect . . . is positive”); Nat’l Research Council of the Nat’l Acads., *A Patent System for the 21st Century 2* (Stephen A. Merrill et al. eds., 2004); Bronwyn H. Hall & Dietmar Harhoff, *Recent Research on the Economics of Patents*, 4 *Ann. Rev. Econ.* 541, 546–49 (2012).

<sup>47</sup> Josh Lerner, *Patenting in the Shadow of Competitors*, 38 *J.L. & Econ.* 463, 470 (1995).

<sup>48</sup> Hemel & Ouellette, *supra* note 2, at 365.

<sup>49</sup> See Mark Boroush, *Nat’l Sci. Found., InfoBrief: U.S. R&D Spending Resumes Growth in 2010 and 2011 but Still Lags Behind the Pace of Expansion of the National Economy 2 tbl.1* (2013).

<sup>50</sup> See Ashish Arora et al., *R&D and the Patent Premium*, 26 *Int’l J. Indus. Org.* 1153, 1173 (2008) (concluding from firm-level surveys and R&D data that patented inventions earn a fifty percent premium).

disputes.<sup>51</sup> They conclude that outside pharmaceuticals and chemicals, total litigation costs exceed total patent rents for U.S. public firms—probably by a factor of two by the late 2000s.<sup>52</sup> While these kinds of advances in measurement are critical to empirical progress, and evidence of rapidly increasing litigation costs should give patent proponents pause, Bessen's results do not prove that patents do not promote innovation: The most innovative firms might have significant benefits, even if the net effect for public firms is negative.<sup>53</sup> These studies also do not show that patents are not welfare enhancing: The social costs and benefits of patents are larger than their effects on public firms. And most importantly, studying the effects of patents alone does not reveal whether we would be better off without patents.

### *B. Case Studies, Interviews, and Surveys*

If weighing all the costs and benefits is too difficult, perhaps one can examine how patents actually worked in specific cases. As exemplified by *This American Life's* much-discussed *When Patents Attack*,<sup>54</sup> patent debates abound with narrative evidence: cursory anecdotes or detailed case studies in which patents seemed to lead to a good or bad result.<sup>55</sup> Of course, careful qualitative case studies can produce valuable data to maximize leverage in testing and refining a theory or to generate new

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<sup>51</sup> Bessen & Meurer, *supra* note 46, at 95–146; James Bessen et al., *The Costs and Benefits of United States Patents 3* (Bos. Univ. Sch. of Law, Working Paper No. 13-24, 2014), available at <http://ssrn.com/abstract=2278255>; see also Ariel Pakes & Mark Schankerman, *The Rate of Obsolescence of Patents, Research Gestation Lags, and the Private Rate of Return to Research Resources*, in *R&D, Patents, and Productivity 73* (Zvi Griliches ed., 1984) (pioneering the renewal approach). Of course, renewal data does not allow one to directly measure the most valuable patents, and stock market approaches omit private firms. See Glynn S. Lunney, Jr., *On the Continuing Misuse of Event Studies: The Example of Bessen and Meurer*, 16 *J. Intell. Prop. L.* 35, 50–51 (2008) (criticizing the use of event studies).

<sup>52</sup> Bessen & Meurer, *supra* note 46, at 141; Bessen et al., *supra* note 51, at 5 fig.1.

<sup>53</sup> But see Bessen & Meurer, *supra* note 46, at 124 (“[T]he more a firm spends on R&D, all else being equal, the *more* likely it is to be sued for infringement.”).

<sup>54</sup> *This American Life: When Patents Attack . . . Part Two!*, Chicago Public Radio (May 31, 2013), available at <http://www.thisamericanlife.org/radio-archives/episode/496/when-patents-attack-part-two>.

<sup>55</sup> For example, Adam B. Jaffe & Josh Lerner, *Innovation and Its Discontents: How Our Broken Patent System Is Endangering Innovation and Progress, and What to Do About It* (2004), primarily relies on anecdotes of what it views as abusive practices.

hypotheses.<sup>56</sup> But the complexity of innovation makes patent case studies challenging.<sup>57</sup> Case studies have shown that patents are not always necessary for innovation<sup>58</sup> but also that private-ordering solutions can prevent patents from becoming a problem.<sup>59</sup> And none of these studies prove that having more or fewer patents would have caused more or less innovation.

Larger surveys can help overcome concerns about generalizing from small numbers of interviewees. In the 1980s and 1990s, U.S. manufacturers reported that patents were generally not essential to the introduction of products other than pharmaceuticals and chemicals, and were less effective than other appropriation means such as secrecy and first-mover advantage.<sup>60</sup> But these surveys show that patents still play a role in appropriation, and other surveys reveal that patents do affect

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<sup>56</sup> See King et al., *supra* note 29, at 45; Gary King & Eleanor Neff Powell, *How Not to Lie Without Statistics* 4–5 (Aug. 22, 2008) (unpublished manuscript), available at <http://gking.harvard.edu/files/gking/files/nolie.pdf>.

<sup>57</sup> See, e.g., Joel Mokyr, *Editor's Introduction: The New Economic History and the Industrial Revolution*, in *The British Industrial Revolution* 1, 1 (Joel Mokyr ed., 2d ed. 1999); George Selgin & John L. Turner, *Strong Steam, Weak Patents, or the Myth of Watt's Innovation-Blocking Monopoly, Exploded*, 54 *J.L. & Econ.* 841, 843 (2011). For a thoughtful discussion of the potential and limitations of innovation case studies, see Lea Shaver, *Illuminating Innovation: From Patent Racing to Patent War*, 69 *Wash. & Lee L. Rev.* 1891 (2012).

<sup>58</sup> See, e.g., Kal Raustiala & Christopher Sprigman, *The Knockoff Economy: How Imitation Sparks Innovation* 14 (2012) (describing how innovation has flourished without IP in fields such as fashion, cuisine, open-source software, computer databases, and the financial industry); Sec'y's Advisory Comm. on Genetics, Health & Soc'y, U.S. Dep't of Health & Human Servs., *Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests* 2 (2010) (finding no case in which a patented genetic test was the first to market).

<sup>59</sup> Adam Mossoff, *The Rise and Fall of the First American Patent Thicket: The Sewing Machine War of the 1850s*, 53 *Ariz. L. Rev.* 165, 209 (2011). But see Ryan L. Lampe & Petra Moser, *Do Patent Pools Encourage Innovation? Evidence from the 19th-Century Sewing Machine Industry* 6 (Nat'l Bureau of Econ. Research, Working Paper No. 15061, 2009), available at <http://www.nber.org/papers/w15061> (suggesting that these patents discouraged innovation).

<sup>60</sup> See Richard C. Levin et al., *Appropriating the Returns from Industrial Research and Development*, 1987 *Brookings Papers on Econ. Activity* 783, 816; Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 *Mgmt. Sci.* 173, 180 (1986); Wesley M. Cohen et al., *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)* 28 (Nat'l Bureau of Econ. Research, Working Paper No. 7552, 2000), available at <http://www.nber.org/papers/w7552>.

firms' investment decisions,<sup>61</sup> and that patents help small firms raise capital and compete against larger firms.<sup>62</sup>

Surveys and interviews are valuable—it is important to know whether the people whom patents are supposed to be helping think the system is working. But while people are somewhat reliable at reporting *what* they have done in the past, they are less good at explaining *why* they made past choices, or at *predicting* future choices.<sup>63</sup> Economists thus prefer data about how people and firms have *actually behaved* under different policy regimes.

### C. Econometric Approaches

To evaluate an innovation policy, one ideally would compare our world to a counterfactual parallel universe. But given real-world constraints, econometric approaches are generally the best tool for teasing out causal relationships from complex innovation data. Because the welfare increase due to innovation is hard to quantify, econometricians use proxies such as R&D spending, patent counts (sometimes weighted by citations), trademark registrations, or surveys.<sup>64</sup> Regressions on cross-country panel data have generally found that stronger patent laws (based on various metrics) are statistically significantly correlated with innovation proxies such as private R&D spending.<sup>65</sup> These studies face a potential endogeneity

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<sup>61</sup> See Robert P. Merges, Uncertainty and the Standard of Patentability, 7 High Tech. L.J. 1, 11 & n.30 (1992) (collecting sources); Roin, *supra* note 37, at 545–47.

<sup>62</sup> See Stuart J.H. Graham et al., High Technology Entrepreneurs and the Patent System: Results of the 2008 Berkeley Patent Survey, 24 Berkeley Tech. L.J. 1255, 1262 (2009); Bronwyn H. Hall & Rosemarie Ham Ziedonis, The Patent Paradox Revisited: An Empirical Study of Patenting in the U.S. Semiconductor Industry, 1979–1995, 32 RAND J. Econ. 101, 104 (2001); Ronald J. Mann, Do Patents Facilitate Financing in the Software Industry?, 83 Tex. L. Rev. 961, 985–86 (2005).

<sup>63</sup> See Marianne Bertrand & Sendhil Mullainathan, Do People Mean What They Say? Implications for Subjective Survey Data, 91 Am. Econ. Rev. 67, 68 (2001); John A. List, Do Explicit Warnings Eliminate the Hypothetical Bias in Elicitation Procedures? Evidence from Field Auctions for Sports cards, 91 Am. Econ. Rev. 1498, 1504 (2001).

<sup>64</sup> See Paul H. Jensen & Elizabeth Webster, Another Look at the Relationship Between Innovation Proxies, 48 Austl. Econ. Papers 252, 253–54 (2009).

<sup>65</sup> See, e.g., Yongmin Chen & Thitima Puttitanun, Intellectual Property Rights and Innovation in Developing Countries, 78 J. Dev. Econ. 474, 475–76 (2005); David M. Gould & William C. Gruben, The Role of Intellectual Property Rights in Economic Growth, 48 J. Econ. Dev. 323, 328 (1996); Sunil Kanwar & Robert Evenson, Does Intellectual Property Protection Spur Technological Change?, 55 Oxford Econ. Papers 235, 238–40 (2003); Keith



problem<sup>66</sup>—increased R&D might cause stronger patent laws (such as through lobbying by R&D-intensive industries), rather than vice versa<sup>67</sup>—although some studies attempt to control for this effect.<sup>68</sup>

Endogeneity problems can be reduced by seeking changes that appear not to stem from domestic lobbying, which can be analyzed as so-called natural experiments.<sup>69</sup> In one of the most comprehensive studies, Josh Lerner examined policy changes in sixty nations over 150 years and found that pro-patent changes tended to increase patenting by foreigners, but decrease domestic patenting, both in the country undergoing the change and in Great Britain (which had relatively stable policy).<sup>70</sup>

But these cross-country studies suffer from another problem, which is less remarked upon but more significant: Patent law has transjurisdictional effects. Increasing patent protection in one small country will not noticeably increase innovation in that country if domestic firms were already innovating for the global market<sup>71</sup>—rather, it could decrease welfare by increasing domestic deadweight loss

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E. Maskus & Mohan Penubarti, How Trade-Related Are Intellectual Property Rights?, 39 *J. Int'l Econ.* 227, 228–29 (1995).

<sup>66</sup> Endogeneity problems, such as this reverse causation issue, occur when an independent variable (here, patent strength) is not determined outside the system (that is, it is endogenous, not exogenous), so that it is correlated with the error term. Endogeneity problems can also result from omitted variables, measurement error, or simultaneity (when an independent and dependent variable are jointly determined). See Jeffrey M. Wooldridge, *Econometric Analysis of Cross Section and Panel Data* 54–55 (2d ed. 2010).

<sup>67</sup> Indeed, patent protection in high-income countries is correlated with R&D spending from five years earlier. Juan C. Ginarte & Walter G. Park, *Determinants of Patent Rights: A Cross-National Study*, 26 *Res. Pol'y* 283, 298–99 (1997). And one study found the correlation of patent rights with R&D intensity “disappears when lagged R&D intensity is included in the regression.” Martin Falk, *What Drives Business Research and Development (R&D) Intensity Across Organisation for Economic Co-operation and Development (OECD) Countries?*, 38 *Applied Econ.* 533, 545 (2006).

<sup>68</sup> See Chen & Puttitanun, *supra* note 65, at 477; Maskus & Penubarti, *supra* note 65, at 232. Other studies argue that endogeneity is unlikely to be a concern. See Gould & Gruben, *supra* note 65, at 338; Kanwar & Evenson, *supra* note 65, at 242 n.17.

<sup>69</sup> E.g., Mariko Sakakibara & Lee Branstetter, *Do Stronger Patents Induce More Innovation? Evidence from the 1988 Japanese Patent Law Reforms*, 32 *RAND J. Econ.* 77, 80 & n.8 (2001); F.M. Scherer & Sandy Weisburst, *Economic Effects of Strengthening Pharmaceutical Patent Protection in Italy*, 26 *Int'l. Rev. Indus. Prop. & Copyright L.* 1009, 1023 (1995).

<sup>70</sup> Lerner, *supra* note 28, at 343, 347–48.

<sup>71</sup> See Daniel Nepelski & Giuditta De Prato, *Does the Patent Cooperation Treaty Work? A Global Analysis of Patent Applications by Non-Residents 20* (Joint Research Ctr. of the European Comm'n, Working Paper No. JRC79541, 2013), available at <http://ipts.jrc.ec.europa.eu/publications/pub.cfm?id=6222>.

without any gain in innovation. Such studies thus reveal little about the effects of similar policy changes in large markets such as the United States—in other words, they measure so-called partial equilibrium effects, not general equilibrium effects. These spillovers will mute the effect of a patent policy change in a single jurisdiction based on the size of that jurisdiction's market.<sup>72</sup> This problem is lessened because there *are* barriers to trade: Inventors are more likely to exploit inventions in their home country.<sup>73</sup> But studies of a single country's patent policy change will understate the policy's impact. In contrast, studies of *non*-patent policies (such as R&D tax credits, which typically benefit inventors only within a jurisdiction) will *overstate* impact if they cause firms to move to that jurisdiction—meaning that empirical comparisons of innovation policies may be biased against patents.

It is thus noteworthy that some studies—including the cross-country panel data studies described earlier—*have* found significant effects from increasing a country's patent protection. In 1986, Taiwan extended the scope of patent protection and improved patent enforcement, and “[a]n abrupt increase [in R&D intensity] took place in 1987 and it stayed at a high level afterwards.”<sup>74</sup> And another study found that the introduction of pharmaceutical patents “in nations with high levels of development, education, and economic freedom do stimulate innovation.”<sup>75</sup>

The United States, as the world's largest market, is least prone to this problem of transjurisdictional spillovers, although there have been relatively few policy changes to form the basis of a natural experiment.<sup>76</sup>

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<sup>72</sup> For example, if there were no trade barriers or economy-of-scale effects, a change that would have caused a twenty percent R&D increase in an isolated market would, if enacted in a country with ten percent of the global market, only cause a two percent increase in that country (and in every other country).

<sup>73</sup> See Jonathan Eaton & Samuel Kortum, *International Technology Diffusion: Theory and Measurement*, 40 *Int'l Econ. Rev.* 537, 539 (1999); Phillip McCalman, *Reaping What You Sow: An Empirical Analysis of International Patent Harmonization*, 55 *J. Int'l Econ.* 161, 173–77 (2001).

<sup>74</sup> Shih-tse Lo, *Strengthening Intellectual Property Rights: Experience from the 1986 Taiwanese Patent Reforms*, 29 *Int'l J. Indus. Org.* 524, 528 (2011).

<sup>75</sup> Yi Qian, *Do National Patent Laws Stimulate Domestic Innovation in a Global Patenting Environment? A Cross-Country Analysis of Pharmaceutical Patent Protection, 1978–2002*, 89 *Rev. Econ. & Stat.* 436, 436 (2007); see also Jean O. Lanjouw & Iain M. Cockburn, *New Pills for Poor People? Empirical Evidence After GATT*, 29 *World Dev.* 265, 287 (2001) (finding limited evidence of an increase in Indian R&D after India was required to strengthen pharmaceutical patent protection).

<sup>76</sup> The creation of the Federal Circuit is sometimes viewed as a pro-patent event, but its effect on R&D is ambiguous. See Hall & Ziedonis, *supra* note 62, at 101–02, 106; Samuel

One such change was the 1994 shift in patent terms from seventeen years from grant date to twenty years from application date, and Professor David Abrams found the length of term extension for different patent classes (which varied based on PTO processing time) to be positively correlated with patent count.<sup>77</sup> As Abrams notes, “research on the incentive effects of patent duration is quite difficult due to the scarcity of policy variation,”<sup>78</sup> although a recent study takes advantage of the *effective* patent term decrease for cancer drugs that require long clinical trials to estimate that the net present value of the life-years at stake due to decreased innovation is \$2.2 trillion.<sup>79</sup> And in another study of de facto variation across inventions, Professor Heidi Williams demonstrated that IP-like contractual restrictions on certain genes led to a twenty to thirty percent decrease in subsequent innovation.<sup>80</sup> These are important results in the contexts of drug-development and gene patents, but lack of similar variation (either actual or effective) makes it difficult to conduct similar studies in other contexts.

In sum, econometric studies show that patent laws affect inventor behavior, and there is some evidence that longer patent terms can promote more investment. But does the R&D caused by patents create value for society, and does that value outweigh the patent system’s significant costs? In some cases, the evidence suggests the answer is yes; for example, the estimated \$2.2 trillion in U.S. life-years at stake due to the decreased effective patent term for some cancer drugs<sup>81</sup> seems unlikely to be offset by the corresponding costs, suggesting that longer exclusivity (such as through FDA regulations) for some drugs would be welfare-enhancing compared to the status quo. In most cases, however, the evidence is more ambiguous on whether patents even provide a net incentive for innovation, much less whether their total welfare effect is positive. And this ambiguity is underscored by the lack of contemporary

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Kortum & Josh Lerner, *Stronger Protection or Technological Revolution: What Is Behind the Recent Surge in Patenting?*, 48 *Carnegie-Rochester Conf. Series on Pub. Pol’y* 247, 248, 289–90 (1998).

<sup>77</sup> Abrams, *supra* note 11, at 1614.

<sup>78</sup> *Id.* at 1624.

<sup>79</sup> Eric Budish, Benjamin N. Roin & Heidi Williams, *Do Fixed Patent Terms Distort Innovation? Evidence from Cancer Clinical Trials* 34 (Nat’l Bureau of Econ. Research, Working Paper No. 19430, 2013), available at <http://www.nber.org/papers/w19430>.

<sup>80</sup> Heidi L. Williams, *Intellectual Property Rights and Innovation: Evidence from the Human Genome*, 121 *J. Pol. Econ.* 1, 24 (2013).

<sup>81</sup> See Budish et al., *supra* note 79, at 1, 34.

measures of innovation outside the patent system.<sup>82</sup> If you have strong pro-patent or anti-patent priors, this review of the existing evidence is unlikely to change your mind.<sup>83</sup>

*D. The Need for Greater Policy Variation*

Whether patents promote innovation thus remains unanswered (and hotly disputed), but in some sense this is also the wrong question. What patent scholars should really care about is not whether patents (as implemented) promote innovation on average, holding all other policies constant. Rather, the question should be: How can policy makers improve (or replace) patent laws—in light of the complex array of other innovation policies with which they interact—to increase social welfare (including not only innovation, but also non-efficiency values such as equity, autonomy, and privacy)? Figuring out whether patent laws promote innovation might help answer this question, but even more important is understanding *why* patent laws work (or not), as well as what it means for them to “work.”

The evidence analyzed thus far generally confirms that patents provide some R&D incentive, but also that patents are not the only (or often the most effective) means of appropriating value. This is not surprising: It was already evident that there are many non-patent incentives, including tax-funded transfers (such as grants and tax credits) and other incentives (such as first-mover advantage, contractual restrictions, and nonmonetary incentives). Patent laws also interact with an array of laws and legal institutions, including immigration, education, contract, tort, antitrust, and the administrative state. But I am not aware of empirical attempts to determine which mix of innovation laws is most effective.<sup>84</sup>

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<sup>82</sup> The studies in this section measured innovation inputs (for example, R&D spending) or outputs as measured by patent counts; there is little current data about unpatented inventions. Petra Moser has studied unpatented nineteenth-century inventions from World’s Fair catalogs. E.g., Petra Moser, Patents and Innovation: Evidence from Economic History, 27 J. Econ. Persp. 23, 24–27 (2013). On the difficulty of measuring technological progress, see John M. Golden, Innovation Dynamics, Patents, and Dynamic-Elasticity Tests for the Promotion of Progress, 24 Harv. J.L. & Tech. 47, 54–59 (2010).

<sup>83</sup> Cf. Lisa Larrimore Ouellette, Cultural Cognition of Patents, 4 IP Theory 28 (2014) (examining motivated reasoning in patent policy debates).

<sup>84</sup> One of the few empirical studies to compare tax incentives, grants, and patents is Falk, *supra* note 67, although it does not show which generates the most private R&D spending.

While policy makers will probably never locate the *optimal* mix of innovation law, patents could be improved along various dimensions. But policy uniformity impedes this progress. The empirical work reviewed in this Part shows that different sources of data can be used to test different aspects of our understanding of patents, but also that policy evaluation depends on variation—across jurisdiction, time, or technology—in the independent policy choice of interest. The causal effect of a patent policy on a given firm at a given time is the difference between (a) that firm’s behavior under the policy and (b) the way *the same firm* would have behaved *at the same time* without the policy (that is, the counterfactual). We cannot observe the counterfactual, so the causal effect must always be estimated, such as by observing how that firm behaves at a different time without the policy, or how a different (but similar) firm behaves at the same time without the policy. But if there are *no* observations without the policy—that is, under complete policy uniformity—one cannot even make these estimates of the policy’s causal effect.

Yet the dominant move in patent law has been toward uniformity.<sup>85</sup> Congress has singled out patents as an area where uniformity is especially desirable: its “central purpose” in creating the Federal Circuit was to promote national uniformity in patent law;<sup>86</sup> the patent term was adjusted in 1994 to comply with TRIPS’s goal of “uniformity of . . . protection for intellectual property around the world”;<sup>87</sup> and the 2011 America Invents Act moved to a first-to-file regime to “promote greater international uniformity.”<sup>88</sup>

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<sup>85</sup> See *supra* notes 5–10 and accompanying text.

<sup>86</sup> H.R. Rep. No. 97-312, at 23 (1981); see also *id.* at 20 (stating, in a section titled “The Need for Increased Uniformity in Patent Law,” that “the Federal Circuit will provide nationwide uniformity in patent law”); S. Rep. No. 97-275, at 2 (1981) (“Congress determines there is a special need for nationwide uniformity [in patent law.]”). There is some question as to whether the Federal Circuit has in fact achieved this goal. See Jason Rantanen & Lee Petherbridge, *Disuniformity*, 66 Fla. L. Rev. 2007 (2014).

<sup>87</sup> General Agreement on Tariffs and Trade (GATT): Intellectual Property Provisions: Joint Hearing on H.R. 4894 and S. 2368 Before the Subcomm. on Intellectual Prop. & Judicial Admin. of the H. Comm. on the Judiciary and the Subcomm. on Patents, Copyrights & Trademarks of the S. Comm. on the Judiciary, 103d Cong. 163 (1994) (statement of Bruce A. Lehman, Assistant Secretary of Commerce and Comm’r of Patents & Trademarks, U.S. Dep’t of Commerce); see Uruguay Round Agreements Act, Pub. L. No. 103-465, § 532, 108 Stat. 4809, 4983–88 (1994).

<sup>88</sup> Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 3(p), 125 Stat. 284, 293 (2011). Also, the 1952 codification of the obviousness standard was “added to the statute for

Uniformity has benefits: It can create administrative savings for both multinational companies<sup>89</sup> and patent offices.<sup>90</sup> And minimum international patent standards prevent countries from freeriding on innovation financed by foreign consumers—a dynamic that, for now, benefits the IP-exporting United States.<sup>91</sup> But the increased uniformity provided by the Federal Circuit and TRIPS might come at the cost of increasingly locking the world into a globally suboptimal innovation system. Given the persistent empirical uncertainty in patent law, this move toward uniformity seems misguided.

The move toward uniformity in patent law is not without critics. Professor John Duffy has argued that the benefits of uniformity must be balanced with the benefits of diversity, and (with Professor Craig Nard) that appellate patent jurisdiction should be spread to an additional circuit (or two) to foster doctrinal innovation.<sup>92</sup> Professors Graeme Dinwoodie and Rochelle Dreyfuss argue for a flexible approach to TRIPS that allows regulatory competition.<sup>93</sup> Professor Paul Gugliuzza questions whether exclusive federal jurisdiction for patent cases is desirable.<sup>94</sup> And some scholars argue that U.S. states should be allowed to offer patent incentives.<sup>95</sup> More unconstrained “laboratories of experimentation” in patent law could provide useful information; for example, even where people can self-select into different policy options, we can learn something from seeing the policies into which they opt. But unconstrained “laboratories” may under-innovate due to the externalities

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uniformity and definiteness.” H.R. Rep. No. 82-1923, at 7 (1952); S. Rep. No. 82-1979, at 6 (1952).

<sup>89</sup> See H.R. Rep. No. 97-312, at 23 (“[U]niformity in [patent] law . . . will be a significant improvement from the standpoint of . . . businesses . . . . This can have important positive ramifications for the nation’s economy.”). But it is possible that patent laws generate the greatest social welfare through their effect on a few small startups that produce disruptive innovations.

<sup>90</sup> See John M. Golden, Proliferating Patents and Patent Law’s “Cost Disease,” 51 *Hous. L. Rev.* 455, 489–92 (2013) (describing the growth in such work-sharing programs).

<sup>91</sup> For a discussion of how this is changing, see *infra* notes 244–45 and accompanying text.

<sup>92</sup> John F. Duffy, *Harmony and Diversity in Global Patent Law*, 17 *Berkeley Tech. L.J.* 685, 703 (2002); Nard & Duffy, *supra* note 27; see also Amanda Frost, *Overvaluing Uniformity*, 94 *Va. L. Rev.* 1567, 1597 (2008) (arguing that courts overvalue legal uniformity, even for multi-state actors).

<sup>93</sup> Dinwoodie & Dreyfuss, *supra* note 25, at 5–6.

<sup>94</sup> Paul R. Gugliuzza, *Patent Law Federalism*, 2014 *Wis. L. Rev.* 11, 14.

<sup>95</sup> Camilla A. Hrdy, *State Patents as a Solution to Underinvestment in Innovation*, 62 *U. Kan. L. Rev.* 487, 488 (2013); Douglas Gary Lichtman, Note, *The Economics of Innovation: Protecting Unpatentable Goods*, 81 *Minn. L. Rev.* 693, 694 (1997).

of both innovation itself (jurisdictions do not internalize all the benefits of innovation policy) and innovation about innovation (jurisdictions also do not internalize the benefits of policy experiments<sup>96</sup>).

This debate between centralized uniformity and local control overlooks a third option, which is comparatively new in the legal academic literature: *centralized* promotion of the policy variation that is critical for empirical progress. The following Parts turn to the growing literature on policy experimentation and explore how these approaches might be used to make progress on some open questions about the patent system.

## II. RANDOMIZED PATENT LAW

As explained in Part I, the challenge to resolving many empirical questions is constructing the counterfactual: Observations about how well (or poorly) patents work do not prove that a different system would be worse (or better). Econometric approaches can compare the effects of different policies (in different jurisdictions or times, or for different technologies) across similar groups, but differences between the groups must be controlled for and will not always be observable. The gold standard for minimizing differences between comparison groups is random assignment of the policy treatment of interest.<sup>97</sup> This Part describes how patent law would benefit from much greater use of randomized experiments, both in the laboratory (Section II.A) and in the field (Section II.B). However, as explained in Section II.C, randomization is not a panacea for patent law's persistent empirical uncertainty.

### A. Laboratory Experiments

Laboratory experiments allow precise control of the environment, enabling clean tests of theories under idealized conditions.<sup>98</sup> Of course, the artificial environment is also the main drawback of lab experiments,

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<sup>96</sup> See Yair Listokin, *Learning Through Policy Variation*, 118 *Yale L.J.* 480, 546 (2008).

<sup>97</sup> See Joshua D. Angrist & Jörn-Steffen Pischke, *Mostly Harmless Econometrics: An Empiricist's Companion* 11 (2009); David Greenberg et al., *Social Experimentation and Public Policymaking* 18 (2003).

<sup>98</sup> See Elizabeth Hoffman & Matthew L. Spitzer, *Experimental Law and Economics: An Introduction*, 85 *Colum. L. Rev.* 991, 993–94 (1985).

as it can be difficult to extrapolate to the real world.<sup>99</sup> But because lab experiments are generally much cheaper than field experiments, they should be used much more widely for initial tests of new patent-related hypotheses.

The recent growth in lab experiments involving IP shows the promise of this technique and suggests paths for new experiments in the patent context. For example, studies of distortions in bargaining over creative works have raised questions about the efficiency of IP licensing markets.<sup>100</sup> Running similar experiments with varied subjects and conditions—including in more complex simulations of IP exchanges,<sup>101</sup> or with repeat players or participants who negotiate through agents—will help test theories of how IP markets function and how to improve their efficiency. Other experiments have attempted to study when subjects decide to “invest” or “patent” in controlled environments.<sup>102</sup> None of these stylized environments maps reality or is alone sufficient to support policy change, but identifying how real people deviate from rational actor models may stimulate the production of new theories.

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<sup>99</sup> This concern extends not only to the environment, but also to the subjects, who are often undergraduate volunteers or Amazon Mechanical Turk workers. But see Jesse Chandler et al., *Nonnaïveté Among Amazon Mechanical Turk Workers: Consequences and Solutions for Behavioral Researchers*, 46 *Behav. Res. Methods* 112, 113 (2014); Filippos Exadaktylos et al., *Experimental Subjects Are Not Different*, 3 *Sci. Rep.* 1, 4 (2013).

<sup>100</sup> See Christopher Buccafusco & Christopher Sprigman, *Valuing Intellectual Property: An Experiment*, 96 *Cornell L. Rev.* 1, 4 (2010); Christopher Buccafusco & Christopher Jon Sprigman, *The Creativity Effect*, 78 *U. Chi. L. Rev.* 31, 32 (2011); Christoph Engel & Michael Kurschilgen, *Fairness Ex Ante and Ex Post: Experimentally Testing Ex Post Judicial Intervention into Blockbuster Deals*, 8 *J. Empirical Legal Stud.* 682, 699 (2011); Andreas Glöckner et al., *The Endowment Effect in Groups With and Without Strategic Incentives* (Max Planck Inst. for Research on Collective Goods, Bonn, Ger.), Oct. 2009, at 15, available at [http://www.coll.mpg.de/pdf\\_dat/2009\\_35online.pdf](http://www.coll.mpg.de/pdf_dat/2009_35online.pdf); Christopher Jon Sprigman et al., *What’s a Name Worth?: Experimental Tests of the Value of Attribution in Intellectual Property*, 93 *B.U. L. Rev.* 1389, 1434–35 (2013).

<sup>101</sup> For a study of a complex simulated patent trading system, see Eskil Ullberg, *Trade in Ideas: Performance and Behavioral Properties of Markets in Patents* 35–59 (2012).

<sup>102</sup> See Uwe Cantner et al., *Competition in Product Design: An Experiment Exploring Innovation Behavior*, 60 *Metroeconomica* 724, 727 (2009); Christoph Engel & Marco Kleine, *Who Is Afraid of Pirates? An Experiment on the Deterrence of Innovation by Imitation* (Max Planck Inst. for Research on Collective Goods, Bonn, Ger.), Nov. 2013, at 28, available at [https://www.coll.mpg.de/pdf\\_dat/2013\\_07online.pdf](https://www.coll.mpg.de/pdf_dat/2013_07online.pdf); Patrizia Sbriglia & John D. Hey, *Experiments in Multi-Stage R&D Competition*, 19 *Empirical Econ.* 291, 291 (1994); Andrew W. Torrance & Bill Tomlinson, *Patents and the Regress of Useful Arts*, 10 *Colum. Sci. & Tech. L. Rev.* 130, 135 (2009); Daniel John Zizzo, *Racing with Uncertainty: A Patent Race Experiment*, 20 *Int’l J. Indus. Org.* 877, 896 (2002).



The most challenging experiments are those that study not the business decision to invest in innovation, but the innovative process itself. Recent experiments by Professors Chris Buccafusco, Zachary Burns, Jeanne Fromer, and Chris Sprigman measured performance on problems of mathematical and verbal inventiveness under a low copyright-like threshold (such that minimal success was sufficient for entry into a lottery) as compared with higher patent-like thresholds (such that high performance was necessary for entry), and they found statistically significant differences between groups.<sup>103</sup> Similar tests of incentive structure could be performed in more realistic innovation environments. For example, one could offer engineering students different rewards for a design project.<sup>104</sup>

Experimenters should also look for real short-term innovation contests where the environment can be controlled. For example, in one ten-day contest between elite programmers (with real-world reputation implications), experimenters found that performance was nearly doubled by either offering a \$1000 prize or allowing programmers to self-sort into those who preferred a competitive environment over team problem-solving.<sup>105</sup> Such small-scale, highly controllable field experiments are a very promising avenue for studying innovation and incentives at relatively low cost.

Laboratory experiments can be used to bring more scientific rigor to many aspects of the patent system beyond innovation or transactions. For example, Professor Greg Mandel has found that subjects are more likely to judge the solution to a problem to be obvious if they are told what the solution is,<sup>106</sup> raising questions about our current method of

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<sup>103</sup> Christopher Buccafusco et al., *Experimental Tests of Intellectual Property Laws' Creativity Thresholds*, 92 *Tex. L. Rev.* 1921, 1978 (2014).

<sup>104</sup> While it is unlikely that engineering undergraduates would create truly novel and nonobvious inventions in a laboratory setting, they might create inventions that are novel and nonobvious over a closed set of prior art to which they are given access.

<sup>105</sup> Kevin J. Boudreau & Karim R. Lakhani, "Fit": Field Experimental Evidence on Sorting, Incentives and Creative Worker Performance 28 (Harvard Bus. Sch., Working Paper No. 11-107, 2011), available at <http://www.hbs.edu/faculty/Publication%20Files/11-107.pdf>.

<sup>106</sup> Gregory N. Mandel, *Patently Non-Obvious: Empirical Demonstration that the Hindsight Bias Renders Patent Decisions Irrational*, 67 *Ohio St. L.J.* 1391, 1451 (2006); Gregory Mandel, *Patently Non-Obvious II: Experimental Study on the Hindsight Issue Before the Supreme Court in KSR v. Teleflex*, 9 *Yale J.L. & Tech.* 1, 39 (2007). It is not clear, however, that subjects who were unaware of the solution reached the normatively "right" decision—though if a cognitive approach to nonobviousness succeeds only as a proxy for an economic approach, this provides stronger support for a test based explicitly on

assessing nonobviousness, and it seems worth replicating this experiment for more complicated technologies. Professors David Schwartz and Chris Seaman used mock jurors to study the effect of different instructions on the presumption of patent validity;<sup>107</sup> a similar experiment could study whether the recently heightened standard for willful infringement matters.<sup>108</sup> To study whether juries and judges differ in their construction of patent claims<sup>109</sup>—the oft-contested legal descriptions of inventions that set the boundaries of the right to exclude—one could present the same evidence to lay subjects and to legally trained subjects (perhaps using third-year law students or underemployed patent lawyers as a proxy for judges) and see how their constructions differ. Or to study whether claim construction turns on linguistic indeterminacy or policy judgments,<sup>110</sup> one could see how subjects vary their constructions (given the same allegedly infringing product) when evidence varies on (a) the patentee’s technical and economic contribution or (b) linguistic facts.

Laboratory experiments could also improve our understanding of the technical value of patent disclosures. Contrary to popular wisdom that scientists never read patents, my survey of nanotechnology researchers

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economic considerations. See Michael Abramowicz & John F. Duffy, *The Inducement Standard of Patentability*, 120 *Yale L.J.* 1590, 1612 (2011); Tun-Jen Chiang, *A Cost-Benefit Approach to Patent Obviousness*, 82 *St. John’s L. Rev.* 39, 105 (2008).

<sup>107</sup> David L. Schwartz & Christopher B. Seaman, *Standards of Proof in Civil Litigation: An Experiment from Patent Law*, 26 *Harv. J.L. & Tech.* 429, 459 (2013); see also *Microsoft Corp. v. i4i Ltd. P’ship*, 131 S. Ct. 2238, 2251 (2011) (“[A]lthough we have no occasion to endorse any particular formulation, . . . the jury may be instructed to consider that it has heard evidence that the PTO had no opportunity to evaluate before granting the patent.”).

<sup>108</sup> The Federal Circuit raised the standard for willful infringement (which can result in treble damages) in *In re Seagate Technology, LLC*, 497 F.3d 1360, 1371 (Fed. Cir. 2007) (en banc), but willful infringement was found in only ten percent fewer cases post-*Seagate*. See Christopher B. Seaman, *Willful Patent Infringement and Enhanced Damages After In re Seagate: An Empirical Study*, 97 *Iowa L. Rev.* 417, 441 (2012). Researchers could investigate whether there is also little effect in the lab, and if so, whether there is some other treatment that causes a more significant change.

<sup>109</sup> Cf. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831 (2015) (holding that underlying factual disputes in patent claim construction are reviewed for clear error); *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388–91 (1996) (holding that claim construction is an issue for the judge, not the jury).

<sup>110</sup> Cf. Tun-Jen Chiang & Lawrence B. Solum, *The Interpretation-Construction Distinction in Patent Law*, 123 *Yale L.J.* 530, 613 (2013) (arguing that claim construction turns on policy judgments and not linguistic indeterminacy).

found that many do read patents for their technical content.<sup>111</sup> I argued that stronger disclosure requirements would likely have a net benefit, but acknowledged the challenge of quantifying the value of better disclosure. This problem could be tackled in the lab. For example, fictitious software patents could be prepared with varying levels of disclosure. Programmers could then be asked to implement the algorithm, and their programs could be compared based on the time needed to produce a functioning program and the program's quality based on metrics such as runtime.<sup>112</sup>

There are few immediate barriers to increased use of laboratory experiments to inform patent policy. As already noted, these experiments are cheap compared with field experiments, but policy makers should recognize the benefits of funding multi-day studies of actual innovation.<sup>113</sup> Legal scholars should continue pursuing these experiments (working with psychologists and others with training in social science research) and using the results to refine theories and formulate new hypotheses.

### *B. Policy Experiments*

Although laboratory experiments are useful for inexpensive initial tests of policy ideas, it is difficult to generalize from the lab environment to the real world. The best way to evaluate a new policy is to conduct a randomized experiment in the field. A number of government-funded randomized policy experiments have been conducted since the 1960s, primarily in social services.<sup>114</sup> Thus far, “the [U.S.] government has

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<sup>111</sup> Ouellette, *supra* note 38, at 570. Respondents also suggested that most patents are not enabled and that patent disclosures could be greatly improved.

<sup>112</sup> The algorithmic challenge should be tailored to the skill of the subjects and the time available for the experiment—different problems would be appropriate for undergraduate students completing a homework assignment than for expert programmers. In the ten-day contest described earlier, the problem was to optimize the contents of a space flight medical kit, and the winning algorithm is now used for all NASA missions. Boudreau & Lakhani, *supra* note 105, at 10.

<sup>113</sup> Some funding is available from the National Science Foundation (“NSF”). Nat’l Sci. Found., FY 2013 Budget Request to Congress, at SBE-1 to -2 (2012) (noting that the NSF provides sixty-two percent of federal funding for academic research in the social, behavioral, and economic sciences, with appropriations around \$250 million per year).

<sup>114</sup> See Greenberg et al., *supra* note 97; Jerry A. Hausman & Davis A. Wise, Introduction to Social Experimentation 1, 1 (Jerry A. Hausman & Davis A. Wise eds., 1985); see, e.g., Katherine Baicker et al., The Oregon Experiment—Effects of Medicaid on Clinical

almost never conducted randomized tests of policies affecting middle- or upper-class individuals, corporations, or the structure of government itself.”<sup>115</sup> But in a recent article, Professors Michael Abramowicz, Ian Ayres, and Yair Listokin have laid out a convincing case for increased use of randomized policy experiments.<sup>116</sup> They argue that, in addition to providing the best solution to omitted variable bias in natural experiments, randomized field experiments are also easier to explain and thus more likely to have real-world impact.<sup>117</sup>

As I will explain in Section II.C, innovation policy presents a hard case for randomization, as illustrated by hypothetical experiments that would randomize across jurisdictions or across patentees. But first, this Section describes how patent policy *could* benefit by randomizing across technologies, across new patent rights, or across patent examiners.

### *1. Randomizing Across Similar Technologies*

Different patent policies could be randomly applied to different technological classes in cases where it is possible to foresee developments and draw boundaries between similar technologies. Although this is not generally possible,<sup>118</sup> it seems feasible for many

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Outcomes, 368 *New Eng. J. Med.* 1713, 1714 (2013); James J. Heckman et al., *The Rate of Return to the HighScope Perry Preschool Program*, 94 *J. Pub. Econ.* 114, 114 (2010).

<sup>115</sup> John O. McGinnis, *Accelerating Democracy: Transforming Governance Through Technology* 54 (2013). But see Abramowicz et al., *supra* note 14, at 991 (describing the “nearly randomized elimination of short-sale restrictions for one-third of firms in the Russell 3000”); Dennis J. Aigner, *The Residential Electricity Time-of-Use Pricing Experiments: What Have We Learned?*, in *Social Experimentation*, *supra* note 114, at 11. Wealthy individuals are frequently affected by random treatment, such as in assignment to government decision makers. See Adam M. Samaha, *Randomization in Adjudication*, 51 *Wm. & Mary L. Rev.* 1, 74 (2009).

<sup>116</sup> Abramowicz et al., *supra* note 14, at 937. Others have also advocated more randomized policy experiments. See Jim Manzi, *Uncontrolled: The Surprising Payoff of Trial-and-Error for Business, Politics, and Society*, at xvi–xvii (2012); McGinnis, *supra* note 115, at 54–56; Cass R. Sunstein, *Nonsectarian Welfare Statements* 12 (*Harvard Law Sch. Pub. Law & Legal Theory*, Working Paper No. 13-33, 2013), available at <http://ssrn.com/abstract=2317909>.

<sup>117</sup> Abramowicz et al., *supra* note 14, at 941–42.

<sup>118</sup> Randomization across technologies will not work when optimal policy varies across those technologies. Cf. Burk & Lemley, *supra* note 12 (citing work on technology-specific tailoring of patent law); Carroll, *supra* note 12 (same); Roin, *supra* note 12 (same). And it will not work when researchers can easily game the system by shifting an invention’s technology classification. Cf. John R. Allison & Starling D. Hunter, *On the Feasibility of Improving Patent Quality One Technology at a Time: The Case of Business Methods*, 21 *Berkeley Tech. L.J.* 729, 786 (2006) (finding that when the PTO implemented more stringent

medical technologies where the problem to be solved is well defined: Society wants better treatments for known diseases. There is strong evidence that patents provide an incentive for pharmaceutical development,<sup>119</sup> but policy makers have little empirical information on the relative effectiveness of different policies that may be more cost effective or lead to improved health outcomes.

Thus far, new drug incentives have not been introduced using randomization, making evaluation difficult. For example, the 1983 Orphan Drug Act provided three new incentives to develop drugs for rare diseases: seven years of market exclusivity, a fifty percent tax credit for clinical trials, and increased grants.<sup>120</sup> The number of new orphan drugs per year increased thirteen-fold, but empirical analyses have not disentangled the effects of the different incentives.<sup>121</sup> Daniel Hemel and I have argued that the combination of exclusivity and tax credits is likely synergistic, but theory cannot tell us whether incentives should have been weighted more toward exclusivity or toward tax credits.<sup>122</sup> And perhaps the incentives are *too* strong: Steven Rattner recently criticized the Act as creating a “jackpot” for companies.<sup>123</sup>

Randomization should be used to improve orphan drug incentives. An amendment to the Orphan Drug Act could randomize over all rare diseases (of which there are about 6800<sup>124</sup>) such that, for example, half receive the status quo while half receive the most promising alternative.<sup>125</sup> Researchers should then measure the number of new clinical trials and new drugs under each system, as well as each system’s

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review of business methods, some applicants shifted their filings to another technology class).

<sup>119</sup> Even critics of the patent system agree that patents provide a net positive incentive to pharmaceutical firms. See, e.g., Bessen & Meurer, *supra* note 46, at 139–40.

<sup>120</sup> Orphan Drug Act, Pub. L. No. 97-414, §§ 2, 4–5, 96 Stat. 2049, 2050–51, 2053–57 (1983).

<sup>121</sup> See M. Miles Braun et al., *Emergence of Orphan Drugs in the United States: A Quantitative Assessment of the First 25 Years*, 9 *Nature Rev. Drug Discovery* 519, 522 (2010); Wesley Yin, *Market Incentives and Pharmaceutical Innovation*, 27 *J. Health Econ.* 1060, 1062 (2008).

<sup>122</sup> See Hemel & Ouellette, *supra* note 2, at 378–80.

<sup>123</sup> Steven Rattner, *An Orphan Jackpot*, *N.Y. Times Opinionator* (June 30, 2013, 9:06 PM), <http://opinionator.blogs.nytimes.com/2013/06/30/the-orphan-jackpot>.

<sup>124</sup> Rare Disease Information, Nat’l Org. for Rare Disorders, <http://www.rarediseases.org/rare-disease-information> (last visited July 12, 2013).

<sup>125</sup> This alternative could be a minor variation, such as nine years of exclusivity and a thirty percent tax credit, or it could be a more radical variation, such as government-run trials or a prize system.

cost (including the cost of supra-competitive prices caused by exclusivity, which are effectively a “shadow” sales tax on these drugs<sup>126</sup>). While any randomized policy experiment should be sensitive to ethical concerns, especially when human lives are at stake, I think that it is, if anything, unethical *not* to pursue such experiments. Given the state of uncertainty about the best incentives for drug development, anyone with an orphan disease should want the experiment to go forward *ex ante*. The experiment should continue until one system emerges as a winner—at which point orphan diseases could be re-randomized using the winning system and whatever then seems to be the most promising alternative. In this manner, progress could slowly be made toward an improved incentive system.

Drug development for non-orphan diseases could also benefit from randomization. One promising drug development policy is the Health Impact Fund (“HIF”), which would give pharmaceutical companies the choice between (1) selling a new drug at high prices and receiving the usual patent reward or (2) selling the drug at marginal cost and receiving prizes based on its assessed global health impact in terms of Quality Adjusted Life Years (“QALYs”).<sup>127</sup> As the world’s largest market, the United States could test the HIF even without support from other countries.<sup>128</sup> But policy makers would learn more about the HIF’s effectiveness if instead of introducing it for all new drugs, it were initially offered for only a random subset of diseases or therapeutic classes. Researchers should then measure relevant outcomes for each group, including R&D spending, new clinical trials and marketing approvals, health impact (including for drugs not registered with the HIF), and total cost.

Although the United States is not currently offering prizes for drug development, funding agencies including the Department of Defense, Department of Energy, and NASA have increasingly offered fixed prizes for other specific technologies, such as \$250,000 for an astronaut glove and \$1.75 million for a wearable power pack.<sup>129</sup> It is unclear whether

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<sup>126</sup> See Hemel & Ouellette, *supra* note 2, at 312–14, 371–73.

<sup>127</sup> Aidan Hollis & Thomas Pogge, *Incentives for Global Health, The Health Impact Fund: Making New Medicines Accessible for All* 92–93 (2008).

<sup>128</sup> *Id.* at 47.

<sup>129</sup> See Deborah D. Stine, Cong. Research Serv., R40677, *Federally Funded Innovation Inducement Prizes* 3–5 tbl.1 (2009). President Obama has urged agencies to increase their use of prizes. See Nat’l Econ. Council et al., *A Strategy for American Innovation: Securing Our Economic Growth and Prosperity* 12 (2011).

these prizes are most effective as alternatives or complements to patents.<sup>130</sup> To study this, a random subset of prizes could require winners to dedicate the invention to the public domain as a condition of receiving the prize,<sup>131</sup> and another random subset could offer twice the award that the agency originally chose as the optimal prize size. One could then measure whether either the ability to maintain patent rights or the larger prize has a significant effect on the rate at which prizes are claimed.

## 2. *Randomizing Across Patents*

Randomly changing the legal rights accompanying some patents (such as shortening their term) would not reveal anything about the causal effect of patents on invention because invention occurs *before* a patent application is filed (and thus before the randomization). But patents may also affect behavior *after* the patent is granted; namely, they might encourage inventors to commercialize their inventions. Randomized field experiments could shed light on these commercialization theories.

To incentivize commercialization, Professor Michael Abramowicz has proposed patent extension auctions,<sup>132</sup> and Professor Ted Sichelman has advocated “commercialization patents”—short-term affirmative rights to commercialize undeveloped invention patents.<sup>133</sup> In contrast, Mark Lemley has argued that these “ex post justifications” for patents are unpersuasive.<sup>134</sup> Under his reasoning, granting patent extensions or

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<sup>130</sup> Patents may not be a useful addition to fixed prizes because (1) their ability to elicit market information is less valuable when the government has already identified a specific goal, and (2) like prizes, they are awarded ex post and thus are of little additional help to researchers facing capital constraints. See Hemel & Ouellette, *supra* note 2, at 376.

<sup>131</sup> Agencies are prohibited from “gain[ing] an interest in intellectual property developed by a participant in a [prize] competition without the written consent of the participant,” 15 U.S.C. § 3719(j)(1) (2012), but they could require relinquishment of patent rights as a prize condition.

<sup>132</sup> Michael Abramowicz, *The Danger of Underdeveloped Patent Prospects*, 92 *Cornell L. Rev.* 1065, 1071–72 (2007).

<sup>133</sup> Sichelman, *supra* note 23. Sichelman is not the first to propose patent rights based on commercialization. See, e.g., William Kingston, *The Innovation Warrant*, in *Direct Protection of Innovation* 59, 59 (William Kingston ed., 1987). Edmund Kitch noted this commercialization benefit of patents, but his “prospect theory” focused more on patents’ role in coordinating follow-on research. Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 *J.L. & Econ.* 265, 276–79 (1977).

<sup>134</sup> Mark A. Lemley, *Ex Ante Versus Ex Post Justifications for Intellectual Property*, 71 *U. Chi. L. Rev.* 129, 130–32 (2004).

new commercialization patents would (at least in most industries) lead to decreased competition, not increased commercialization.<sup>135</sup>

These competing theories could be tested by subjecting Abramowicz's or Sichelman's proposal to a randomized trial. After firms or individuals have qualified for a patent extension, the government could randomly grant only some of these new rights (ideally on discrete products, not components). Researchers could then track whether each invention is available in the marketplace and, if so, the approximate number of firms from which it is available.<sup>136</sup> It may be most fruitful to initially test these ideas only for those areas of technology where we expect commercialization theory to have the most purchase. Analogizing these new rights to lottery tickets would make them more politically palatable, and this experiment would be unlikely to raise constitutional problems.<sup>137</sup>

### 3. Randomizing Across Examiners

A final example of how randomized field experiments could improve the patent system is in the process of patent examination at the PTO and its foreign counterparts.<sup>138</sup> The PTO is frequently criticized for granting

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<sup>135</sup> Id. at 148–49.

<sup>136</sup> A similar experiment could be conducted in countries that already offer short patents for commercialization by randomly denying a subset of such patents. See generally Protecting Innovations by Utility Models, World Intellectual Prop. Org., [http://www.wipo.int/sme/en/ip\\_business/utility\\_models/utility\\_models.htm](http://www.wipo.int/sme/en/ip_business/utility_models/utility_models.htm) (last visited July 12, 2013). But see Sichelman, *supra* note 23, at 398–99 (arguing that these patents have limited effectiveness because patentees do not commit to commercialization). But the random denial of an established right is likely to be less politically palatable than the random grant of a new right.

<sup>137</sup> As Judge Friendly explained in rejecting a constitutional challenge to a welfare experiment, “the Equal Protection clause should not be held to prevent a state from conducting an experiment designed for the good of all, including the participants, on less than a statewide basis” and objections to allowing officials to arbitrarily select recipients of benefits “are inapposite to the selection, on a random but rational basis, of certain areas of the state to try out a program for the very purpose of determining whether it, or some variation of it should be made applicable to all.” *Aguayo v. Richardson*, 473 F.2d 1090, 1109 (2d Cir. 1973). For a thorough discussion of ethical and equality concerns with randomizing law, see Abramowicz et al., *supra* note 14, at 963–74.

<sup>138</sup> Patents are examined by national offices or by regional offices such as the European Patent Office (“EPO”) (which operates concurrently with national patent offices throughout Europe). See Frequently Asked Questions: Patents, World Intellectual Prop. Org., [http://www.wipo.int/patents/en/faq\\_patents.html](http://www.wipo.int/patents/en/faq_patents.html) (last visited July 12, 2013). Patents granted by regional offices are country specific, although the European Union is creating a unified patent system. See Unitary Patent & Unified Patent Court, *supra* note 8.



too many invalid patents, in part because of the limited time examiners have to examine the average patent.<sup>139</sup> Invalid patents can create significant social costs when they become the subject of expensive patent litigation. It is not clear, however, that spending more resources on patent examination would be efficient. Most patents never become important or disputed, so it probably makes sense to thoroughly consider only the patents that eventually matter.<sup>140</sup>

While determining the optimal amount of time to spend on patent examination is difficult, randomized experiments could improve patent examination *within the current time constraints*. The PTO employs about 8000 examiners,<sup>141</sup> who are grouped by technology within “art units” and are managed in groups of thirteen to twenty by supervisory patent examiners (“SPEs”).<sup>142</sup> Applications are assigned to SPEs based on technology, and SPEs assign applications to examiners in a process that is essentially random (and that could be made actually random).<sup>143</sup> Proposals for improving examination could be tested by randomizing over either individual examiners or SPE groups, depending on the extent to which the treatment could be isolated. The PTO already randomly audits examiners: The Office of Patent Quality Assurance reviews a random sample of all examiner actions (which will catch both false

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<sup>139</sup> See, e.g., Jaffe & Lerner, *supra* note 55, at 34; Joseph Farrell & Robert P. Merges, Incentives to Challenge and Defend Patents: Why Litigation Won’t Reliably Fix Patent Office Errors and Why Administrative Patent Review Might Help, 19 Berkeley Tech. L.J. 943, 944 (2004). The time allotted to examination of each patent varies by technology and the examiner’s experience but is typically around twenty hours. See Michael D. Frakes & Melissa F. Wasserman, Does Agency Funding Affect Decisionmaking?: An Empirical Assessment of the PTO’s Granting Patterns, 66 Vand. L. Rev. 67, 135–36 (2013).

<sup>140</sup> See Mark A. Lemley, Rational Ignorance at the Patent Office, 95 Nw. U. L. Rev. 1495, 1497 (2001); see also Hemel & Ouellette, *supra* note 2, at 365 (estimating that the costs of litigation are only about half the costs of prosecution). But see Jonathan S. Masur, Costly Screens and Patent Examination, 2 J. Legal Analysis 687, 688 (2010) (arguing that costly examination has a screening value distinct from improving quality).

<sup>141</sup> U.S. Patent & Trademark Office, U.S. Dep’t of Commerce, Performance and Accountability Report: Fiscal Year 2012, at 10 (2012).

<sup>142</sup> See David S. Kim & Glenn M. Kubota, Behind the Scenes at the USPTO: Accounting for the Supervisory Patent Examiner, Morrison & Foerster IP Q. Newsl., Summer 2011, at 2.

<sup>143</sup> Mark A. Lemley & Bhaven Sampat, Examiner Characteristics and Patent Office Outcomes, 94 Rev. Econ. & Stat. 817, 822 (2012); see U.S. Patent & Trademark Office, U.S. Dep’t of Commerce, Manual of Patent Examining Procedure § 903.08(b) (8th ed., rev. 9 2012). A primary examiner I spoke with saw no logistical reason that assignment could not be randomized.

positives and false negatives).<sup>144</sup> Experimenters could thus compare audit results of examiners operating under different policies.

Note that while some aspects of examination—such as whether an examiner located a clearly novelty-defeating piece of prior art—can be evaluated more objectively than others, this experimental approach does not require judgments about whether granting more or fewer patents increases innovation. Whatever the threshold for more contested doctrines such as obviousness and enablement,<sup>145</sup> examination should at least be *reliable*, in the sense of different examiners giving the same result for the same patent application. And it seems likely that examination is more reliable with more intense scrutiny (although this should be verified). So while examination results cannot be compared to some objectively correct result, they can at least be compared to the results of closer scrutiny of the same patents.

The PTO has already experimented on a non-random basis with numerous pilot programs.<sup>146</sup> These are promising steps, but the PTO would learn even more from these pilots by initially testing them on a randomized basis. Similarly, the PTO could measure the effect of randomly varying the “count” system (which determines how much credit examiners receive for different activities) across examiners, while adjusting quotas to keep the net resources devoted to examination constant.<sup>147</sup> As another example, Congress could test the proposal of

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<sup>144</sup> U.S. Patent & Trademark Office, U.S. Dep’t of Commerce, Adoption of Metrics for the Enhancement of Patent Quality: Fiscal Year 2011, at 4 (2010).

<sup>145</sup> For the basic requirements for patentability, see 35 U.S.C. §§ 101–103, 112 (2012).

<sup>146</sup> See, e.g., Full First Action Interview Pilot Program, U.S. Patent & Trademark Office, [http://www.uspto.gov/patents/init\\_events/faipp\\_full.jsp](http://www.uspto.gov/patents/init_events/faipp_full.jsp) (last visited July 12, 2013); Peer Review Pilot FY2011, U.S. Patent & Trademark Office, [http://www.uspto.gov/patents/init\\_events/peerpriorartpilotindex.jsp](http://www.uspto.gov/patents/init_events/peerpriorartpilotindex.jsp) (last visited July 12, 2013); Press Release, No. 07-19, U.S. Patent & Trademark Office, USPTO Celebrates a Decade of Telework (June 4, 2007), available at <http://www.uspto.gov/news/pr/2007/07-19.jsp>.

<sup>147</sup> From the 1970s to 2010, the PTO used the same count structure. U.S. Gov’t Accountability Office, GAO-07-1102, U.S. Patent and Trademark Office: Hiring Efforts Are Not Sufficient to Reduce the Patent Application Backlog 7 (2007). This system may have created incentives for examiners to encourage more requests for continued examination (“RCEs”). See Arti K. Rai, Growing Pains in the Administrative State: The Patent Office’s Troubled Quest for Managerial Control, 157 U. Pa. L. Rev. 2051, 2064–65 (2009). There were “significant changes” in 2010. Press Release, No. 10-08, U.S. Patent & Trademark Office, Recently Announced Changes to USPTO’s Examiner Count System Go into Effect (Feb. 18, 2010), available at [http://www.uspto.gov/news/pr/2010/10\\_08.jsp](http://www.uspto.gov/news/pr/2010/10_08.jsp). Because the count system was changed for all examiners at once, measuring the effect of the change is difficult, although the PTO can gain some information from measuring effects across time. It may be possible to make further improvements; for example, one examiner I spoke with

Professors Michael Frakes and Melissa Wasserman to restrict the renewal fees that the PTO may retain (to avoid biases) by requiring renewal fees resulting from patents granted under randomly selected SPEs (who are aware of their assignment) to be diverted to general treasury funds, and then comparing grant rates under different SPEs.<sup>148</sup>

### *C. The Limitations of Randomization*

The previous Section described ways in which the patent system could benefit from randomized field experiments, but randomization is not a panacea for the empirical uncertainty in patent law. Some economists have criticized over-reliance on randomized trials for social policies and development, noting both technical problems such as “randomization bias” (where experimental subjects differ from those normally subject to the policy) and the concern that even the best experiments result only in a mean treatment effect for a specific situation, with no indication of *why* a policy worked or whether it would succeed in other contexts.<sup>149</sup> Professor Angus Deaton argues that “heterogeneity is not a technical problem calling for an econometric solution but a reflection of the fact that we have not started on our proper business, which is trying to understand what is going on.”<sup>150</sup> These limitations are particularly salient for innovation. For example, while it might be appealing to think that randomizing across jurisdictions or patenting entities could lead to important empirical gains, this Section argues that such experiments would not be worth their costs.

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suggested a creative system that would enable the amount of credit an examiner receives for an individual case to track the difficulty of the application.

<sup>148</sup> Frakes & Wasserman, *supra* note 139, at 121. PTO resistance could be reduced by a commitment to provide a fixed lump sum in exchange for the renewal fee diversion. Of course, it is possible that the mechanism behind the effect measured by Frakes and Wasserman is so subtle that examiner awareness of the experiment would eliminate the effect.

<sup>149</sup> See, e.g., Angus Deaton, *Instruments, Randomization, and Learning About Development*, 48 *J. Econ. Literature* 424, 426, 445 (2010); James J. Heckman & Jeffrey A. Smith, *Assessing the Case for Social Experiments*, 9 *J. Econ. Persp.* 85, 86 (1995). But see Abhijit V. Banerjee & Esther Duflo, *The Experimental Approach to Development Economics*, 1 *Ann. Rev. Econ.* 151, 152 (2009); Guido W. Imbens, *Better LATE Than Nothing: Some Comments on Deaton (2009) and Heckman and Urzua (2009)*, 48 *J. Econ. Literature* 399, 399–400 (2010).

<sup>150</sup> Deaton, *supra* note 149, at 430.

*1. Randomizing Across Countries*

An experiment in which patent policies (for example, the status quo under TRIPS versus no patents) were randomly assigned by country (with the hope of observing the effect of patents on R&D spending or economic growth) would avoid problems with endogeneity and omitted variables that plagued the natural experiments in Section I.C. But such an experiment would encounter at least five significant problems. (1) As Section I.C describes, patents create transjurisdictional spillovers for both users (who benefit from the resulting knowledge without sharing its cost) and innovators (who are able to obtain patents in foreign markets), so one might see better outcomes in no-patent countries even if this is not the general equilibrium outcome. (2) Countries would have to be allowed to opt in to the experiment (due to national sovereignty),<sup>151</sup> and the results might not apply to countries that did not volunteer. (3) The measured average treatment effect will depend on factors that vary between countries (such as whether they have effective alternatives to patents, the availability of capital, and the composition of industries) and thus might be of little use for determining the optimal policy for a specific country.<sup>152</sup> (4) The nature of innovation can change: An experiment fifty years ago might have little relevance in today's networked information economy where user-centered innovation is increasingly rivaling a manufacturer-centered approach.<sup>153</sup> (5) Although there are many proposals for improving innovation policy, the high political and financial cost of international policy randomization and the

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<sup>151</sup> Cf. John Goering, Comments on Future Research and Housing Policy, *in* *Choosing a Better Life? Evaluating the Moving to Opportunity Social Experiment* 383, 383–401 (John Goering & Judith D. Feins eds., 2003) (describing an opt-in field experiment in which poor families who received vouchers to move to low-poverty areas were compared with others who wanted to move but were not chosen by the random lottery).

<sup>152</sup> See Deaton, *supra* note 149, at 441 (“The mean treatment effect . . . may be of limited value for a . . . policymaker contemplating specific patients or policies.”).

<sup>153</sup> See Benkler, *supra* note 4, at 460–73; Eric von Hippel, *Democratizing Innovation* 112–17 (2005); Deven R. Desai & Gerard N. Magliocca, *Patents, Meet Napster: 3D Printing and the Digitization of Things*, 102 *Geo. L.J.* 1691, 1719–20 (2014). The point is not that we know that the effectiveness of patents will vary over time—it is that we do not know that their effectiveness will not vary over time, and there are plausible reasons that optimal innovation policy today might look different from optimal innovation policy a few decades ago, and we may see further changes in the future. This point applies broadly: All evidence involves past events, and policy makers should evaluate whether the evidence's applicability has changed over time. Cf. Ouellette, *supra* note 38, at 565–66 (arguing that old surveys about how researchers use patents may be outdated in an era where patents are readily searchable online).

lengthy time required for effective experiments<sup>154</sup> would make it possible to test only a small number of alternatives.

Experiments on more specific aspects of patentability would have similar problems. For example, even if the patentability of genes or software or other controversial subject matter areas could be randomized across countries, innovation in these fields changes rapidly, so the results might have little applicability by the time the experiment is complete.

Slightly more progress could be made by focusing on outcomes specific to an individual country. For developing countries with small markets, the added incentive of domestic patent laws is small compared with the incentive of foreign protection in larger markets; the main argument for why patent laws benefit developing countries is that they increase foreign direct investment (“FDI”).<sup>155</sup> But whether patent laws in fact increase FDI for developing countries is an open empirical question.<sup>156</sup> To address this question, the World Trade Organization (“WTO”) could allow patent laws to be suspended for a random selection of small developing countries that would prefer not to be bound by TRIPS, and then FDI in those countries could be compared with FDI in the control group of countries that volunteered for the experiment but were not allowed to relax their patent laws. There are potential problems with randomization bias (if countries that volunteer for the experiment are significantly different from countries that do not) and with measuring only a partial equilibrium effect (such as if there is a fixed amount of FDI that goes to patent-protective countries in the experiment but would have gone to countries without patents if none of the developing countries had patents). But the result could still provide

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<sup>154</sup> The time-to-market for new innovations can be under a year for software or insurance products but is typically well over a decade in fields such as oil and gas drilling, pharmaceuticals, and fuel cells. Roin, *supra* note 12, at 719 tbl.1.

<sup>155</sup> See Branstetter & Saggi, *supra* note 41 (laying out these arguments).

<sup>156</sup> Compare Walter G. Park & Douglas C. Lippoldt, *Technology Transfer and the Economic Implications of the Strengthening of Intellectual Property Rights in Developing Countries* 28 (OECD Trade Policy, Working Paper No. 62, 2008), available at <http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?doclanguage=en&cote=tad/tc/wp%282007%2919/final> (concluding that stronger patent protection stimulates FDI), with Etienne Pfister & Bruno Deffains, *Patent Protection, Strategic FDI and Location Choices: Empirical Evidence from French Subsidiaries’ Location Choices in Emerging Economies*, 12 *Int’l J. Econ. Bus.* 329, 344 (2005) (“[S]tronger patent protection in countries with a high GDP or with a low R&D intensity seems to reduce the attractiveness to FDI.”).

some evidence to rebut or support the argument that patent laws benefit developing countries by increasing FDI.

This FDI experiment would thus be more successful than an attempt to measure the net innovation incentive caused by patents. It could provide a qualified answer to a disputed policy question: “Does patent protection for developing countries increase FDI on average?” However, the answer to this question does not seem sufficiently valuable to justify the experiment for at least three reasons. First, the answer—the *average* treatment effect—reveals little about whether patent laws increase FDI in any given context. FDI seems likely to be influenced by many legal policy levers beyond patent laws, including the state of contract and trade secrecy law, workforce skill (which is related to education and immigration laws), labor laws, investment laws, and trade barriers. Perhaps eliminating patents increases FDI in countries with certain contract laws, but in countries without those laws there is a bigger drop in FDI, so the average effect is negative. But such contract laws should not be treated as a heterogeneity problem to be averaged away. They are a critically important variable that should be part of our theory of *how* patent laws influence FDI.

Second, FDI is also likely to be influenced by more nuanced factors that are less easily observable. It seems plausible that countries whose leaders use diplomatic skill and effort to attract FDI will have more FDI—variables that are difficult to observe and impossible to randomly assign (one cannot tell some countries to be more skillful or to put in more effort). And third, FDI is not the ultimate policy outcome of interest—it is simply an argument about how patents might benefit developing countries. But if the argument is that developing countries should have patents because it benefits them, should they not decide what they view as a “benefit”? An individual country would seem to have a comparative advantage in both defining its own success and understanding all the complicated policy levers for achieving that success. Perhaps a better approach would be to incentivize developing countries to use their local knowledge and experiment with their own policies in ways that promote global innovation and development goals—a different approach to policy experimentation, which I will return to in Part III.

*2. Randomizing Across Universities*

Randomization's limitations are not confined to the international context. For example, suppose patenting policies were randomized over universities to test whether the Bayh-Dole Act is the best legal framework for promoting the commercialization of university research.<sup>157</sup> Some universities could remain under the status quo (in which patents and exclusive licenses for federally funded research are allowed<sup>158</sup>), and others could be required to use a "market test" of offering research under a nonexclusive license for a nominal fee before an exclusive license is granted. While mandatory participation would be more feasible than in the international context, an opt-in system (in exchange for a monetary incentive) would still be more likely, leading to significant randomization bias concerns. This experiment would also measure only partial equilibrium effects: It might lead to re-sorting of professors across universities that would not occur if all universities adopted the same policy.<sup>159</sup> Schools might also not behave as they would if the changes were permanent, such as by delaying licenses or acting differently because they are being watched.<sup>160</sup> And a final problem is that measurements would be difficult and costly. Significant funding would be required to measure technology transfer that occurs outside the patent system and to measure qualitative changes in research (including changes in scientific norms).<sup>161</sup>

It might be possible to overcome these problems with sufficient political and financial resources, but it is not clear that the outcome

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<sup>157</sup> See Bhaven N. Sampat, *Patenting and US Academic Research in the 20th Century: The World Before and After Bayh-Dole*, 35 *Res. Pol'y* 772, 778–86 (2006).

<sup>158</sup> See 35 U.S.C. §§ 200–212 (2012).

<sup>159</sup> There is some evidence that varying patent royalties causes such sorting. See Saul Lach & Mark Schankerman, *Incentives and Invention in Universities*, 39 *RAND J. Econ.* 403, 427 (2008). To minimize this problem, the experiment could use matched samples (so that if one professor leaves, her corresponding match is also not counted) or an "intent to treat" methodology (counting professors who move with the university to which they were originally assigned). See Abramowicz et al., *supra* note 14, at 958–59 (providing an overview of these techniques).

<sup>160</sup> See John G. Adair, *The Hawthorne Effect: A Reconsideration of the Methodological Artifact*, 69 *J. Applied Psychol.* 334, 334–36 (1984).

<sup>161</sup> A recent study of exogenous variation in the availability of venture capital funding for life-science researchers at top U.S. universities found that greater funding leads to increased patenting but also "changes the type of innovation being pursued: it leads to shorter-horizon, less-cited, and more narrowly-focused projects." Julian Kolev, *Credit Constraints and Their Impact on Innovation: Evidence from Venture Capital Exits* (Nov. 21, 2012) (unpublished manuscript) (on file with author).

would be worth it. Even though “assessment of the social welfare effects of Bayh-Dole . . . remains an open empirical question,”<sup>162</sup> an empirical study is not needed to determine whether universities should grant exclusive patent licenses when firms are eager to commercialize the inventions without exclusive rights. There is no compelling theoretical justification for Bayh-Dole besides the idea that exclusive rights are sometimes necessary for commercialization.<sup>163</sup> The obstacles to amending Bayh-Dole are (1) showing that there is an effective way to sort out which inventions require exclusive rights and (2) overcoming political constraints. A randomized study would probably be no more likely to lead to adoption of the “market test” approach than encouraging a few universities to adopt the policy to show that it is (or is not) feasible.

In conclusion, while innovation policy would benefit from more randomized experiments, innovation is a hard case for field randomization. Even if a global autocrat could control spillovers and randomization bias, she could not design a randomized trial that would reveal the “best” innovation policy mix because the effectiveness of policies (as well as the definition of “best”) will vary with many time- and jurisdiction-dependent factors. A policy designed by a central planner cannot account for these case-specific, dynamic conditions. Policy makers should use randomized experiments only when (1) adoption of a well-defined policy depends on its effect on something observable (and not on buy-in from regulated parties); (2) the policy can be randomly (and ideally mandatorily) assigned to different units (such as different technologies) such that there are minimal spillovers; and (3) the policy’s effect is expected to be sufficiently constant across units and time that the mean treatment effect will be relevant for future policy decisions.

### III. REGULATED PATENT FEDERALISM

Over the past three decades, while patent law has become increasingly centralized with uniform rules, Professor Charles Sabel and a variety of coauthors have extolled increased policy variation through a

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<sup>162</sup> Sampat, *supra* note 157, at 773.

<sup>163</sup> See Lemley, *supra* note 3, at 621–22; Lisa Larrimore Ouellette, Comment, Addressing the Green Patent Global Deadlock Through Bayh-Dole Reform, 119 *Yale L.J.* 1727, 1731 (2010).



governance regime they term “experimentalism.”<sup>164</sup> Experimentalism is characterized by a “center” and “local units” that “set and revise goals . . . in an iterative process with four basic elements”: (1) collaboratively defined “framework goals”; (2) “broad discretion” for local units to meet the goals; (3) “peer review” that “require[s] . . . local units to describe and explain their efforts”; and (4) revision of the goals.<sup>165</sup> This work is part of a broader “New Governance” literature, which encompasses issues ranging from management to democratic legitimacy,<sup>166</sup> but I am most interested in the ability of this structure to promote *learning*.<sup>167</sup> Experimentalism’s “governing norm” is “the capacity for learning and adaptation”<sup>168</sup>—a valuable feature in the dynamic field of innovation.

As an example of the experimentalist structure, child welfare systems in Alabama and Utah give substantial discretion to local caseworkers to promote the “best interests” of the child, but this discretion is cabined by requiring such choices to be “collaborative and explicit,” and by subjecting a subset of cases to intensive peer review.<sup>169</sup> The “local” units also can be larger than individual actors: The European Union has used experimentalist governance—in which countries’ implementation of

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<sup>164</sup> Sabel’s early work focused on experimentalism in corporate governance. See, e.g., Michael J. Piore & Charles F. Sabel, *The Second Industrial Divide: Possibilities for Prosperity*, 300–01 (1984) (describing the corporate use of “flexible specialization” in response to market disorder and uncertainty). He later expanded these ideas to government regulation. See, e.g., Dorf & Sabel, *supra* note 15, at 315, 345.

<sup>165</sup> Sabel & Simon, *supra* note 15, at 79.

<sup>166</sup> See generally Orly Lobel, *New Governance as Regulatory Governance*, in *The Oxford Handbook of Governance* 65 (David Levi-Faur ed., 2012) (analyzing the emerging field of new governance). This literature is also tied to dialogic visions of federalism, including accounts of the power of local units to shape debate by being uncooperative. See Heather K. Gerken, *The Supreme Court, 2009 Term—Foreword: Federalism All the Way Down*, 124 *Harv. L. Rev.* 4, 61–69 (2010) (describing the role of states experimenting with different approaches to problems).

<sup>167</sup> Other scholars besides Sabel and his coauthors have also explored how a decentralized regulatory structure can lead to policy learning. See, e.g., Daniel A. Farber, *Environmental Protection as a Learning Experience*, 27 *Loy. L.A. L. Rev.* 791, 798 (1994); Jody Freeman, *Collaborative Governance in the Administrative State*, 45 *UCLA L. Rev.* 1, 28–29 (1997).

<sup>168</sup> Sabel & Simon, *supra* note 15.

<sup>169</sup> Kathleen G. Noonan, Charles F. Sabel & William H. Simon, *Legal Accountability in the Service-Based Welfare State: Lessons from Child Welfare Reform*, 34 *Law & Soc. Inquiry* 523, 541, 556 (2009).

broad framework goals is improved through peer review—for issues ranging from telecommunications to occupational health and safety.<sup>170</sup>

Experimentalism and randomized field experiments both involve promotion of local policy variation by central planners, which I have argued is critical to empirical progress in patent law. But these two approaches are otherwise radically different. Randomized experiments are comparatively short term, with the goal of identifying (and then mandating) the “right” answer based on quantifiable (and often efficiency-based) metrics; experimentalism is a process of dynamic governance that can more easily accommodate diverse values. Randomization tests external constraints on local units who are subjects of, not participants in, the experiments; experimentalism depends upon the participation and buy-in from the local units. Randomized experiments are controlled by central planners who precisely specify the relevant policy choices; experimentalism elicits policy suggestions, metrics, and goals from actors throughout the system.

Experimentalism appears promising for promoting policy variation and learning for many innovation issues. It can increase local buy-in, promote local experiments, elicit local knowledge about heterogeneous conditions, generate better measures of whether policies are succeeding in light of local values, and increase focus on the mechanisms through which innovation laws act. To be sure, without some use of chance it is difficult to assess whether a policy—including experimentalism itself—is working. In some cases it may be possible to solve this problem by introducing experimentalist techniques on a randomized basis. But even where this is infeasible, experimentalism may be a better approach than the current focus on patent uniformity.

#### *A. Patent Examination*

The experimentalism literature has focused most heavily on the administrative state, so its most obvious application in patent policy is in the administrative process of patent examination at the PTO and its foreign counterparts. The problem of improving examination within limited time constraints also provides a good illustration of the distinction between randomized experiments and an experimentalist approach.

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<sup>170</sup> See Charles F. Sabel & Jonathan Zeitlin, *Learning from Difference: The New Architecture of Experimentalist Governance in the EU*, 14 *Eur. L.J.* 271, 273–86 (2008).

Subsection II.B.3 proposed that randomized experiments be used to evaluate examination policies, such as changing the “counts” assigned to different activities, restricting the renewal fees that the PTO may retain, and introducing pilot programs. These top-down randomized experiments can be used to adjust examiners’ external constraints. But random assignment is ineffective for telling examiners how to spend their time within those external constraints, or for improving their skills and intrinsic motivation, even though improving the nuanced process of examination and the norms within the PTO may be even more important for addressing the PTO’s problems than getting the right external constraints.<sup>171</sup>

As explained in Subsection II.B.3, examiners work in groups of thirteen to twenty under an SPE. Examiners begin as assistant examiners whose decisions must be reviewed; after a rigorous review process they can become primary examiners with “signatory authority” to issue office actions without review.<sup>172</sup> Primary examiners thus receive little substantive supervision, although all decisions are subject to random audits by the Office of Patent Quality Assurance.<sup>173</sup> Primary examiners review the work of some assistant examiners, but assistant examiners do not review anyone’s work.

Examiners are given training on various databases that they can search for prior art, as well as somewhat detailed rules about patentability standards in the *Manual of Patent Examining Procedure*,<sup>174</sup> but they are given little formal instruction on the process of examination.<sup>175</sup> Which databases should be searched? How should search queries be constructed? How do you know when to stop

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<sup>171</sup> See Iain M. Cockburn, Samuel Kortum & Scott Stern, Are All Patent Examiners Equal? Examiners, Patent Characteristics, and Litigation Outcomes, *in* *Patents in the Knowledge-Based Economy* 19, 52–53 (Wesley M. Cohen & Stephen A. Merrill eds., 2003) (emphasizing the importance of norms for improving the non-mechanistic process of patent examination); Mark Lemley, Fixing the Patent Office 7, 10 (Nat’l Bureau of Econ. Research, Working Paper No. 18081, 2012) (citing Lemley & Sampat, *supra* note 143) (arguing that human resource policies such as “training examiners to search better” could improve examination).

<sup>172</sup> See Kim & Kubota, *supra* note 142; Lemley & Sampat, *supra* note 143, at 818–19. Starting in 2000, an additional “second pair of eyes” review was required for business method patents, but this program has since been shut down. See Lemley, *supra* note 171, at 8–9.

<sup>173</sup> See *supra* note 144 and accompanying text.

<sup>174</sup> See U.S. Patent & Trademark Office, *supra* note 143.

<sup>175</sup> Of course, the best SPEs might provide successful informal instruction.

searching? Given the limited time available, should more energy be devoted to prior art searches or to investigating whether the invention's description is adequate for replication? These *process* questions seem at least as important as the *structure* questions examined in Subsection II.B.3, but the non-mechanical process of examination cannot be specified in a precise way that could then be randomly varied. And the optimal process will vary based on the technology,<sup>176</sup> the specific patent, and the examiner's skills (for example, different search strategies might work better for a non-native English speaker).

These process questions could be tackled with an experimentalist approach. The PTO already has the necessary elements for experimentalism: The "center" is the PTO leadership (or the SPEs), the "local units" are individual examiners, the "framework goal" is to improve examination efficiency within time and budgetary constraints, and examiners have (by necessity) broad discretion in how to meet that goal. The PTO could institute a peer review system modeled after experimentalist systems such as child welfare administration in Alabama and Utah. The optimal process of patent examination—how examiners can most efficiently use the limited time available to make the best judgment of whether an application should be granted—cannot be specified with any more precision than the optimal process of serving the "best interests of the child" in child welfare administration. But as in the child welfare context, an experimentalist approach could improve examination by creating a process for examiners to share tacit knowledge and diffuse positive norms.

For example, the PTO could set aside a few days each year for extensive group discussions of a few applications. The examiner responsible for each application could explain how she did her prior art search, why she made the rejections she did, why she did or did not ask for claims to be amended or words to be defined, etc. And her peers could describe how they might have done things differently.<sup>177</sup> It would

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<sup>176</sup> The PTO is transitioning from a classification system with 150,000 subdivisions to a new Cooperative Patent Classification system with 260,000 subdivisions. See Kristin Whitman, Ready or Not, the Cooperative Patent Classification Has Arrived!, Intellogist Blog (July 12, 2012), <http://intellogist.wordpress.com/2012/07/12/ready-or-not-the-cooperative-patent-classification-has-arrived>.

<sup>177</sup> One examiner informed me that the PTO has previously conducted a few training sessions in a roundtable format, where examiners had intense discussions about other ways to conduct prior art searches for sample applications, and that these sessions were very useful.

not be possible to engage in such extensive review of a statistically significant number of each examiner's applications, but the goal would be qualitative learning, not quantitative quality control. Another possibility would be to sometimes assign two examiners to one case, especially as a way of training new examiners. Given the time it can take to understand a single application, this would enable even more in-depth discussion than a qualitative group review, as it would force two examiners to agree on how the examination process should proceed.

While these interventions would likely improve examination, peer review is also costly. To address the difficult question of how much peer review is cost-justified, the experimentalist literature could learn from the literature on randomization: Even though the examination process itself cannot be randomized, the approach to improving it could be. For example, various experimentalist interventions (including group peer reviews or team examination) could be tested on a random selection of SPE groups, and as with the interventions in Subsection II.B.3, results of Office of Patent Quality Assurance audits could be compared across groups.

As I have noted, the PTO's leadership has already demonstrated great willingness to experiment with pilot programs, and they (or experimentally inclined leaders at any foreign patent office) could also implement the experiments proposed in this article.<sup>178</sup> Encouragingly, one examiner told me that the PTO fosters innovation about examination through an intranet site for examiners to suggest ideas, and that the management reviews these ideas for feasibility. Some of these suggestions, coming from those immersed in the examination process, may create more significant gains than the ideas sketched out above. My goal is not to have the PTO conduct specific policy experiments—it is to have the PTO (and other patent offices) consider the benefits of randomization and experimentalism when testing new policies.

### *B. Patent Adjudication*

Although the experimentalism literature has not discussed the courts, there are many parallels between experimentalism and the U.S. judicial

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<sup>178</sup> One obstacle to implementing randomized PTO experiments may be the examiners' union, the Patent Office Professional Association. But the union might not object if the PTO makes clear that the average benefits and bonuses for each random group will be the same, and that the experiments will ultimately improve conditions for all examiners.

system. The federal courts (which have exclusive jurisdiction over the patent laws<sup>179</sup>) involve a series of “centers” and “local units” (with the courts of appeals as centers to the district courts and local units to the U.S. Supreme Court). Judges likely agree on framework goals—finding the “best” interpretation of statutes, upholding the Constitution, resolving disputes fairly and efficiently—although the meaning of these goals is the subject of frequent debate. Judges have broad discretion in how to meet these goals: District judges often receive formal deference, and courts of appeals have de facto discretion because the Supreme Court reviews only a fraction of their decisions. But this discretion is constrained because courts must justify their decisions, and they are subject to feedback and peer review. For example, a panel of judges on a court of appeals might have its decision vacated by its en banc court, reversed by the Supreme Court, or rejected by a sister circuit that finds the decision unpersuasive.

Courts are not well positioned to measure the incentive effects of their rulings, though they could encourage submission of more rigorous empirical evidence.<sup>180</sup> But they are very well positioned to improve procedural aspects of patent litigation. Does a more deferential standard of review for claim construction make it more predictable?<sup>181</sup> How do juries differ from judges in patent cases?<sup>182</sup> Could trials be more efficient? Would routine fee shifting reduce litigation?<sup>183</sup> Could the asymmetry that causes defendants to focus on non-infringement rather than invalidity be reduced?<sup>184</sup>

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<sup>179</sup> See 28 U.S.C. § 1338 (2012). But see *Gunn v. Minton*, 133 S. Ct. 1059, 1068 (2013).

<sup>180</sup> In some cases, courts could also mandate experimental solutions, perhaps including randomized trials. Public law litigation has already resulted in experimentalist remedies, such as rules that “incorporate a process of reassessment and revision with continuing stakeholder participation.” Charles F. Sabel & William H. Simon, *Destabilization Rights: How Public Law Litigation Succeeds*, 117 *Harv. L. Rev.* 1016, 1069 (2004).

<sup>181</sup> See Jonas Anderson & Peter S. Menell, *Informal Deference: A Historical, Empirical, and Normative Analysis of Patent Claim Construction*, 108 *Nw. U. L. Rev.* 1, 76–77 (2014).

<sup>182</sup> See Kimberly A. Moore, *Judges, Juries, and Patent Cases—An Empirical Peek Inside the Black Box*, 99 *Mich. L. Rev.* 365, 409 (2000) (suggesting that “there are some differences in judge and jury resolution of patent cases” that are “impossible to quantify” based on existing data).

<sup>183</sup> See Thomas F. Cotter, *Comparative Patent Remedies: A Legal and Economic Analysis* 148–49 (2013).

<sup>184</sup> See Roger Allan Ford, *Patent Invalidity Versus Noninfringement*, 99 *Cornell L. Rev.* 71, 102–12 (2013).

Courts could also improve substantive patent law when the open question is about the administrability of a standard, rather than its theoretical soundness. For example, it seems clear from a theoretical perspective that a more economic approach to assessing nonobviousness (including examining evidence of independent invention) would be more efficient,<sup>185</sup> although it is unclear whether such a standard is administrable in practice. Doctrinal innovation could help answer this question.

District courts' role as laboratories of experimentation for patent litigation has been recognized: Professor Xuan-Thao Nguyen has highlighted their procedural innovations with local patent rules,<sup>186</sup> and Professor Jeanne Fromer has argued that they could improve technology-specific tailoring of patent law.<sup>187</sup> These efforts may be aided by the pilot program to allow certain district judges to hear more patent cases.<sup>188</sup> But the usual experimentalist appellate structure has been eliminated through the centralization of patent appeals in the Federal Circuit.<sup>189</sup> As discussed previously, Nard and Duffy have argued that patent appeals should be spread to one or two additional courts, which would require the Federal Circuit to explain its decisions—and its rejection of competing arguments—in a way that is persuasive to its peers.<sup>190</sup> They also illustrate another important lesson that experimentalism can learn from randomization: To prevent the results of doctrinal experiments from being tainted by self-selection, appellate jurisdiction of district court cases could be *randomly* assigned after the

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<sup>185</sup> See Abramowicz & Duffy, *supra* note 106, at 1676–77; Chiang, *supra* note 106.

<sup>186</sup> Nguyen, *supra* note 27, at 477–83.

<sup>187</sup> Fromer, *supra* note 27, at 321–22; Jeanne C. Fromer, *Patentography*, 85 N.Y.U. L. Rev. 1444, 1507 (2010). But see Megan M. La Belle, *The Local Rules of Patent Procedure*, 46 *Ariz. St. L.J.* (forthcoming 2015) (manuscript at 40) (on file with the Virginia Law Review Association) (advocating uniform rules to govern patent procedure).

<sup>188</sup> See Rochelle C. Dreyfuss, *Percolation, Uniformity, and Coherent Adjudication: The Federal Circuit Experience*, 66 *SMU L. Rev.* 505, 535–36 (2013); *supra* note 6 and accompanying text.

<sup>189</sup> See 28 U.S.C. § 1295(a) (2012) (giving the Federal Circuit exclusive appellate patent jurisdiction).

<sup>190</sup> Nard & Duffy, *supra* note 27, at 1668; cf. Rochelle Cooper Dreyfuss, *Lecture, What the Federal Circuit Can Learn from the Supreme Court—and Vice Versa*, 59 *Am. U. L. Rev.* 787, 803 (2010) (noting that the Federal Circuit “rarely provides insight into the policy rationale for its own decisions”). For an argument that the Supreme Court can facilitate experimentation under the current appellate structure, see John M. Golden, *The Supreme Court as “Prime Percolator”*: A Prescription for Appellate Review of Questions in Patent Law, 56 *UCLA L. Rev.* 657, 720 (2009).

district court filing.<sup>191</sup> Experimentalist systems should be aware of how self-selection into local units might affect results.<sup>192</sup>

As Nard and Duffy explain, the value of sharing appellate patent jurisdiction will be enhanced if the additional courts start “fresh” with patent precedent, rather than adopting Federal Circuit precedent or following their own pre-Federal Circuit case law.<sup>193</sup> I would go further: Congress should specify that it is spreading appellate patent jurisdiction because it values the innovation and learning that disuniformity allows (in contrast to the uniformity-focused legislative history of the Federal Circuit’s creation), and that when given a choice between adopting the same rule as the Federal Circuit or a different rule that could plausibly be better (or at least is not demonstrably worse), the different rule should be presumptively favored. An explicit congressional statement to this effect might help overcome the natural bias toward harmonization that is caused by judicial review. And the Supreme Court should recognize the value of leaving a circuit split unresolved when the disuniformity causes little harm and there are insufficient data to determine which is the better rule.

Although jurisdictional reform seems unlikely, centralization of patent appeals in a single appellate court may have seemed equally unlikely before it happened (barely over thirty years ago). The Federal Circuit continues to be subject to frequent Supreme Court rebukes<sup>194</sup> and

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<sup>191</sup> Nard & Duffy, *supra* note 27, at 1668; cf. 28 U.S.C. § 2112(a)(3) (2012) (stating that challenges to agency action filed in multiple districts shall have the court of appeals determined by “random selection”); Samaha, *supra* note 115, at 5 (noting other random aspects of adjudication).

<sup>192</sup> As noted previously, patent examination experiments would benefit from ensuring that patents are randomly assigned to examiners. See *supra* note 143 and accompanying text.

<sup>193</sup> Nard & Duffy, *supra* note 27, at 1672–74.

<sup>194</sup> For rebukes on patent issues since 2006, see *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2111, 2114–15, 2120 (2013); *Gunn v. Minton*, 133 S. Ct. 1059, 1062–63, 1068–69 (2013) (reversing a Texas Supreme Court decision that had followed a Federal Circuit rule); *Caraco Pharmaceutical Laboratories, Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1679–80, 1688 (2012); *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289, 1305 (2012); *Bilski v. Kappos*, 130 S. Ct. 3218, 3223–24, 3226, 3231 (2010) (affirming the judgment but stating that the Federal Circuit was wrong to hold that the “machine-or-transformation test” was the sole test for the patentability of processes under 35 U.S.C. § 101); *Quanta Computer, Inc. v. LG Electronics, Inc.*, 553 U.S. 617, 621, 638 (2008); *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 407, 415, 426–28 (2007); *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 132, 137 (2007); *Microsoft Corp. v. AT&T Corp.*, 550 U.S. 437, 447, 457–59 (2007); *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 390–94 (2006). Cf. *Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S.



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scholarly criticism,<sup>195</sup> and it might be possible to channel this criticism into appellate reform.

*C. Innovation Policy*

The examples of patent examination and adjudication illustrate how experimentalism could improve patent policy at the edges, such as by improving the quality of issued patents, making litigation more efficient, and testing the administrability of substantive patent standards. But the hardest case for patent experimentation is varying substantive policy with the goal of testing not administrability, but broader welfare effects. As described in Part II, randomized experiments should be used when choosing between well-defined policies with stable, measurable outcomes and when minimizing spillovers is possible (such as by randomizing over technologies), but the number of contexts where these conditions will be met is limited.

What should be done for the majority of issues where it is unclear which of many innovation policy options is optimal, and where testing policies through a controlled experiment is infeasible? One could advocate for (arbitrarily) choosing one policy to at least gain the benefits of harmonization, but there is not even evidence that a uniform policy is more efficient than a diverse mix of innovation policies.<sup>196</sup> Furthermore, as I have argued, policy uniformity makes it much more difficult to make any empirical progress. And I have seen no justification for the current approach of harmonizing across patent law but not across other innovation laws such as R&D tax incentives, grants, or prizes.<sup>197</sup> In

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28, 32–33, 46 (2006) (vacating the Federal Circuit’s opinion, but noting that “respondent reasonably relied on our prior opinions”).

<sup>195</sup> See Dreyfuss, *supra* note 5, at 789 (“[O]bservers of the patent system have voiced increasingly vociferous complaints about the state of patent jurisprudence, and by extension about the Federal Circuit.”); Golden, *supra* note 190, at 718 (arguing that the Federal Circuit should have recognized problems with its nonobviousness and patentable subject matter doctrines before Supreme Court review because “[s]eparate reports by the Federal Trade Commission and the National Academy of Sciences had highlighted problems with existing doctrine” and “[s]cholarly and professional criticism had often been severe”).

<sup>196</sup> For example, diversity could allow researchers with socially beneficial projects that are not incentivized under the innovation policy in one jurisdiction to pursue their projects in a different jurisdiction that does incentivize their projects.

<sup>197</sup> While there is some limited coordination across research grants, see, e.g., Donors, Int’l Fin. Facility for Immunisation, <http://www.iffim.org/donors> (last visited July 12, 2013), most non-patent coordination efforts have been unsuccessful, see, e.g., Next Step: A Pilot, Health Impact Fund, <http://healthimpactfund.org/next-steps> (last visited July 12, 2013).

these contexts, the experimentalist approach appears promising for promoting policy diversity while maintaining the benefits of central coordination to limit the problems of externalities.

Since the 2000s, the European Commission (“EC”) has taken steps toward experimentalist innovation policy with its Open Method of Coordination (“OMC”) and other mechanisms for transnational learning.<sup>198</sup> Innovation-related framework goals include the objective of increasing R&D intensity (R&D spending as a percentage of GDP) to 3%, with public R&D spending of 1% of GDP,<sup>199</sup> as well as an “action plan” with intermediate goals.<sup>200</sup> Member states have discretion in setting their own innovation policies, but they are subject to monitoring and reporting requirements. States are compared quantitatively along many dimensions of innovation, including R&D intensity, education, scientific publications, the percentage of small- and medium-sized enterprises innovating in-house, patents and trademarks, and employment in knowledge-intensive industries.<sup>201</sup> States are also subject to detailed and prescriptive (albeit voluntary) peer reviews. For example, Slovenia was told that its “poorly coordinated system and non-transparent support schemes” should be addressed with an “inter-Ministerial Cabinet Committee approach”; that grants should be awarded based on “research excellence” rather than the “hardly competitive” system of funding to particular research groups (with a “success rate of . . . 95% (!)”; and that language requirements should be relaxed “at least to enable postgraduate courses and programs in English” to attract foreign students and academics.<sup>202</sup> Recommendations for Belgium included increasing coordination between its “complex and fragmented” regional innovation programs (including by opening

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<sup>198</sup> See generally Nina McGuinness & Conor O’Carroll, *Benchmarking Europe’s Lab Benches: How Successful Has the OMC Been in Research Policy?*, 48 *J. Common Market Stud.* 293 (2010) (describing the progress of the OMC).

<sup>199</sup> See Barcelona European Council, *Presidency Conclusions 20* (Mar. 15–16, 2002).

<sup>200</sup> *Comm’n of the European Cmty’s., Investing in Research: An Action Plan for Europe 3* (2003).

<sup>201</sup> *European Comm’n, Innovation Union Scoreboard 2013*, at 4–5 (2013). The Organisation for Economic Co-operation and Development (“OECD”) provides similar benchmarking, which “focuses more on learning for improving performance in general without common political objectives.” Marianne Paasi, *Collective Benchmarking of Policies: An Instrument for Policy Learning in Adaptive Research and Innovation Policy*, 32 *Sci. & Pub. Pol’y* 17, 18 (2005).

<sup>202</sup> Frits von Meijenfeldt et al., *European Research Area & Innovation Comm., Policy Mix Peer Reviews: Country Report—Slovenia 14*, 21–22, 29 (2010).

regional funding programs to teams from other regions), focusing on science education at younger ages to address a future “skills shortage,” and increasing public R&D expenditures from 0.85% of GDP to the 1% target.<sup>203</sup>

The main problem with the 3% OMC is that unlike in an ideal experimentalist structure, there is no “hard” central control. The 3% goal is non-binding, peer reviews are voluntary, and there are no incentives for success or penalties for failure, creating “a clear mismatch between the scale of the task and the resources deployed to meet this goal.”<sup>204</sup> (The value of harder mechanisms is illustrated by another OMC on researcher mobility that was far more successful in achieving specific policy outcomes by using specific requirements in an area of EC competence (immigration) and “the carrot of co-financing.”<sup>205</sup>) Still, the 3% target may have “succeeded in focusing attention”<sup>206</sup> and serving as a “mobilizing factor” that led to “a common cognitive framework in R&D” and “dramatically increased focus on science and technology in national political agendas.”<sup>207</sup> A comprehensive assessment found some specific evidence of policy learning.<sup>208</sup> For example, the Netherlands introduced an “innovation voucher” mechanism of small grants to facilitate technology transfer between public institutions and small businesses, and after the vouchers’ success was demonstrated through a randomized study,<sup>209</sup> the policy spread to many other member states.<sup>210</sup>

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<sup>203</sup> Joaquín Serrano Agejas et al., European Research Area & Innovation Comm., Policy Mix Peer Reviews: Country Report—Belgium 3, 5, 7 (2011).

<sup>204</sup> McGuinness & O’Carroll, supra note 198, at 311; see also Esko Aho et al., Indep. Expert Grp. on R&D & Innovation, Creating an Innovative Europe 13 (2006) (arguing that the 3% target is “a necessary but not sufficient condition for an innovative Europe”).

<sup>205</sup> McGuinness & O’Carroll, supra note 198, at 305–06, 309.

<sup>206</sup> European Comm’n, Europe 2020: A Strategy for Smart, Sustainable and Inclusive Growth 10 (2010); see R&D Expenditure, European Comm’n Eurostat, [http://epp.eurostat.ec.europa.eu/statistics\\_explained/index.php/R\\_%26\\_D\\_expenditure](http://epp.eurostat.ec.europa.eu/statistics_explained/index.php/R_%26_D_expenditure) (last updated Sept. 25, 2014) (reporting progress).

<sup>207</sup> McGuinness & O’Carroll, supra note 198, at 307; see also Susana Borrás, Policy Learning and Organizational Capacities in Innovation Policies, 38 *Sci. & Pub. Pol’y* 725, 730 (2011) (reviewing the literature on the benefits of the OMC).

<sup>208</sup> Expert Grp. for the Follow-up of the Research Aspects of the Revised Lisbon Strategy, European Comm’n, The Open Method of Coordination in Research Policy: Assessment and Recommendations 25–26, 29 (2009).

<sup>209</sup> Maarten Cornet, Björn Vroomen & Marc van der Steeg, Do Innovation Vouchers Help SMEs to Cross the Bridge Towards Science? 3 (CPB Neth. Bureau for Econ. Policy Analysis, Discussion Paper No. 58, 2006).

<sup>210</sup> See Borrás, supra note 207, at 732.

My point is not that the EC's innovation policy is ideal—it is simply that a transjurisdiction experimentalist approach to innovation is possible, and that it can be integrated with randomized field experiments as appropriate. By requiring a certain amount of R&D spending (which ideally would include the “shadow” reward to patentees<sup>211</sup>) rather than requiring a specific innovation policy such as twenty-year patents, countries could overcome the problem with the externalities of innovation while providing greater room for policy experimentation and removing the asymmetry that privileges patents above other mechanisms for rewarding innovators.

Of course, as I have already explained, experimentalism does not solve the difficulties with gathering meaningful evidence of the average effects of new policies where spillovers, heterogeneities, and dynamic effects make randomized experiments infeasible or not useful. And unlike in the administrative context, it would be difficult to test international experimentalism on a randomized basis. But the experimentalist approach alone can still promote learning, as the E.U. experience demonstrates. For example, it will produce varied observational data to test theoretical and structural models,<sup>212</sup> and it may be possible to analyze some policy changes as “natural experiments.”<sup>213</sup> The experimentalist structure—particularly the requirements of articulation and peer review—will also directly encourage more robust theory development, as well as the development of more qualitative evidence such as case studies and interviews. These approaches may be

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<sup>211</sup> See Hemel & Ouellette, *supra* note 2, at 311–12.

<sup>212</sup> Professor Chris Ansell has suggested that experimentalism could be analyzed under the framework of design science, which “moves away from hypothesis testing under controlled conditions and instead focuses on generating richer observations about the wider set of interactions between the design and its context.” Ansell, *supra* note 30, at 172.

<sup>213</sup> As described in Section I.C, although studies are limited by the lack of policy variation, some empirical progress has already been made through these techniques. While the experiments described there focus on whether patents promote innovation, a number of other studies have taken advantage of natural variation to study other aspects of the patent system. See, e.g., David S. Abrams & R. Polk Wagner, *Poisoning the Next Apple? The America Invents Act and Individual Inventors*, 65 *Stan. L. Rev.* 517, 562 (2013); Joshua S. Gans, David H. Hsu & Scott Stern, *The Impact of Uncertain Intellectual Property Rights on the Market for Ideas: Evidence from Patent Grant Delays*, 54 *Mgmt. Sci.* 982, 982 (2008); Josh Lerner, *Patenting in the Shadow of Competitors*, 38 *J.L. & Econ.* 463, 463 (1995); Michael Noel & Mark Schankerman, *Strategic Patenting and Software Innovation*, 61 *J. Indus. Econ.* 481, 481 (2013); Stuart Graham & Deepak Hegde, *Do Inventors Value Secrecy in Patenting? Evidence from the American Inventor's Protection Act of 1999*, at 3 (Nov. 2, 2012) (unpublished manuscript), available at <http://ssrn.com/abstract=2170555>.

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better suited to making empirical progress on *why* patent policies work. As Angus Deaton explains,

Without a prior theory and within its own evidentiary standards, [a randomized controlled trial] targeted at “finding out what works” is not informative about mechanisms, if only because there are always multiple mechanisms at work. . . . Learning about theory, or mechanisms, requires that the investigation be targeted toward that theory, toward *why* something works, not *whether* it works. Projects can rarely be replicated, though the mechanisms underlying success or failure will often be replicable and transportable. . . .

. . .

In the end, there is no substitute for careful evaluation of the chain of evidence and reasoning by people who have the experience and expertise in the field.<sup>214</sup>

Experimentalism also directly encourages *innovation* in innovation policy—the development of creative policy inputs for testing, such as the Netherlands’ innovation vouchers. Just as experimentalism is likely more effective than top-down randomization for improving the nuanced process of prior art searching, it will also be superior for nuanced policies whose implementation depends on buy-in from the local units, as seems likely to be the case for policies such as awarding research grants or attracting FDI.

Finally, experimentalism might be able to improve the metrics by which policies are judged. I have argued that the goal of an evidence-based patent regime should be to increase social welfare, and yet I have not defined what this means. Increasing efficiency is an important component of welfare, but the choice between policies also necessarily implicates important value judgments, such as the extent to which innovation should be subsidized by everyone or only by users of the resulting products.<sup>215</sup> Indeed, some scholars have argued that the persistent empirical uncertainty over what is “efficient” in IP law means policy makers should focus much more heavily on other values.<sup>216</sup> These

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<sup>214</sup> Deaton, *supra* note 149, at 441–42, 450.

<sup>215</sup> See Hemel & Ouellette, *supra* note 2, at 345–52.

<sup>216</sup> See Robert P. Merges, *Justifying Intellectual Property* 2–4 (2011); Amy Kapczynski, *The Cost of Price: Why and How to Get Beyond Intellectual Property Internalism*, 59 *UCLA L. Rev.* 970, 970 (2012); Oskar Liivak, *Maturing Patent Theory from Industrial Policy to*

non-efficiency values are easier to measure when central planners encourage local units to take an active role in defining success.

In sum, experimentalism maintains a Hayekian recognition of the value of local knowledge.<sup>217</sup> Given the extent of empirical uncertainty about innovation policy and the lack of consensus about what increases social welfare, the best approach for many issues may be to encourage greater policy variation through an experimentalist method that generates local investment in improving innovation policy, promotes local values, and allows greater exploration of what policy options are even possible.

#### IV. TOWARD EXPERIMENTALIST PATENT POLICY

Thus far, I have described a variety of approaches to patent policy experimentation that can help make progress on the key question for patent scholars: How can patent policy be improved, in light of the array of other innovation policies, to increase social welfare? I have argued for a pluralistic approach, in which some issues are tested through randomized laboratory or field experiments and others are explored through experimentalism's blend of bottom-up learning and robust feedback. As I have explained, these different approaches will be most valuable in different contexts: Randomized laboratory experiments are optimal for inexpensive initial tests of new ideas. Randomized field experiments should be used to evaluate well-defined policy options with measurable outcomes that are expected to be relatively stable across time and across jurisdictions, and when spillovers between assignments can be minimized. And experimentalism is valuable for generating buy-in, promoting local policy innovations, eliciting local knowledge about the applicability of different policies to heterogeneous conditions, and generating better measures of whether policies are succeeding in light of local values.

But who should decide when to use which approach, and how should different methods of policy experimentation be blended? These are difficult questions, worthy of articles of their own, but I will note that

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Intellectual Property, 86 *Tul. L. Rev.* 1163, 1165 (2012); David McGowan, Copyright Nonconsequentialism, 69 *Mo. L. Rev.* 1, 1–2 (2004); Alfred C. Yen, The Interdisciplinary Future of Copyright Theory, 10 *Cardozo Arts & Ent. L.J.* 423, 424 (1992).

<sup>217</sup> Friedrich A. Hayek, The Use of Knowledge in Society, 35 *Am. Econ. Rev.* 519, 519–20 (1945).

experimentalism itself may be a promising institutional structure for choosing whether policy randomization or the experimentalist approach of regulated local autonomy is more appropriate for a given issue. Forcing local units to justify their policy choices based on existing evidence may highlight the gaps in our empirical knowledge and may encourage local units to consent to having their policy set randomly where that is the most promising way to make progress. But there are still complex questions of which institutions should be the “centers” of these experimentalist systems. This Part lays out a few considerations for implementation of patent experimentalism in the domestic and international arenas and concludes by suggesting that these institutions could learn from trends in medicine toward a personalized, evidence-based approach.

#### *A. Domestic Institutional Choice*

As noted above, laboratory experiments, district court experiments, and PTO experiments are all already occurring to varying extents. This should be encouraged, especially in ways that are more transparent and reproducible. As Professors Gary King and Eleanor Neff Powell explain, knowledge develops by “iterating between theory development and building empirical evidence,”<sup>218</sup> and researchers should seek “new observable implications of the same theory, collect those data, and see whether they are consistent with the theory.”<sup>219</sup> Laboratory experiments can complement the kinds of evidence described in Part I, including qualitative case studies and econometric studies. Based on this iteration between theory and experiment, scholars should suggest policy changes that seem ready for broader testing<sup>220</sup>—and we should also be clear about the limitations of existing theories and data.<sup>221</sup>

The main challenge for an evidence-based patent regime will be creating variation in substantive innovation policies. I have described two approaches to central promotion of policy variation: field

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<sup>218</sup> King & Powell, *supra* note 56, at 2.

<sup>219</sup> *Id.* at 4.

<sup>220</sup> For example, it seems more likely than not that longer exclusivity or increased funding for drugs requiring long clinical trials would be an improvement. See Budish et al., *supra* note 79, at 1–2.

<sup>221</sup> Cf. Lee Epstein & Gary King, *The Rules of Inference*, 69 U. Chi. L. Rev. 1, 15–17 (2002) (finding that every one of hundreds of law review articles reviewed violated at least one basic rule of inference).

experiments in which specific policies are randomly assigned to local units, and experimentalist regimes in which local units have a voice in setting goals and metrics and discretion in choosing policies to meet these goals. In Parts II and III, I gave examples of when each of these approaches might be promising (including blended examples in which the use of experimentalism itself is randomly assigned). Some of these experiments would initially require acts of Congress, but who should run these experiments and interpret the data?<sup>222</sup>

One possibility is the PTO's Office of the Chief Economist ("OCE"), which was created in March 2010 with research goals including "[u]ncovering how IP relates to economic growth, performance and employment."<sup>223</sup> Alternatively, Professors Stuart Benjamin and Arti Rai have called for a new innovation agency, which could be appropriate for these second-order questions of innovation about innovation policy.<sup>224</sup> Abramowicz, Ayres, and Listokin have argued that the Office of Management and Budget ("OMB") or a new agency should be tasked with running and interpreting the results of all policy experiments.<sup>225</sup> And Professor John McGinnis has suggested that a congressional agency, modeled on the Congressional Budget Office, should recommend experiments to be inserted into new legislation.<sup>226</sup>

These are all plausible options, and the decision raises standard issues of administrative law and institutional choice. But I note here one less obvious consideration: Policy makers should be attentive to evidence on how to design and communicate experiments so that the resulting knowledge has the policy impact it should, rather than being explained away through motivated reasoning by those who do not find it

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<sup>222</sup> This Article focuses on government-driven innovation policy, so the "who" is typically a government actor. It is worth noting, however, that private companies offer diverse innovation incentives to their employees, and that this may be a fertile ground for future empirical study.

<sup>223</sup> Press Release, No. 10-63, U.S. Patent & Trademark Office, USPTO Chief Economist Unveils Agency's New Economic Research Agenda During Conference on Intellectual Property and the Innovation Economy (Dec. 9, 2010), available at [http://www.uspto.gov/news/pr/2010/10\\_63.jsp](http://www.uspto.gov/news/pr/2010/10_63.jsp).

<sup>224</sup> Stuart Minor Benjamin & Arti K. Rai, Fixing Innovation Policy: A Structural Perspective, 77 *Geo. Wash. L. Rev.* 1, 1, 6 (2008).

<sup>225</sup> Abramowicz et al., *supra* note 14, at 982–84. A possible location within the OMB is the Office of Information and Regulatory Affairs ("OIRA"). See generally Cass R. Sunstein, The Office of Information and Regulatory Affairs: Myths and Realities, 126 *Harv. L. Rev.* 1838 (2013) (describing OIRA).

<sup>226</sup> McGinnis, *supra* note 115, at 55.



cognitively congenial. In a separate essay, I argue that patent discourse seems to have a similar pathology to other polarized debates over facts (such as over climate change), with cultural values shaping priors and affecting the weight given to new evidence.<sup>227</sup> Before investing in an expensive randomized experiment, it may be prudent to fund smaller experiments on whether acceptance of new evidence on patents depends on how it is communicated or who is doing the experiments.

From this perspective, the PTO's OCE might be suboptimal as a center for patent experimentation due to the possibility of perceived bias. The OCE's first report did not inquire into how IP relates to growth: It simply quantified the economic contribution (not the IP-specific contribution) of an extremely broad list of "IP-intensive" industries as five trillion dollars.<sup>228</sup> The PTO website advertised this as "IP Contributes \$5 Trillion and 40 Million Jobs to US Economy," leading to praise from pro-patent commentators<sup>229</sup> and criticism from patent reformers.<sup>230</sup> Even if the OCE later authors a report that does quantify the economic contribution of IP, it might do little to lessen the polarization over patents because of the OCE's position within the PTO. An independent agency might thus be preferable for coordinating U.S. experiments with substantive innovation policy.

### *B. International Policy and TRIPS Constraints*

The biggest hurdle to experimentation with substantive patent law is the international TRIPS agreement, which requires WTO members (that is, almost all countries<sup>231</sup>) to make twenty-year patents "available for

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<sup>227</sup> Ouellette, *supra* note 83, at 28; see also Dan M. Kahan, Ellen Peters, Maggie Wittlin, Paul Slovic, Lisa Larrimore Ouellette, Donald Braman & Gregory Mandel, The Polarizing Impact of Science Literacy and Numeracy on Perceived Climate Change Risks, 2 *Nature Climate Change* 732, 732 (2012) (finding that increased science literacy increases polarization over climate change).

<sup>228</sup> Econ. & Statistics Admin. & U.S. Patent & Trademark Office, U.S. Dep't of Commerce, Intellectual Property and the U.S. Economy: Industries in Focus 45 (2012).

<sup>229</sup> See, e.g., Renee C. Quinn, IP Contributes \$5 Trillion and 40 Million Jobs to US Economy, IP Watchdog (Apr. 11, 2012, 6:24 PM), <http://www.ipwatchdog.com/2012/04/11/ip-contributes-5-trillion-and-40-million-jobs-to-us-economy>.

<sup>230</sup> See, e.g., Stephan Kinsella, USPTO/Commerce Dept. Distortions: "IP Contributes \$5 Trillion and 40 Million Jobs to Economy," Ctr. for the Study of Innovative Freedom (Apr. 20, 2012), <http://c4sif.org/2012/04/uspto-commerce-dept-distortions-ip-contributes-5-trillion-and-40-million-jobs-to-economy>.

<sup>231</sup> See Members and Observers, World Trade Org., [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/org6\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm) (last visited July 12, 2013).

any inventions . . . in all fields of technology.”<sup>232</sup> But there is still some room for diversity. TRIPS explicitly recognizes the value of local implementation,<sup>233</sup> and patents are not required for medical methods, “animals other than micro-organisms,” or inventions that do not meet the open-textured requirements of being “new,” involving an “inventive step,” and being “capable of industrial application.”<sup>234</sup> Countries may grant “limited exceptions” to patent rights or, in some cases, compulsory licenses.<sup>235</sup>

Numerous scholars have advocated an expansive interpretation of TRIPS flexibilities,<sup>236</sup> and some countries have been pushing against patent harmonization. For example, India has made use of TRIPS flexibilities in the pharmaceutical sector,<sup>237</sup> and the Indian Supreme Court recently affirmed the high bar for obtaining “evergreening” patents.<sup>238</sup> Similarly, Canada has raised the utility bar for pharmaceutical patents based on the benefit promised in the patent application.<sup>239</sup> The United States or U.S. companies are challenging these decisions,<sup>240</sup> but

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<sup>232</sup> TRIPS, *supra* note 8, arts. 27, 33.

<sup>233</sup> Id. art. 1 (“Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.”).

<sup>234</sup> Id. art. 27.

<sup>235</sup> Id. arts. 30–31; see also World Trade Organization, Declaration on the TRIPS Agreement and Public Health ¶ 5b, Nov. 14, 2001, 41 I.L.M. 755, 755 (2002) (expressly confirming the right of each country to determine exhaustion rules and permit parallel imports).

<sup>236</sup> See, e.g., Dinwoodie & Dreyfuss, *supra* note 25, at 201; Cynthia M. Ho, Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights 223–51 (2011); Kapczynski, *supra* note 8, at 1574; Katherine J. Strandburg, Evolving Innovation Paradigms and the Global Intellectual Property Regime, 41 Conn. L. Rev. 861, 896–97 (2009). Professor Sarah Rajec argues that tailored laws should be evaluated based on their “harm to concerns of certainty, fairness, economy, and public choice.” Sarah R. Wasserman Rajec, Evaluating Flexibility in International Patent Law, 65 Hastings L.J. 153, 208 (2013).

<sup>237</sup> See Ho, *supra* note 236, at 91–124; Kapczynski, *supra* note 8, at 1573–75.

<sup>238</sup> *Novartis AG v. Union of India*, A.I.R. 2013 S.C. 1311, 1367–68 (India) (concluding that a patent on a cancer drug with enhanced stability and bioavailability is invalid under § 3(d) of the Indian Patents Act, which requires enhanced “therapeutic efficacy”).

<sup>239</sup> See *Eli Lilly Can. Inc. v. Novopharm Ltd.* (2010), [2012] 1 F.C.R. 349, para. (76 Can. Fed. Ct. App.) (“Where the specification does not promise a specific result, no particular level of utility is required; a ‘mere scintilla’ of utility will suffice. However, where the specification sets out an explicit ‘promise’, utility will be measured against that promise.”).

<sup>240</sup> See Notice of Intent to Submit a Claim to Arbitration Under NAFTA Chapter Eleven ¶ 55, *Eli Lilly & Co. v. Canada* (Nov. 7, 2012), available at <http://www.international.gc.ca/trade-agreements-accords-commerciaux/assets/pdfs/disp-diff/eli-01.pdf> (challenging Canada’s “promise” doctrine); Demetrios Marantis, Office of the U.S. Trade Representative, Exec.

should instead welcome these innovations because of the potential for policy learning.

While TRIPS allows minor experiments with patent policy as well as experiments with using alternative incentives as *supplements* to the current patent regime (such as conditioning enhanced R&D tax credits on relinquishment of patent protection or agreement to shorter patent terms<sup>241</sup>), more radical patent experimentation would require a TRIPS amendment. As I have argued, there is no good reason to require international coordination on patents but not on other rewards for innovators such as R&D tax credits, grants, or prizes. Of course, I recognize that the political economy of patent reform makes amending TRIPS highly unlikely.<sup>242</sup> An attraction of TRIPS for the United States is that it prevents U.S. consumers from subsidizing technology for the world by ensuring that some of the costs of U.S. R&D are borne by consumers overseas who pay higher prices for U.S.-patented products. But the global IP political landscape is shifting. Many advanced economies—including France, Germany, Spain, and Japan—are now net IP importers.<sup>243</sup> And although the IP-exporting United States has likely been a net beneficiary under TRIPS,<sup>244</sup> this too may be changing. The number of patents granted to foreign inventors has been growing faster than the number of patents granted to U.S. inventors, and since 2008, the PTO has issued more patents to foreigners than to U.S. residents.<sup>245</sup> Perhaps as the United States joins other advanced economies as no

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Office of the President, 2013 Special 301 Report, at 38 (2013), available at <http://www.ustr.gov/sites/default/files/05012013%202013%20Special%20301%20Report.pdf> (“The United States is concerned that the recent decision by India’s Supreme Court with respect to India’s prohibition on patents for certain chemical forms absent a showing of ‘enhanced efficacy’ may have the effect of limiting the patentability of potentially beneficial innovations.”).

<sup>241</sup> See Hemel & Ouellette, *supra* note 2, at 370.

<sup>242</sup> See generally F.M. Scherer, *The Political Economy of Patent Policy Reform in the United States*, 7 J. Telecomm. & High Tech. L. 167, 201–07 (2009) (describing the opposing interests in patent reform debates).

<sup>243</sup> See Keith E. Maskus, *Intellectual Property Rights in the Global Economy* 81 (2000).

<sup>244</sup> See Nat’l Sci. Bd., *1 Science and Engineering Indicators 2008* ch. 6, at 6 (2008) (noting that the United States continues to be a net IP exporter); Keith E. Maskus, *Intellectual Property Rights and Economic Development*, 32 Case W. Res. J. Int’l L. 471, 493 (2000) (estimating that TRIPS would lead to net inflow of \$5.8 billion into the United States per year).

<sup>245</sup> See Dennis Crouch, *Does the Shift in IP Ownership Predict a Political Shift in the IP Debate?*, *Patently-O* (Mar. 11, 2013), <http://www.patentlyo.com/patent/2013/03/does-the-shift-in-ip-ownership-predict-a-political-shift-in-the-ip-debate.html>.

longer being a clear winner under TRIPS, there will be some momentum for reform.

If the WTO or another international organization emerges as the center of global patent experimentalism, it can learn from the European Union's OMC experience. As discussed in Section III.C, by requiring a policy output such as public R&D spending of one percent of GDP, rather than a specific policy input such as twenty-year patents, countries can avoid the problems with externalities in innovation policy while allowing room for experimentation.<sup>246</sup> But at least three improvements should be made if the OMC approach is transferred to the broader international context. (1) Financial incentives should be used to enforce objectives, the way the WTO's threat of trade sanctions has given teeth to the TRIPS regime. (2) Although the OMC has focused on mutual learning with the ultimate goal of *harmonization* of innovation policy, one of the framework goals of international patent experimentalism should be policy variation itself—countries should be rewarded for trying a different policy when the outcome is ambiguous based on existing theory and data. (3) Countries should be encouraged to use their increased autonomy to experiment with incentives in ways that are susceptible to measurement; for example, even if a new incentive is not tested with a randomized trial, it may still be introduced in ways susceptible to counterfactual analysis.<sup>247</sup>

Even if the constraints of TRIPS prove too rigid for significant patent policy variation in the short term, countries can still experiment with non-patent innovation policies. Countries are free to offer different rewards to innovators as *optional* substitutes for patents. And as previously discussed, innovation is also influenced by a host of other laws and institutions beyond these financial rewards, and it may be easier to experiment with these non-patent policies. The difficulties of learning from uniform patent policy should provide a cautionary tale for efforts to increase uniformity in these other innovation policies. For example, variation in the enforceability of noncompete agreements has suggested that they discourage employee mobility and slow economic

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<sup>246</sup> See *supra* notes 198–203 and accompanying text.

<sup>247</sup> See Heidi Williams, *Innovation Inducement Prizes: Connecting Research to Policy*, 31 *J. Pol'y Analysis & Mgmt.* 752, 770 (2012) (describing an ex post counterfactual analysis for a recent trial advance market commitment for a pneumococcal vaccine).

growth,<sup>248</sup> and the possibility of learning more from this and other variations in trade secrecy protection weighs against enacting a federal trade secrets act.<sup>249</sup>

*C. Learning from Personalized, Evidence-Based Medicine*

Finally, I would urge any institution that is implementing a patent experimentalist regime (and the scholars who study such institutions) not only to adopt a pluralistic approach to policy experiments, but also to continue to learn—including from outside the legal field—about how to improve this experimental process. In particular, patent experimentalists might borrow from the medical literature, where researchers face a similar problem of isolating the causal effects of particular treatments in complex systems.

The evidentiary gold standard of randomized controlled trials evolved in the context of medical treatments.<sup>250</sup> But randomized trials of medical treatments are not perfect: They raise the same concerns as those discussed above for randomized policy experiments, in that they reveal only the average treatment effect for the trial group. Randomized controlled trials of medical interventions “often lack external validity,” and regulators have been urged to pay more attention to assessing the generalizability of trial results.<sup>251</sup> And the criticism of focusing on “what works” at the expense of “why” has also been leveled in the medical context.<sup>252</sup>

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<sup>248</sup> Ronald J. Gilson, *The Legal Infrastructure of High Technology Industrial Districts: Silicon Valley, Route 128, and Covenants Not to Compete*, 74 N.Y.U. L. Rev. 575, 578 (1999).

<sup>249</sup> Cf. *Protecting American Trade Secrets and Innovation Act of 2012*, S. 3389, 112th Cong. § 2 (2012) (providing federal jurisdiction for theft of trade secrets).

<sup>250</sup> See Marcia L. Meldrum, *A Brief History of the Randomized Controlled Trial: From Oranges and Lemons to the Gold Standard*, 14 *Hematology/Oncology Clinics N. Am.* 745, 745–46 (2000); see also *Upjohn Co. v. Finch*, 422 F.2d 944, 946 (6th Cir. 1970) (upholding the FDA’s decision to forbid the sale of a drug that did not satisfy its new regulations requiring well-controlled trials); 21 C.F.R. § 314.126 (2012) (laying out FDA requirements for well-controlled studies).

<sup>251</sup> Peter M. Rothwell, *External Validity of Randomised Controlled Trials: “To Whom Do the Results of This Trial Apply?”*, 365 *Lancet* 82, 82 (2005).

<sup>252</sup> See, e.g., Robert B. Nussenblatt et al., *Translational Medicine—Doing It Backwards*, 8 *J. Translational Med.*, Feb. 2010, at 3 (criticizing the “[l]ack of sufficient rigor in conceptualizing clinical studies aimed not only at validation of therapies but also of learning from all results so as to better design subsequent trials.”).

The past few decades have seen trends in medical research toward “personalized medicine,” which focuses on understanding the mechanisms by which different treatments operate so that they can be applied to the right patients at the right time.<sup>253</sup> There has also been evidence that well-designed observational studies can be as effective as randomized trials,<sup>254</sup> coupled with optimism about the role of electronic health records in speeding the “progression of knowledge.”<sup>255</sup> The medical community’s incorporation of diverse sources of evidence to optimize health outcomes for heterogeneous patients may be instructive for patent experimentalists’ efforts to optimize innovation outcomes over heterogeneous jurisdictions and technologies.

Additionally, to focus attention on where the gaps in its knowledge are, it might be useful for an innovation agency (or other center of patent experimentalism) to follow the lead of the evidence-based medicine movement in *grading* the available evidence on different issues.<sup>256</sup> Just as “some questions about therapy do not require randomised trials . . . or cannot wait for the trials to be conducted,”<sup>257</sup> some patent policy decisions need to be made with lower confidence in available evidence. Like experimentalism, evidence-based medicine seeks to blend the best external evidence with the local clinical experience to solve complex problems,<sup>258</sup> and there are probably additional lessons that patent experimentalism—and legal experimentation more generally—could learn from this field.

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<sup>253</sup> See, e.g., Lynda Chin et al., *Cancer Genomics: From Discovery Science to Personalized Medicine*, 17 *Nature Med.* 297, 297 (2011) (stating that “a solid mechanism-based understanding” of how cancer treatments function is necessary for progress); Geoffrey S. Ginsburg & Huntington F. Willard, *Genomic and Personalized Medicine: Foundations and Applications*, 154 *Translational Res.* 277, 286 (2009) (“Personalized medicine seeks to use advances in knowledge about genetic factors and biological mechanisms of disease coupled with unique considerations of an individual’s patient care needs . . . .” (quoting Nomination of Kathleen G. Sebelius: Hearing Before the S. Comm. on Fin., 111th Cong. 190 (2009) (responses to questions for the record by Hon. Kathleen Sebelius))).

<sup>254</sup> See John Concato et al., *Randomized, Controlled Trials, Observational Studies, and the Hierarchy of Research Designs*, 342 *New Eng. J. Med.* 1887, 1890 (2000).

<sup>255</sup> Charles P. Friedman et al., *Achieving a Nationwide Learning Health System*, 2 *Sci. Translational Med.*, Nov. 2010, at 1.

<sup>256</sup> See, e.g., Gordon H. Guyatt et al., *GRADE: An Emerging Consensus on Rating Quality of Evidence and Strength of Recommendations*, 336 *Brit. Med. J.* 924, 924 (2008).

<sup>257</sup> David L. Sackett et al., *Evidence Based Medicine: What It Is and What It Isn’t*, 312 *Brit. Med. J.* 71, 72 (1996).

<sup>258</sup> See *id.* at 71; R. Brian Haynes et al., *Clinical Expertise in the Era of Evidence-Based Medicine and Patient Choice*, 7 *Evidence-Based Med.* 36, 38 (2002).

## CONCLUSION

I make no claim that the approach to promoting innovation in innovation policy laid out above will be easy to achieve. But I think it is valuable to set aside perceived political constraints and ask: “If public-interest-minded scholars had complete freedom to design patent policy, is uniformity really a desirable goal? Would it be possible to learn more from nonuniform patent policy? And if so, what kind of nonuniformity would we want?” This Article has attempted to answer these questions.

I have argued that empirical progress depends critically on policy variation, but also on the *right kind* of policy variation. Because jurisdictions do not internalize either all the benefits of their innovation policies or all the benefits of their *innovations with* innovation policies, and because these spillovers complicate empirical evaluation, complete local autonomy is not the right answer. Rather, policy experiments should be deliberately promoted by central planners. Randomization should be used when choosing between well-defined policy options with measurable outcomes that are expected to be relatively stable, and when the policies can be randomly assigned such that there are minimal spillovers between experimental groups. When these conditions are not met, experimentalism’s regulated local autonomy may be the best way to make progress. In particular, experimentalism is valuable for generating buy-in from local units, for promoting local innovation with policy design, for eliciting local knowledge about the applicability of different policies to heterogeneous conditions, and for generating better measures of whether policies are succeeding in light of local values.

Patents and other innovation laws involve government interference to correct market failures. But the government is not omniscient; patents themselves represent a somewhat Hayekian recognition of the distribution of knowledge, allowing central planners to elicit privately held information about potential innovations.<sup>259</sup> Experimentalism might allow central planners to make a similar move with innovation law itself, eliciting local information about policy improvements. But just as patents are suboptimal when the government *does* have good information about potential R&D projects,<sup>260</sup> regulated local autonomy is not always the best choice for promoting patent policy variation.

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<sup>259</sup> Hayek himself was skeptical that the patent system actually induces innovation. F.A. Hayek, *The Fatal Conceit: The Errors of Socialism* 37 (W.W. Bartley III ed., 1989).

<sup>260</sup> See Hemel & Ouellette, *supra* note 2, at 330.

In 2005, Mark Lemley described the difficulty of optimizing IP protection:

We may not know exactly how to calibrate the right level of intellectual property protection, but we can be reasonably certain that neither “no protection” nor “absolute control over externalities” is the right answer. Hard as it is to get the balance right, we will never do it if we simply stop trying.<sup>261</sup>

Given the ambiguity of the evidence discussed in Part I and the array of non-patent innovation incentives, I do not think we are even certain that “no protection” is not the right answer. (In other words, I think the existing evidence would receive a low “grade” on an evidence-based-medicine-like grading scale.<sup>262</sup>) But I strongly agree that we should not stop trying, which is what we are doing by pushing the world toward a uniform system with ambiguous welfare consequences.

Finally, while this Article has developed a framework for policy experimentation in the innovation context, the pros and cons of different approaches to experimentation that this Article has explored are trans-substantive, so this framework applies to policy learning beyond patents. As I have explained, patent law presents a hard case for experimentation because of measurement difficulties, spillovers, and its impact on multinational actors with long time horizons, but these problems are not unique to patents. And designing useful policy experiments will be even easier in fields that do not have all of these difficulties, and that have not already been pushed so strongly toward uniformity. I doubt there is a legal field without important open empirical questions, so most fields will likely benefit from increased attention to how policy diversity can be promoted in the way that is most conducive to evidence-based learning.

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<sup>261</sup> Lemley, *supra* note 45, at 1067.

<sup>262</sup> See *supra* notes 256–58 and accompanying text (proposing such a scale).