

**THE NEW MODEL OF INTEREST GROUP  
REPRESENTATION IN PATENT LAW**

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**ABSTRACT**

*Traditional public choice theory postulates that interest group representation is primarily responsible for the passage of legislation in a variety of areas. Intellectual property scholars have largely embraced public choice theory as accurately explaining the enactment of intellectual property laws, agreeing both that the general assumptions of the public choice model are met and that specific statutes bear the scars of the interest group negotiation process. This Article contends that the reality of legislative enactment in patent law diverges from this conventional wisdom. Drawing on three case studies—the Federal Courts Improvement Act of 1982, the Bayh-Dole Act, and the Hatch-Waxman Act—this Article argues that in actuality, legislative enactments in patent law occur along a spectrum of interest group representation. In this space, laws are often passed where the relevant interest groups are unorganized or even nonexistent. This Article goes on to inductively establish a set of factors that both seek to explain these cases and to distinguish them from copyright statutes, which often adhere quite closely to traditional public choice predictions. Having suggested several factors and identified ways in which they provide testable hypotheses, the Article ultimately considers the implications of the analysis both for those wishing to enact statutes that would alter patent rights and for scholars of public choice theory and intellectual property.*

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## INTRODUCTION

The various fields of intellectual property (IP) law have been marked by seemingly ever-increasing levels of protection. The first United States Copyright Act, passed in 1790, conferred an initial protection term of fourteen years, with the potential for a fourteen-year extension where certain conditions were met.<sup>1</sup> Over time, this protection grew sequentially to an initial twenty-eight year period subject to a fourteen-year renewal period,<sup>2</sup> a twenty-eight-year period subject to a twenty-eight year renewal period,<sup>3</sup> life of the author plus fifty years,<sup>4</sup> and most recently, life of the author plus seventy years.<sup>5</sup> Such increases in protection terms have also taken place in patent law, although the increases there have been much less frequent and dramatic. The 1790 Patent Act provided for patent rights “for any term not exceeding fourteen years,”<sup>6</sup> which was subsequently extended to seventeen years from the date of patent issuance<sup>7</sup> and then to twenty

<sup>1</sup> Copyright Act of 1790, ch. 15, § 1, 1 Stat. 124, 124 (1790).

<sup>2</sup> Copyright Act of Feb. 3, 1831, ch. 16, §§ 1, 16, 4 Stat. 436, 439 (1831).

<sup>3</sup> Copyright Act of Mar. 4, 1909, ch. 320, §§ 23–24, 35 Stat. 1080–1081 (1909).

<sup>4</sup> Copyright Act of 1976, Pub. L. 94-553, § 302(a), (c), 90 Stat. 2541, 2572 (1976).

<sup>5</sup> 17 U.S.C. § 302(a) (2012).

<sup>6</sup> Patent Act of 1790, ch. 7, § 1, 1 Stat. 109 (1790).

<sup>7</sup> Patent Act of Mar. 2, 1861, ch. 88, § 16, 12 Stat. 246, 249 (1861).

years from the date of filing.<sup>8</sup> Yet it is not simply the duration of intellectual property protection which has been extended. Legislation has strengthened substantive rights, weakened affirmative defenses, and broadened the reach of remedies.

On balance, such legislation is likely good for much of the regulated industry. However, increasingly, such legislation may be bad for consumers, particularly where follow-on development of artistic and scientific works is needed or desired. The copyright statute denies follow-on creators a copyright in any work unlawfully using preexisting material,<sup>9</sup> and while patent law permits follow-on inventors to patent their improvements, the follow-on inventor cannot practice their invention without first obtaining a license from the original patentee (creating a “blocking patent” situation).<sup>10</sup> Whether the need for and lack of such innovation present a problem worthy of intervention depends on the particular technological context, but in general the continued expansion of IP protections should give observers pause. IP rights, by design, impose short-term costs on consumers for the sake of incentivizing future innovation. But if the incremental social loss from granting a particular entitlement to holders of copyrights or patents exceeds the incremental reward they can reap, that entitlement should not be granted.<sup>11</sup>

Yet consumers thus far seem relatively powerless<sup>12</sup> to prevent the congressional enactment of various protectionist measures in intellectual property. Scholars, particularly in their examinations of copyright statutes, have ascribed this result to the stranglehold the relevant interest groups have over the legislative process, arguing that IP legislation is a classic example of public choice theory in action.<sup>13</sup> Further, they observe that protectionist measures in this area exhibit a “one-way ratchet” quality.<sup>14</sup> That is, the

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<sup>8</sup> 35 U.S.C. § 154(a)(2) (2012). A more detailed account can be found in Tyler T. Ochoa, *Patent and Copyright Term Extension and the Constitution: A Historical Perspective*, 49 J. COPYRIGHT SOC’Y U.S.A. 19 (2001). Of course, this change only extends patent duration for patents whose pendency is less than three years.

<sup>9</sup> 17 U.S.C. § 103(a) (2012) (“[P]rotection for a work employing preexisting material in which copyright subsists does not extend to any part of the work in which such material has been used unlawfully.”).

<sup>10</sup> Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 TEX. L. REV. 989, 1009–10 (1997).

<sup>11</sup> See, e.g., Louis Kaplow, *The Patent-Antitrust Intersection: A Reappraisal*, 97 HARV. L. REV. 1813, 1829–30 (1984).

<sup>12</sup> For one notable recent counterexample, see *infra* note 56 and accompanying text.

<sup>13</sup> See *infra* note 51.

<sup>14</sup> See Yochai Benkler, *Through the Looking Glass: Alice and the Constitutional Foundations of the Public Domain*, LAW & CONTEMP. PROBS., Winter/Spring 2003, at 173, 197.

protections provided in these statutes, once enacted, cannot feasibly be weakened through legislative means.<sup>15</sup> Where prospects for legislative change are bleak, opponents of increasingly restrictive intellectual property laws may turn to voluntary private ordering schemes like Creative Commons or patent pools, but these by necessity will have a smaller absolute effect than would the repeal of protectionist legislation.

But what if the conventional wisdom is wrong? What if public choice theory can only explain the continued passage of increasingly protective IP legislation in the copyright area, but it lacks applicability in the context of patents? In some ways, the resulting picture would appear even worse for would-be patent reformers, as the prospect that protectionist statutes are being enacted even without the vigorous support of the regulated industry might seem to pose an even greater hurdle to legislative action in the opposite direction. But in other ways, such a challenge to the conventional wisdom would suggest that there exist open avenues for legislative involvement where none were previously thought to exist. If there is room for motivated consumer groups to actually impact the legislative process, patent reformers might be able to achieve their goals through legislation after all. Indeed, they might even be able to overcome the one-way ratchet problem.

This Article proceeds in four parts. Part I provides background on public choice theory, paying specific attention to the interest group branch of the theory and the ways in which it has been applied to explain legislation in the intellectual property arena. Part I concludes that, despite some work to the contrary, public choice theory remains the accepted descriptive explanation for the enactment of intellectual property legislation of all kinds, including patent law. Part II then considers three case studies: the Federal Courts Improvement Act of 1982, the Bayh-Dole Act, and the Hatch-Waxman Act. This Part seeks to rebut the conventional wisdom in this area, demonstrating that although standard public choice theory does provide rational explanations for the enactment of each of these statutes, the factual history surrounding their enactment does not support the theoretical account. That is, the traditional version of public choice theory does not necessarily hold in the patent context.

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<sup>15</sup> See, e.g., Jessica Litman, *War Stories*, 20 CARDOZO ARTS & ENT. L.J. 337, 344 (2002) (“Recently, copyright legislation has seemed to be a one-way ratchet, increasing the subject matter, scope, and duration of copyright with every amendment.”); Rebecca Tushnet, *Copy This Essay: How Fair Use Doctrine Harms Free Speech and How Copying Serves It*, 114 YALE L.J. 535, 543 (2004) (“Legally, then, copyright has been a one-way ratchet, covering more works and granting more rights for a longer time.”).

Yet the goal of this paper is not so much to discredit the conventional approach as it is to refine the standard public choice analytic in light of the variables observed in the three case studies and to sketch the outlines of a taxonomy of interest group representation that might be useful in other areas of law. Part III thus considers the descriptive accounts of legislation presented in Part II and begins to establish inductively a set of factors that seek both to explain these cases and to distinguish them from statutes enacted in the copyright context, in which a more extreme version of public choice theory operates. Having identified a number of factors and examined ways in which they might provide testable hypotheses, Part III considers the implications of the preceding argument for scholars as well as for activists who seek to enact patent reform proposals of various types. Part IV concludes.

## I. PUBLIC CHOICE THEORY AND ITS APPLICATION TO INTELLECTUAL PROPERTY

This Part first provides a brief overview of public choice theory, specifically focusing on the branch of public choice theory referred to as interest group theory and its relationship to the causes and sources of legislative enactments. This Part will then go on to consider the ways in which the existing intellectual property literature has applied public choice theory to explain congressional action in the intellectual property area.

### A. *Public Choice Theory and the Causes of Legislation*

The central thesis of public choice theory as it regards the enactment of legislation can be stated quite simply: “statute[s] represent private rather than public interests, because of the undue influence of special interest groups.”<sup>16</sup> Starting from the proposition that “legislation is a good demanded and supplied much as other goods, so that legislative protection flows to those groups that derive the greatest value from it, regardless of overall social welfare,”<sup>17</sup> public choice theory endeavors to provide a descriptive explanation of both how and when such interest groups are able to control the political process. Public choice theory is therefore formally agnostic about whether such interest group control is “good” or “bad,” from

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<sup>16</sup> DANIEL A. FARBER & PHILIP P. FRICKEY, *LAW AND PUBLIC CHOICE: A CRITICAL INTRODUCTION* 1 (1991).

<sup>17</sup> Richard A. Posner, *Economics, Politics, and the Reading of Statutes and the Constitution*, 49 U. CHI. L. REV. 263, 265 (1982).

a normative perspective,<sup>18</sup> although admittedly “[m]uch of the literature on interest groups conveys a strong flavor of disapproval.”<sup>19</sup>

The theory of collective action as articulated by Professor Mancur Olson provides the logical linchpin for the explanation of interest group power. Olson’s argument is as follows: Because the general benefits of legislative action (such as the enactment of statutes building interstate highways) redound to the general population, any one person’s attempt to influence such legislative action will typically have a minute effect. Where the benefits of legislative action are diffuse in this way, economically rational individuals can be expected to “free ride” on the activist efforts of others. Due to this free rider problem, individuals benefiting from these broadly diffused public goods will have great difficulty identifying each other and coming together to advocate for such legislation. However, a small, identifiable group with a concentrated, defined interest will face no such difficulties coming together. Thus, legislative activity will be dominated by comparatively small interest groups with members who would reap a disproportionate share of any legislated benefit, while the costs of such legislation are dispersed far more widely.<sup>20</sup> These small groups may therefore levy far greater political power than the “large groups . . . normally supposed to prevail in a democracy.”<sup>21</sup>

This branch of public choice theory may have implications beyond the enactment of legislation. For instance, influential scholars and judges have argued that public choice theory justifies stricter judicial review of statutes that result from interest-group pressure.<sup>22</sup> Relatedly, Professor William Eskridge and others have argued that where a given statute displays

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<sup>18</sup> Robert D. Tollison, *Public Choice and Legislation*, 74 VA. L. REV. 339, 339 (1988).

<sup>19</sup> FARBER & FRICKEY, *supra* note 16, at 33.

<sup>20</sup> See MANCUR OLSON, JR., *THE LOGIC OF COLLECTIVE ACTION: PUBLIC GOODS AND THE THEORY OF GROUPS* 128 (1965); see also JAMES M. BUCHANAN & GORDON TULLOCK, *THE CALCULUS OF CONSENT* 292 (1965) (“[A]ctivities may be approved which cause benefits to accrue to selected individuals and groups but which impose costs generally on all members of the community.”); Posner, *supra* note 17, at 266 (“[T]he literature concludes that effective interest groups are usually small and directed toward a single issue. The benefits of a redistribution in their favor are concentrated, the costs of organizing the group are small, and the costs of the redistribution are so widely diffused that nobody has much incentive to oppose it.”).

<sup>21</sup> OLSON, *supra* note 20, at 128.

<sup>22</sup> See, e.g., Frank H. Easterbrook, *The Supreme Court, 1983 Term—Foreword: The Court and the Economic System*, 98 HARV. L. REV. 4, 51–54 (1984) (presenting a form of review grounded in antitrust law for relevant statutes); Cass R. Sunstein, *Interest Groups in American Public Law*, 38 STAN. L. REV. 29, 69 (1985) (proposing “strengthened rationality review” in order to “ensure that representatives have exercised some form of judgment instead of responding mechanically to interest-group pressures”).

the classic public choice theory pattern—where its benefits are concentrated among a small group but its costs are diffused over a wide population—judges ought to interpret the statute narrowly and “refuse to provide special benefits unless clearly required by statute.”<sup>23</sup> Professor Einer Elhauge has rejected both such arguments, however, concluding that “interest group theory provides no persuasive grounds to alter whatever conclusions one would otherwise reach about judicial lawmaking authority.”<sup>24</sup> Public choice theory has also been applied to agency behavior, with “agency capture” serving as another application of the theory.<sup>25</sup>

Of course, the “strong” version of public choice theory, in which all statutes are justified on pure interest group grounds,<sup>26</sup> has rightfully been subject to challenge. Judge Abner Mikva, recalling his five terms in the Illinois state legislature and additional five terms in the United States House of Representatives,<sup>27</sup> argued that “the motivations of politicians are far too mixed to be understood through the generalizations” made by public choice theory.<sup>28</sup> Empirical research has borne this out, noting that other factors like “ideology—beliefs about the public interest—do[] indeed influence congressional votes.”<sup>29</sup> Public choice theory also fails to account for

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<sup>23</sup> William N. Eskridge, Jr., *Politics Without Romance: Implications of Public Choice Theory for Statutory Interpretation*, 74 VA. L. REV. 275, 299 tbl.2 (1988); see also Cass R. Sunstein, *Interpreting Statutes in the Regulatory State*, 103 HARV. L. REV. 405, 471 (1989) (suggesting the requirement of a “clear statement before courts will construe statutes as amounting to naked wealth transfers”).

<sup>24</sup> Einer R. Elhauge, *Does Interest Group Theory Justify More Intrusive Judicial Review?*, 101 YALE L.J. 31, 48 (1991).

<sup>25</sup> See, e.g., Michael J. Burstein, *Rules for Patents*, 52 WM. & MARY L. REV. 1747, 1795–96 (2011) (“[T]he regulated interests are concentrated and able to bring significant resources to bear to ensure that the policies the regulator enacts suit their interests. Countervailing forces, meanwhile, tend to be diffuse and less able to exert significant influence. The result is that agency policy systemically tilts toward the interests of the regulated entities.”).

<sup>26</sup> FARBER & FRICKEY, *supra* note 16, at 7.

<sup>27</sup> Abner J. Mikva, *Foreword: Symposium on the Theory of Public Choice*, 74 VA. L. REV. 167, 167 (1988).

<sup>28</sup> *Id.* at 169; see also FARBER & FRICKEY, *supra* note 16, at 2 (describing Judge Mikva’s Foreword and noting that “not even five terms in that notorious den of iniquity, the Illinois state legislature, had prepared [Mikva] for the political villainy depicted in the public choice literature”); RICHARD FENNO, *CONGRESSMEN IN COMMITTEES* 1 (1973) (articulating the three basic goals of a legislator: achieving reelection, gaining power in their house of Congress, and enacting good laws).

<sup>29</sup> FARBER & FRICKEY, *supra* note 16, at 7; Elhauge, *supra* note 24, at 43 (“These scholars convincingly demonstrate that noneconomic factors such as altruism and ideology play at least some role in political participation and decisionmaking”); Arti K. Rai, *Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform*, 103 COLUM. L. REV. 1035, 1067 (2003) (“[I]deology, as well as a desire to advance the public interest, no

precisely *how* these interest groups are supposed to control legislators, given the well-known problems articulated in the literature on principal-agent theory.<sup>30</sup> And perhaps most glaringly, the strong version of the interest group theory fails to explain the existence of “economy-wide legislation” that imparts diffuse benefits to all citizens.<sup>31</sup> Thus, it must be true that interest group theory “cannot offer a complete theory of regulation.”<sup>32</sup>

Yet even given these critiques of the theory, public choice theory retains great descriptive power in explaining wide swathes of existing legislation. The now-seminal study by Kay Schlozman and John Tierney, even while admitting that “the government is not some anemometer measuring the force of the prevailing organized interest breezes,”<sup>33</sup> found that the effect of interest group pressure on Congress could “range from insignificant to determinative,” depending on “the configuration of a large number of factors—among them the nature of the issue, the nature of the demand, the structure of political competition, and the distribution of resources.”<sup>34</sup> For instance, interest group influence is likely to be quite strong where “the group’s goals are narrow and have low visibility.”<sup>35</sup> Similarly, where legislation is “applicable to a particular industry,” interest group theory likely has comparatively greater explanatory power.<sup>36</sup> Ultimately, the “best picture of the political process” is one in which “constituent interest, special interest groups, and ideology all influence legislative conduct,” and the relative weights of these factors in a given situation determine the level of interest group influence.<sup>37</sup>

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doubt influences the actions of many political actors.”). *But see* OLSON, *supra* note 20, at 162 (“There is to be sure always *some* ideologically oriented behavior in any society . . . . Yet it is striking how relatively minor the ideological sacrifices for the political parties in the United States are.”).

<sup>30</sup> See FARBER & FRICKEY, *supra* note 16, at 27; *see also* Joseph P. Kalt & Mark A. Zupan, *Capture and Ideology in the Economic Theory of Politics*, 74 AM. ECON. REV. 279, 282–84 (1984).

<sup>31</sup> Posner, *supra* note 17, at 272; *see* Elhauge, *supra* note 24, at 43 (“[T]he preferences of regulators and the general public sometimes prevail over the preferences of interest groups.”).

<sup>32</sup> Elhauge, *supra* note 24, at 43.

<sup>33</sup> KAY LEHMAN SCHLOZMAN & JOHN T. TIERNEY, ORGANIZED INTERESTS AND AMERICAN DEMOCRACY 402 (1986).

<sup>34</sup> *Id.* at 317.

<sup>35</sup> FARBER & FRICKEY, *supra* note 16, at 19.

<sup>36</sup> Posner, *supra* note 17, at 271.

<sup>37</sup> Daniel A. Farber & Philip P. Frickey, *The Jurisprudence of Public Choice*, 65 TEX. L. REV. 873, 900–01 (1987); *see also* FARBER & FRICKEY, *supra* note 16, at 33 (arguing that a theory postulating “(1) that reelection is an important motive of legislators, (2) that constituent and contributor interests thereby influence legislators, and (3) that small, easily



***B. Existing Scholarship Applying Public Choice Theory to Intellectual Property***

As an initial matter, scholars generally agree that the conditions of public choice theory are met in the intellectual property context. Specifically, the benefits of IP-strengthening legislation<sup>38</sup> are typically concentrated in a few interest groups or stakeholders with the greatest motivation to act, while the costs of the legislation are diffused both over a given population and often over multiple generations.<sup>39</sup> Thus there is, in general, a “systematic imbalance in favor of the expansion and deepening of exclusive rights to information at the expense of the public domain”<sup>40</sup> of the type likely to give rise to interest group-driven legislation. At least some scholars believe that, due to this imbalance, the rights provided by existing legislation will be excessive from a social welfare perspective.<sup>41</sup>

Several scholars have focused specifically on the enactment of individual intellectual property laws, identifying the relevant interest groups and explaining their involvement in lobbying, drafting, and enacting statutes. The majority of this scholarship has focused on copyright statutes. Professor Jessica Litman’s work on the 1976 Copyright Act as a

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organized interest groups have an influence disproportionate to the size of their membership” is “far more supportable than the strong version”); Elhauge, *supra* note 24, at 43; Rai, *supra* note 29, at 1067–68.

<sup>38</sup> Of course, in the patent context, much of the expansion of rights can be more directly traced to the Federal Circuit. Yet because the Federal Circuit itself is the product of a statute—a statute explicitly designed to increase the protections provided to patentees—legislative enactments remain a critical focus of study.

<sup>39</sup> See WILLIAM M. LANDES & RICHARD A. POSNER, *THE POLITICAL ECONOMY OF INTELLECTUAL PROPERTY LAW* 14 (2004) (noting the “inherent asymmetry between the value that creators of intellectual property place on having property rights and the value that would-be copiers place on the freedom to copy without having to obtain a license”); Benkler, *supra* note 14, at 196 (“[T]he benefits of such rights are clearly seen by, and expressed by, well-defined interest holders that exist at the time the legislation is passed. In contrast, most of the social costs—which are economic, social, political, and moral—are diffuse and likely to be experienced in the future by parties not yet aware of the fact that they will be affected by the extension of rights.”); Robert P. Merges, *One Hundred Years of Solicitude: Intellectual Property Law, 1900–2000*, 88 CAL. L. REV. 2187, 2236 (2000).

<sup>40</sup> Benkler, *supra* note 14, at 196.

<sup>41</sup> See *id.* at 198 (“[T]he political economy of legislation is such that the legislature will systematically tend to create exclusive rights beyond what is economically efficient, as well as beyond what gives proper consideration to the implications of these rights for democracy and autonomy.”); see also Glynn S. Lunney, Jr., *The Death of Copyright: Digital Technology, Private Copying, and the Digital Millennium Copyright Act*, 87 VA. L. REV. 813, 871 (2001) (“Copyright today goes much further than the public interest requires . . .”).

demonstration of the “process of drafting copyright statutes through negotiations among industry representatives”<sup>42</sup> is by now canonical. In fact, the involvement of interest groups in the 1976 statute may even go beyond most forms of involvement in the legislative process postulated by public choice theorists. As Litman notes, “most of the statutory language was not drafted by members of Congress or their staffs at all. Instead, the language evolved through a process of negotiation among authors, publishers, and other parties with economic interests in the property rights the statute defines.”<sup>43</sup> Litman has told a similar story in the context of the more recent 1998 enactment of the Digital Millennium Copyright Act (DMCA).<sup>44</sup> Professor Robert Merges has emphasized the interest group lobbying behind the Sonny Bono Copyright Term Extension Act of 1998, noting the “absence of effective lobbying against the Act.”<sup>45</sup> Justice Stephen Breyer, dissenting in *Golan v. Holder*,<sup>46</sup> similarly noted that in enacting § 514 of the Uruguay Round Agreements Act, which restored the United States copyrights in millions of preexisting works formerly in the public domain, “Congress, with one minor exception, heard testimony only from the representatives of existing copyright holders.”<sup>47</sup>

Many scholars have made similar arguments in the patent arena.<sup>48</sup> They argue that, according to “public choice theory . . . each new

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<sup>42</sup> Jessica D. Litman, *Copyright Legislation and Technological Change*, 68 OR. L. REV. 275, 282 (1989) [hereinafter Litman, *Technological Change*]; see generally *id.*; Jessica D. Litman, *Copyright, Compromise, and Legislative History*, 72 CORNELL L. REV. 857 (1987) [hereinafter Litman, *Legislative History*].

<sup>43</sup> Litman, *Legislative History*, *supra* note 42, at 860–61; see also Lunney, *supra* note 41, at 898 (“Ordinary consumers seldom play any direct role in the extended (and often private) negotiating sessions required to craft such compromises. The consumer interest is represented only indirectly in these sessions, when it happens to coincide with the interest of one of the participants. Such coincidences are rare.”); William F. Patry, *Copyright and the Legislative Process: A Personal Perspective*, 14 CARDOZO ARTS & ENT. L.J. 139, 141 (1996) (“In my experience, some copyright lawyers and lobbyists actually resent members of Congress and staff interfering with what they view as their legislation and their committee report.”).

<sup>44</sup> JESSICA LITMAN, DIGITAL COPYRIGHT 144–45 (2001) (“There is no overarching vision of the public interest animating the Digital Millennium Copyright Act. None. Instead, what we have is what a variety of different private parties were able to extract from each other in the course of an incredibly complicated four-year multiparty negotiation.”); see also Christina Bohannon, *Reclaiming Copyright*, 23 CARDOZO ARTS & ENT. L.J. 567, 590–602 (2006).

<sup>45</sup> Merges, *supra* note 39, at 2236–37.

<sup>46</sup> 132 S. Ct. 873 (2012).

<sup>47</sup> *Id.* at 907 (Breyer, J., dissenting).

<sup>48</sup> See, e.g., Andrew P. Morriss & Craig Allen Nard, *Institutional Choice & Interest Groups in the Development of American Patent Law: 1790–1865*, 19 SUP. CT. ECON. REV. 143,

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amendment to the patent statute represents an opportunity for counterproductive special interest lobbying,<sup>49</sup> and that “a lack of general familiarity with the specialized issues raised by patent law may intensify the room for capture by special interest groups.”<sup>50</sup> Still other scholars speak of public choice theory in the context of intellectual property statutes more broadly, suggesting that they may view copyright and patent law as similar in this regard, embracing public choice theory as providing an accurate descriptive explanation for the congressional enactment of IP laws.<sup>51</sup>

Not all scholars agree that the traditional public choice theory account holds today. Professor Amy Kapczynski has described an “emerging countermobilization”<sup>52</sup> to the strengthening of IP rights. In her view, even in its presently nascent form, this countermobilization has already had “a significant impact on IP law.”<sup>53</sup> She provides as examples the “successes of the access-to-medicines campaign in obtaining an amendment to TRIPS<sup>54</sup> and bringing down the prices of HIV/AIDS medicines; the success of free-software programmers in preventing the codification of software patents in Europe; and the expansive growth of the private ordering schemes introduced by proponents of free software and the

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145 (2011) (“Using public choice theory, we argue that patent law is best understood by focusing on the choice of institutions made by interest groups in their efforts to alter the law.”).

<sup>49</sup> Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1637 (2003).

<sup>50</sup> Liza Vertinsky, *Comparing Alternative Institutional Paths to Patent Reform*, 61 ALA. L. REV. 501, 526 (2010).

<sup>51</sup> See, e.g., Amy Kapczynski, *The Access to Knowledge Mobilization and the New Politics of Intellectual Property*, 117 YALE L.J. 804, 820 (2008) (“The most widely accepted explanation for [the strengthening of IP since the mid-1970s] is derived from public choice theory.”); Mark A. Lemley, *The Constitutionalization of Technology Law*, 15 BERKELEY TECH. L.J. 529, 532 (2000) (“Congress in recent years seems to have abdicated its role in setting intellectual property policy to the private interests who appear before it.”); Robert P. Merges, *Intellectual Property Rights and the New Institutional Economics*, 53 VAND. L. REV. 1857, 1875 (2000) (noting the “broad consensus that industry groups have unusually broad input into the drafting of IPR-related legislation”); Gideon Parchomovsky & Philip J. Weiser, *Beyond Fair Use*, 96 CORNELL L. REV. 91, 112–13 (2010) (“[P]ublic choice theory explains how and why agencies set up to regulate a certain industry or economic sector will sometimes act to advance the narrow interests of the regulated industry or sector. This problem is omnipresent, and there are reasons to believe that it is especially acute in the intellectual property context.” (footnote omitted)).

<sup>52</sup> Kapczynski, *supra* note 51, at 820.

<sup>53</sup> *Id.* at 836.

<sup>54</sup> TRIPS, the Trade-Related Aspects of Intellectual Property Rights Agreement, is a WTO treaty providing minimum IP standards across a wide range of subject matters for the nations that are WTO members.

Creative Commons.”<sup>55</sup> Kapczynski’s arguments seem even more powerful in light of more recent developments, such as the consumer movements that succeeded in halting the progression of the Stop Online Piracy Act (SOPA) and the Protect IP Act (PIPA) through Congress in early 2012.<sup>56</sup>

Yet for every consumer movement that eventually succeeds in preventing the enactment of more restrictive IP laws, there are opposing examples of swift interest group action to halt proposed reform efforts.<sup>57</sup> The story in late 2012 of the Republican Study Committee’s (RSC) memo, *Three Myths About Copyright Law and Where to Start to Fix It*,<sup>58</sup> is one example. The memo, written by then-RSC staffer Derek Khanna, argued that the current copyright law “destroys entire markets”<sup>59</sup> in many ways, including by “[h]ampering scientific inquiry,” “[s]tiffling the creation of a public library,” “[d]iscouraging added-value industries,” and “[p]enaliz[ing] legitimate journalism and oversight.”<sup>60</sup> The memo advocated a number of policy solutions to these identified problems, including reforming copyright’s existing statutory damages regime,<sup>61</sup> expanding the fair use defense,<sup>62</sup> and even limiting copyright terms.<sup>63</sup> Within hours of posting the memo to its website, however, the RSC pulled the document, and news outlets soon reported that industry lobbyists were responsible for the flip-flop.<sup>64</sup> Khanna was subsequently fired.<sup>65</sup>

<sup>55</sup> Kapczynski, *supra* note 51, at 836.

<sup>56</sup> Yochai Benkler, *Seven Lessons from SOPA/PIPA/Megaupload and Four Proposals on Where We Go from Here*, TECHPRESIDENT (Jan. 25, 2012), <http://techpresident.com/news/21680/seven-lessons-sopapipamegaupload-and-four-proposals-where-we-go-here>. Of course, the movement was surely familiar to the scholars who argued against the “White Paper” in the mid-1990s. See William W. Fisher III, *The Growth of Intellectual Property: A History of the Ownership of Ideas in the United States* 24–25, <http://cyber.law.harvard.edu/people/ffisher/iphistory.pdf>.

<sup>57</sup> Cf. Peter S. Menell, *The Challenges of Reforming Intellectual Property Protection for Computer Software*, 94 COLUM. L. REV. 2644, 2651 (1994) (“Intellectual property reform is particularly dominated by interest group politics.”).

<sup>58</sup> Derek S. Khanna, *Three Myths About Copyright Law and Where to Start to Fix It*, REPUBLICAN STUDY COMM. (Nov. 16, 2012), <http://www.scribd.com/doc/113633834/Republican-Study-Committee-Intellectual-Property-Brief>.

<sup>59</sup> *Id.* at 9 (emphasis omitted).

<sup>60</sup> *Id.* at 4–6.

<sup>61</sup> The statutory damages regime is codified at 17 U.S.C. § 504(c) (2012).

<sup>62</sup> The existing fair use defense is codified at 17 U.S.C. § 107 (2012).

<sup>63</sup> See Khanna, *supra* note 58 at 7–8.

<sup>64</sup> See, e.g., Timothy B. Lee, *Influential GOP Group Releases, Pulls Shockingly Sensible Copyright Memo*, ARSTECHNICA (Nov. 18, 2012, 2:00 PM), <http://arstechnica.com/tech-policy/2012/11/influential-gop-group-releases-shockingly-sensible-copyright-memo>; Mike Masnick, *That Was Fast: Hollywood Already Browbeat the Republicans into Retracting*

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Further, none of Kapczynski's examples as articulated above are precisely targeted to the situation presented here: legislative *enactments* in the IP space.<sup>66</sup> It is certainly possible that consumer groups are gaining in their ability to *prevent* the enactment of interest group legislation, or to establish private ordering schemes like Creative Commons to mitigate the worst consequences of IP-protectionist legislation. But the field of intellectual property has not yet witnessed a serious, sustained effort to pass legislation that would walk back various intellectual property protections, whether it would do so by weakening substantive rights, by strengthening affirmative defenses, or by limiting remedies for infringement. Many scholars have expressed skepticism that we will ever see such an effort.<sup>67</sup> As such, the prevailing wisdom in the IP space remains very much a story of interest group control over the legislative process.<sup>68</sup>

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*Report on Copyright Reform*, TECHDIRT (Nov. 17, 2012, 4:59 PM), <http://www.techdirt.com/articles/20121117/16492521084/hollywood-lobbyists-have-busy-saturday-convince-gop-to-retract-copyright-reform-brief.shtml>.

<sup>65</sup> Timothy B. Lee, *Staffer Axed by Republican Group over Retracted Copyright-Reform Memo*, ARSTECHNICA (Dec. 6, 2012, 11:15 AM), <http://arstechnica.com/tech-policy/2012/12/staffer-axed-by-republican-group-over-retracted-copyright-reform-memo>.

<sup>66</sup> For example, the discussed Amendment to the TRIPS Agreement was intended to broaden developing countries' abilities to employ compulsory licenses for pharmaceuticals, but many developing countries have signed free-trade agreements (FTAs) with the United States in which they bargain away their ability to take advantage of this Amendment. Too often, even when countries manage to issue compulsory licenses, they experience some form of retaliation from the pharmaceutical industry. *See, e.g.*, Anthony D. So & Rachel Sachs, *Making Intellectual Property Work for Global Health*, 53 HARV. INT'L L.J. ONLINE 106, 113 (2012) ("Abbott retaliated to Thailand's compulsory license on its drug lopinavir/ritonavir . . . by withdrawing seven pending applications for registration of new medicines from the Thai Food and Drug Administration. These withdrawals effectively withheld these seven drugs, which temporarily included the heat-stable version of Kaletra, from the Thai market.").

<sup>67</sup> *See* Benkler, *supra* note 14, at 196 ("[I]t is never the case that the diffuse and future users will band together to expand fair use. Even if they were to band together, it is impossible that copyright owners would remain unaware of the initiative and fail to offer substantial opposition in the legislative process.").

<sup>68</sup> As in the more general literature regarding public choice theory, scholars have discussed the potential extensions of these arguments into related fields, such as agency capture. *See, e.g.*, Parchomovsky & Weiser, *supra* note 51, at 113 (2010) ("[T]he content industry exercises enormous influence over the legislative process, leading Congress to pass unbalanced legislation that favors the interests of the content industry over that of the public at large. There is no reason to believe that the content industry will not similarly influence an administrative body established to regulate it." (footnote omitted)); *see also* Rai, *supra* note 29, at 1066–67 (describing various channels through which interest groups might seek to influence regulators).

The next Part of this Article will challenge the veracity of this conventional wisdom as it pertains to statutes passed in the patent law space, arguing that not only do the postulates of public choice theory not always apply to enacted legislation in that area, but also that there is a spectrum or taxonomy of organizational relationships that may operate instead.

## II. A TAXONOMY OF INTEREST GROUP REPRESENTATION

This Part will consider three case studies in the field of patent legislation—the Federal Courts Improvement Act of 1982,<sup>69</sup> the Bayh-Dole Act of 1980,<sup>70</sup> and the Hatch-Waxman Act of 1984<sup>71</sup>—in order to examine the veracity of the conventional wisdom regarding public choice theory’s descriptive power in the patent law context. Within each case, this Part will provide a brief historical overview of the enactment of the statute and, in the course of doing so, will focus primarily on identifying the relevant interest group or groups and the role (if any) they played in the enactment of the statute.

The analysis in this Part seeks to establish two main claims. First, public choice theory is inadequate as a descriptive explanation for several important statutes in patent law. Among these three cases, only the history behind the Hatch-Waxman Act resembles the circumstances predicted by public choice theory, and even in that case there are complicating factors regarding interest group alignment. Second, not only is public choice theory inadequate as a descriptive explanation of such legislation, but further, the character of legislative enactments is far from binary (in other words, far from a situation where public choice theory either explains the behavior or it does not). That is, there is a spectrum or taxonomy of potential relationships between interest groups and the government, and sometimes even between opposing interest groups. Statutory histories may thus be most appropriately viewed as reflecting more or fewer public choice theory elements, rather than simply fitting within the mold of the theory or not. These additional insights help inform the standard public choice theory analytic.

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<sup>69</sup> Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25 (codified in scattered sections of 2, 5, 7, 10, 15, 16, 18, 19, 22, 26, 28, 30, 31, 35, 40, 41, 42, 44, & 50 U.S.C.).

<sup>70</sup> Patent and Trademark Law Amendments Act, 35 U.S.C. §§ 200–12 (2012).

<sup>71</sup> Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified in scattered sections of 21, 15, & 35 U.S.C.).

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As this Article only examines three statutes in detail,<sup>72</sup> its attempt to inductively establish such a taxonomy is, by necessity, imprecise. However, taken together, these three statutes strongly suggest that there are at least two dimensions of the taxonomy to consider. The first is the presence or absence of a regulated interest group. Here, I use the terms “presence” or “absence” in a way that is tied to general circumstances in the world rather than to the specific circumstances of the statute. That is, if a law is responsible for the creation of an industry or specific stakeholder group, then that group is “absent” at the time of its creation. For instance, the Patient Protection and Affordable Care Act (ACA)<sup>73</sup> establishes a new service delivery model known as the accountable care organization (ACO). Because this delivery model was previously unknown, ACOs were “absent” for the passage of the ACA. Similarly, the pharmaceutical industry is “present” for statutes that are enacted today, even if the industry had no role to play in their enactment.

The “absent” category within the taxonomy is an analytically useful one to include, as it has been understudied relative to its importance across varying areas of law. The problem of the “invisible stakeholder” is present in many fields, but it has particularly been recognized in fields such as environmental law,<sup>74</sup> health law,<sup>75</sup> and the field of public health.<sup>76</sup> Essentially, the idea is that laws are often passed with either the goal or

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<sup>72</sup> However, there are admittedly few other patent-related statutes to choose from. The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (to be codified in scattered sections of 35 U.S.C.), was the first major overhaul of the patent regime since the Patent Act of 1952, Pub. L. No. 82-593, 66 Stat. 792 (codified as amended in scattered sections of 35 U.S.C.), and some of its provisions have only very recently taken effect.

<sup>73</sup> Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified in scattered sections of 26 and 42 U.S.C.).

<sup>74</sup> See E. Donald Elliott, Bruce A. Ackerman, & John C. Millian, *Toward a Theory of Statutory Evolution: The Federalization of Environmental Law*, 1 J. L. ECON. & ORG. 313, 317 (1985) (“[T]he surprisingly strong environmental statutes of the early 1970s were not passed in response to lobbying by well-organized national environmental groups; on the contrary, it is the other way around—the statutes of the early 1970s made it possible to consolidate national environmental groups.”).

<sup>75</sup> As noted above, the ACA’s creation of accountable care organizations is one such example. See Abbe R. Gluck, *Intrastatutory Federalism and Statutory Interpretation: State Implementation of Federal Law in Health Reform and Beyond*, 121 YALE L.J. 534, 619 (2011).

<sup>76</sup> Cf. Scott Burris, *The Invisibility of Public Health: Population-Level Measures in a Politics of Market Individualism*, 87 AM. J. PUB. HEALTH 1607, 1608–09 (1997) (examining the use of individual-level healthcare interventions as compared to population-level public health interventions that function to alter the existing choice architecture).

effect of incentivizing the development of certain stakeholders.<sup>77</sup> But where those stakeholders are “absent” during the incubation and passage of the law—not merely uninvolved in the process, but not even existing in the world—the legislative process is inherently speculative in a way that is not true when the relevant interest group exists, but perhaps is uninvolved in the particular statute. Sometimes the result is positive, and a helpful new technology or stakeholder group comes into existence. Yet sometimes the law may have the unintended effect of stifling innovation or of hamstringing a group’s reform efforts. In some respects, the analysis is similar to that of the often-discussed “future generations” problem.<sup>78</sup>

The second dimension in play is situational, regarding the ways in which a given interest group relates to a particular proposed bill. An interest group may be “present” in society, but it may also be disorganized and play little or no role in the enactment of a statute. Or it may be very organized and extremely influential. Alternatively, it may be present and well-organized, but in a way that pits it directly against another interest group, ultimately rendering it uninfluential.

Because this second dimension is more heterogeneous than the first (presence or absence has more of a binary character), I will refrain from attempting to characterize the suggested taxonomy visually in this article (for instance, in a 2x2 matrix, or along a spectrum of involvement). However, the analysis herein is suggestive of a series of general conclusions, which will be explored in more detail in Part III.

#### ***A. Absent: The Creation of the Court of Appeals for the Federal Circuit***

Today, it is difficult to imagine the United States’ system of patent law without the Court of Appeals for the Federal Circuit, the semi-specialized appellate court whose jurisdiction is defined by subject matter, not geography. The Federal Circuit hears all appeals from the United States District Courts in cases arising under the Patent Act as well as all appeals from several specialized Article I courts, including the Court of Federal

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<sup>77</sup> See *infra*, part III.A; see also, e.g., Health Information Technology for Economic and Clinical Health (HITECH) Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, 123 Stat. 115 (2009) (codified in scattered sections of 42 U.S.C.) (incentivizing physicians to expand their use of electronic medical records (EMRs), which should have the effect of incentivizing innovation in the EMR space).

<sup>78</sup> Cf. generally Deven R. Desai, *The Life and Death of Copyright*, 2011 WIS. L. REV. 219 (analyzing issues of intergenerational equity in copyright law).



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Claims and the Merit Systems Protection Board.<sup>79</sup> The court was created by the Federal Courts Improvement Act of 1982 (FCIA), and its impact on the field has been far-reaching.<sup>80</sup> Yet the history behind the FCIA reveals that the statute was not the product of interest group lobbying, although both the strong and weak forms of the interest group theory of legislation predict that it would have been susceptible to such pressure.

The first congressional<sup>81</sup> move toward the establishment of the FCIA was the creation of the 1972 Commission on Revision of the Federal Court Appellate System, which would come to be known as the Hruska Commission after its Chairman, Senator Roman Hruska. The Commission conducted extensive fact-finding on a range of judiciary reform issues, concluding that broad conflicts among the laws of the circuits persisted across a range of subject matters, including patent law, and that there was a serious need to achieve national uniformity in these areas.<sup>82</sup> The Commission's vehicle of choice for addressing these conflicts was a National Court of Appeals, or a "Junior Supreme Court" (as it was called by its critics), on which circuit judges would sit on a revolving basis to screen cases before they arrived at the Supreme Court, resolving some conflicts

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<sup>79</sup> 28 U.S.C. § 1295(a)(1) (2012) (providing jurisdiction over appeals "in any civil action arising under, or in any civil action in which a party has asserted a compulsory counterclaim arising under, any Act of Congress relating to patents"); *id.* § 1295(a)(3) (providing jurisdiction over appeals "from a final decision of the United States Court of Federal Claims"); *id.* § 1295(a)(9) (providing jurisdiction over an appeal from a "final order or final decision of the Merit Systems Protection Board"); *see* U.S. JUDICIAL CONFERENCE COMM. ON THE BICENTENNIAL OF THE CONSTITUTION OF THE U.S., THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT: A HISTORY, 1982–1990 at xii (Marion T. Bennett ed., 1991) [hereinafter *FEDERAL CIRCUIT: A HISTORY*]; Eric G. Bruggink, "Unfinished Business," 71 *GEO. WASH. L. REV.* 879, 879 (2003).

<sup>80</sup> *See infra* notes 98–106 and accompanying text.

<sup>81</sup> In 1971, the judiciary had already begun thinking about related problems. That year, then-Chief Justice Burger appointed a Study Group, chaired by Professor Paul Freund, to examine a range of problems plaguing the Supreme Court's caseload—among them the great disparities and concomitant uncertainty in the law across circuits, as the Court was unable to review every developing split. *FEDERAL CIRCUIT: A HISTORY*, *supra* note 79, at 3. The idea of a National Court of Appeals, so central to the recommendations of the Hruska Commission, came out of this Study Group. *Id.* at 3–4. For a detailed comparison of the Freund Proposal with the report of the Hruska Commission, Office for Improvements in the Administration of Justice (OIAJ) proposal, and ultimate FCIA, see generally Harold C. Petrowitz, *Federal Court Reform: The Federal Courts Improvement Act of 1982—And Beyond*, 32 *AM. U. L. REV.* 543 (1983).

<sup>82</sup> *FEDERAL CIRCUIT: A HISTORY*, *supra* note 79, at 4.

and sending others to the Court.<sup>83</sup> The Commission's proposal, however, was not enacted into law.<sup>84</sup>

Progress stagnated until 1977, when President Carter appointed Griffin Bell as Attorney General.<sup>85</sup> Bell created the Office for Improvements in the Administration of Justice (OIAJ), headed by Assistant Attorney General Daniel Meador.<sup>86</sup> And, "[t]hrough research and wide-ranging consultations with members of Congress, judges, government agencies, and practicing lawyers, [OIAJ] sought to find weak spots and inefficiencies in the system and to propose solutions."<sup>87</sup> In July 1978, Meador circulated a proposal that would have merged the Court of Claims and the Court of Customs and Patent Appeals to create a new circuit court with jurisdiction over cases within the purview of those two courts as well as "exclusive appellate jurisdiction in civil tax, environmental, and patent cases."<sup>88</sup> But Meador's attempt to give his proposed court jurisdiction over tax and environmental cases was highly contentious, and these subjects were largely excised from the court's jurisdiction before the final proposal was sent to Congress.<sup>89</sup>

Senator Ted Kennedy, then Chairman of the Senate Judiciary Committee, introduced into the Senate both the Administration's proposal and his own similar bill.<sup>90</sup> A "clean" version of the Senate bill passed with bipartisan support on October 30, 1979, but only with an additional amendment by Senator Dale Bumpers. The Bumpers Amendment would have "reversed the judicial presumption in law that an agency rule or regulation was valid."<sup>91</sup> Subsequently, Congressman Peter Rodino, Jr., Chairman of the House Committee on the Judiciary, introduced a bill into that chamber, and it passed in the House in September 1980. Yet the House bill did not contain the Bumpers Amendment and the House leadership was hostile to that provision. The House never considered the Senate's bill, and

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<sup>83</sup> *Id.* at 3–4.

<sup>84</sup> *Id.* at 4.

<sup>85</sup> Daniel J. Meador, *Griffin Bell at the Intersection of Law and Politics: The Department of Justice, 1977–1979*, 24 J.L. & POL. 529, 538 (2008).

<sup>86</sup> FEDERAL CIRCUIT: A HISTORY, *supra* note 79, at 4.

<sup>87</sup> Meador, *supra* note 85, at 538.

<sup>88</sup> FEDERAL CIRCUIT: A HISTORY, *supra* note 79, at 5.

<sup>89</sup> *Id.* The Federal Circuit does have jurisdiction over tax refund appeals, as a suit for money damages against the government, but it does not exercise jurisdiction over other tax cases.

<sup>90</sup> *Id.*

<sup>91</sup> *Id.* at 6.

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as the Senate was unable to eliminate the Bumpers Amendment from the legislation, both bills died at the end of the 96th Congress.<sup>92</sup>

After the election of President Reagan in 1980, there was great uncertainty regarding the prospects of judiciary reform. Yet the enthusiasm for such bills increased in the 97th Congress, with the apparent support of the Judicial Conference of the United States, and thus movement toward passage of such bills accelerated.<sup>93</sup> Senate and House bills proposed to create the Court of Appeals for the Federal Circuit, adopting Meador's general recommendation to merge the Court of Claims and the Court of Customs and Patent Appeals<sup>94</sup> and to add additional jurisdiction over certain other areas of law.<sup>95</sup> The bills passed their respective houses with wide bipartisan support,<sup>96</sup> and in March 1982, the reconciled bill was presented to President Reagan for his signature. The FCIA was signed into law on April 2, 1982.<sup>97</sup>

Under the typical patent law account of the Federal Circuit's creation, the court was intended to tackle two large problems. The first and most obvious problem was the disuniformity in the application of patent law across the courts of appeals, which created a large incentive to engage in forum shopping.<sup>98</sup> Businesses operating nationally "needed uniformity in interpretation of the patent laws in order to make decisions conducive to research and productivity."<sup>99</sup> The Supreme Court rarely accepted patent cases for review, and even if it had accepted such cases more frequently, it would have been practically impossible for the Court to resolve all such

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<sup>92</sup> *Id.*

<sup>93</sup> *Id.* at 6–7.

<sup>94</sup> See Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, § 127, 96 Stat. 25, 36–39.

<sup>95</sup> See FEDERAL CIRCUIT: A HISTORY, *supra* note 79, at 7 (listing areas of jurisdiction).

<sup>96</sup> Richard H. Seamon, *The Provenance of the Federal Courts Improvement Act of 1982*, 71 GEO. WASH. L. REV. 543, 583 (2003).

<sup>97</sup> FEDERAL CIRCUIT: A HISTORY, *supra* note 79, at 7–8.

<sup>98</sup> See *id.* at xi, 3; S. REP. NO. 97-275, at 5 (1981); H.R. REP. NO. 97-312, at 23 (1981) (noting that the law's "central purpose [was] to reduce the widespread lack of uniformity and uncertainty of legal doctrine that exist[ed] in the administration of patent law"); see also Haldane R. Mayer, *United States Court of Appeals for the Federal Circuit 20th Anniversary Judicial Conference: "A Salute to the Federal Circuit,"* 217 F.R.D. 548, 560 (2002) (remarks of Donald Dunner) ("Before 1982, there were tremendous attitudinal differences and other differences between the circuits. If you wanted to declare a patent invalid, you would go to the Eighth Circuit, which never saw a patent that it wanted to find valid. If you wanted a court that was more hospitable to patents, you would go to the Seventh Circuit, you would go to the Fifth Circuit, maybe the Sixth Circuit.").

<sup>99</sup> FEDERAL CIRCUIT: A HISTORY, *supra* note 79, at xii.

disputes.<sup>100</sup> Second and relatedly, some of the circuit courts “tended not to give any deference to the administrative examination process and invalidated many patents” out of fears “about the dangers of monopoly” and “low regard for the expertise of the Patent Office.”<sup>101</sup> Thus, not only was forum shopping rampant, but it had potentially great costs for patent holders, as the uncertainty in the field threatened to decrease incentives for innovation. The Department of Justice Committee on Revision of the Federal Judicial System went so far as to describe the situation as a “crisis for litigants who seek justice, for claims of human rights, for the rule of law, and [] therefore a crisis for the Nation.”<sup>102</sup> Retrospective views of the Federal Circuit generally agree that the creation of the court has solved the uniformity problem,<sup>103</sup> although some scholars lament the proliferation of intra-Circuit splits or apparent panel-dependency of outcomes.<sup>104</sup> And there is near-universal agreement that the Federal Circuit is more pro-patent than were the circuit courts prior to the FCIA,<sup>105</sup> but there is disagreement both about the specific causes of this shift and about its normative desirability.<sup>106</sup>

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<sup>100</sup> S. Rep. No. 97-275, at 3 (describing the Supreme Court as operating at or near “full capacity”); *see also* S. Rep. No. 96-304, at 9 (1979); H.R. Rep. No. 97-312, at 22.

<sup>101</sup> FEDERAL CIRCUIT: A HISTORY, *supra* note 79, at 10.

<sup>102</sup> H.R. Rep. No. 97-312, at 17 (quoting REPORT OF THE DEPARTMENT OF JUSTICE COMMITTEE ON REVISION OF THE FEDERAL JUDICIAL SYSTEM 1 (1977)).

<sup>103</sup> *See* FEDERAL CIRCUIT: A HISTORY, *supra* note 79, at xiii (“A large portion of the work of a judge of the Federal Circuit is the review of draft opinions before issuance to ensure that intra-circuit conflicts are not created. Conflicts between our own decisions would defeat a major *raison d’être* for the court’s creation.”); Rochelle Cooper Dreyfuss, *The Federal Circuit: A Case Study in Specialized Courts*, 64 N.Y.U. L. REV. 1, 74 (1989); Mayer, *supra* note 98, at 560 (remarks of Donald Dunner); Seamon, *supra* note 96, at 545.

<sup>104</sup> *See* Rochelle Cooper Dreyfuss, *The Federal Circuit: A Continuing Experiment in Specialization*, 54 CASE W. RES. L. REV. 769, 776 (2004) (presenting arguments to support “the concern that the court is not making fruitful attempts to achieve consensus”); Paul R. Michel, *The Court of Appeals for the Federal Circuit Must Evolve to Meet the Challenges Ahead*, 48 AM. U. L. REV. 1177, 1191 (1999) (noting the panel-dependency criticism, but ultimately contending that such complaints are “exaggerated”).

<sup>105</sup> *See* Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289, 290 (2003) (“The Federal Circuit has further extended the Supreme Court’s expansive approach to patent eligibility while relaxing the stringency of standards for patent protection, such as utility and nonobviousness.”); John R. Thomas, *Formalism at the Federal Circuit*, 52 AM. U. L. REV. 771, 794 (2003) (“Today it is quite clear that [at the Federal Circuit] . . . few innovations will fail to comprise patentable subject matter . . .”).

<sup>106</sup> *See* Thomas, *supra* note 105, at 792–98 (noting the Federal Circuit’s preference for rules over standards in its “continuing drive for doctrinal stability within the patent law,” *id.* at 794, and the relationship of this preference to the observed phenomenon that specialized courts come to support their specialty).

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The question remains, though, precisely how the FCIA was able to pass through the gauntlet of bicameralism and presentment, particularly where analogous bills and proposals before it had failed. Theoretically, public choice theory might provide one possible explanation. Specifically, given the two problems of disuniformity and antipathy that the Federal Circuit was designed to address, the essential conditions of even the weak version of public choice theory would seem to hold. This is a case in which the regulated industry is likely to feel strongly about the issue and to present a united front in urging for the adoption of legislation, while at the same time the salience of the issue to the general population is likely to be low.

To be sure, at least some assertions have been made that industry and the patent bar played roles throughout this process. Federal Circuit Judge Marion Bennett, in recounting the history leading up to the FCIA's adoption, asserts that Meador's 1978 proposal received strong support from the patent community,<sup>107</sup> and that the industry's support for the FCIA intensified after President Reagan's election.<sup>108</sup> Further, the very fact that the FCIA was enacted with such a clear focus on the resulting court's jurisdiction over patent cases may be thought of as additional evidence for industry's involvement. Specifically, the "structural defect" of disuniformity in patent law arose out of the "regional organization of the existing courts of appeals, none of whose decisions were binding on the others and only a small fraction of whose decisions were reviewed by the United States Supreme Court."<sup>109</sup> This "defect" is not unique to patent law, yet patent law is unique among areas of federal law in spawning such an involved reform movement. Thus, it would seem that the second concern behind the Federal Circuit's enactment—the animosity at the time of many circuit courts toward patents—may have provided the requisite additional impetus for the judiciary reform agenda.<sup>110</sup> This is precisely the type of interest that would seem to suggest the behind-the-scenes involvement of the regulated industry.

Yet there is no clear evidence that either industry or the patent bar organized itself and intervened in the legislative process to speed the enactment of the FCIA or to encourage the enactment of previous judicial

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<sup>107</sup> FEDERAL CIRCUIT: A HISTORY, *supra* note 79, at 5.

<sup>108</sup> *Id.* at 6.

<sup>109</sup> Seamon, *supra* note 96, at 544.

<sup>110</sup> *See id.*, at 568–69 (“[P]roponents of the FCIA argued that the inconsistency and uncertainty in patent law stifled industrial innovation. . . . [T]his extrajudicial effect struck a national nerve because of fear that the United States had lost its ‘competitiveness.’”).

reform efforts.<sup>111</sup> Statements that industry, broadly speaking, merely supported the proposals do not rise to the level of involvement required to establish that industry was *responsible* for the enactment of the statute under the principles of public choice theory. Statements made by patent lawyers, industry, and representatives thereof at the Senate and House hearings on the FCIA are closer but alone do not rise to the level of responsibility required under the theory. Unlike in the copyright context, this is not a situation in which the regulated parties provided the statutory language, negotiated with each other throughout the process, or performed any other such task that would have driven the statute's passage.

Indeed, even the evidence that industry broadly supported the reform proposals should be qualified. Daniel Meador's painstaking account of his work in the years leading up to the enactment of the FCIA and subsequent establishment of the Federal Circuit notes that the 1979 precursor to the FCIA was opposed by the "leaders of the Patent Law Association of Chicago and of the New York Patent Law Association."<sup>112</sup> Apart from this reference and brief notes that patent lawyers and representatives from their particular bar associations were included in the multi-day hearings on the 1979 bills held by the Senate and House, Meador's detailed history is tellingly devoid of any mention of industry's involvement in the enactment of the FCIA. Indeed, in Meador's view, "had it not been for OIAJ there would today be no Federal Circuit," as no other institution, including the bar, provided the requisite leadership.<sup>113</sup>

Relatedly, there is compelling evidence to suggest that the real story is one of "congressional pioneering in the field of court structuring,"<sup>114</sup> and that industry, even if it were involved in propelling the FCIA through Congress, was somewhat marginalized throughout the process. The structure of the statute itself is one such example. If industry had in fact been responsible for the enactment of the FCIA, we would expect to see a truly specialized court, focused entirely on patent law issues, rather than the semi-specialized court we see in reality. The House Report on the FCIA specifically addressed this issue and recognized the greater potential for

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<sup>111</sup> Even first-hand accounts arguing that industry played a key role in the development of the court recognize the divisions within industry and the opposition from segments of the bar. See, e.g., Pauline Newman, *Origins of the Federal Circuit: The Role of Industry*, 11 FED. CIR. B.J. 541, 543 (2002). But see, e.g., Paul Gugliuzza, *Rethinking Federal Circuit Jurisdiction*, 100 GEO. L.J. 1437, 1456–58 (2012).

<sup>112</sup> Daniel J. Meador, *Origin of the Federal Circuit: A Personal Account*, 41 AM. U. L. REV. 581, 595 (1992).

<sup>113</sup> *Id.* at 608, 619.

<sup>114</sup> Howard T. Markey, *The Court of Appeals for the Federal Circuit: Challenge and Opportunity*, 34 AM. U. L. REV. 595, 595 (1985).

capture in the creation of a court with limited jurisdiction.<sup>115</sup> Donald Dunner, then-President of the American Patent Law Association, even lauded the proposed merger of the Court of Claims and the Court of Customs and Patent Appeals as “absolutely ingenious” for its ability to eliminate concerns about “the tunnel vision problem” of a completely specialized court.<sup>116</sup> Congress’ creation of a court with such wide jurisdiction would thus seem to belie the idea that industry was involved in this process in a purely self-interested way of the type postulated by public choice theory.<sup>117</sup>

Further, the personalities of the various executive branch individuals involved in the lead-up to the FCIA loom large in the literature on the subject. All accounts of Attorney General Bell’s tenure at the Department of Justice and his creation of the OIAJ suggest that he placed great emphasis on the “non-political nature of the Department, thus making it more likely that Congress would see those proposals as high-minded efforts to improve the system and not as part of a partisan agenda.”<sup>118</sup> Daniel Meador himself has been described as the “father of the court.”<sup>119</sup> Discussions of OIAJ’s role more broadly take pains to emphasize its non-partisan character. As Meador recounts:

Once OIAJ developed a bill and obtained its introduction in Congress, the assistant attorney general and the lawyers working under him actively engaged in discussions with both the Democratic and Republican staffs of the House and

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<sup>115</sup> H.R. Rep. No. 97-312, at 31; *see also generally* Simon Rifkind, *A Special Court for Patent Litigation? The Danger of a Specialized Judiciary*, 37 A.B.A. J. 425 (1951) (warning of the dangers of such a specialized court).

<sup>116</sup> *Hearings on H.R. 6033, H.R. 6934, H.R. 3806, and H.R. 2414 before the Subcomm. on Courts, Civil Liberties, and the Admin. of Justice of the Comm. on the Judiciary, House of Representatives*, 96th Cong., 93 (1980) [hereinafter 1980 House Hearing]; *see also id.* at 629 (statement of Harry F. Manbeck on behalf of Comm. for Econ. Dev.) (supporting a proposal to give the Federal Circuit “added jurisdiction over matters besides patent appeals” because this would “keep the court from being over-specialized”).

<sup>117</sup> Harold H. Bruff, *Specialized Courts in Administrative Law*, 43 ADMIN L. REV. 329, 334-35 (1991) (“In forming the CAFC, Congress sought to avoid overspecialization and capture by creating ‘a varied docket spanning a broad range of legal issues.’” (quoting H.R. Rep. No. 97-312, at 31)).

<sup>118</sup> Meador, *supra* note 85, at 538.

<sup>119</sup> Mayer, *supra* note 98, at 559 (remarks of then-Chief Judge Mayer); *see also id.* at 557 (then-Chief Judge Mayer noting that his association with the Federal Circuit “goes back to the mid-1970s, when what was to become the court was but a gleam in the eye of Professor Dan Meador”); Seamon, *supra* note 96, at 559 (describing Meador as “[t]he father of the FCIA”).

Senate Judiciary Committees, in an effort to secure bipartisan passage. They were in effect lobbying for those bills, thus engaging in political activity. However, there were never any “deals” offered, no quid pro quo discussed. OIAJ never suggested trading something, such as favorable consideration of a proposed judicial nominee, for support of a bill. The effort was entirely to explain the bill and make a case for its passage.<sup>120</sup>

These accounts suggest that the interaction between Congress and neutral members of the executive branch was a key driving factor in moving these bills forward, rather than interaction between Congress and the various regulated industries.<sup>121</sup>

There is additional evidence that Congress carefully considered and debated each aspect of the judicial reform issue, in contrast to the enactment of several copyright-related bills as briefly recounted in the previous Part. Senator Dennis DeConcini, the Chairman of the Senate Judiciary Subcommittee on Improvements in Judicial Machinery, recalls the Subcommittee’s “lengthy debate over the proper methods to reduce the enormous burden placed on the judicial system.”<sup>122</sup> Senator DeConcini notes the Subcommittee’s conclusion that patent cases “realistically had little chance of Supreme Court review” as compared to other areas of substantive law that differed among the circuits, perhaps due to patent law’s technical nature, exacerbating the need to standardize such decisions and making patent law a central topic of the Subcommittee’s discussions.<sup>123</sup>

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<sup>120</sup> Meador, *supra* note 85, at 538–39.

<sup>121</sup> Seamon, *supra* note 96, at 596 (“Many good, timely ideas die in the halls of Congress. The FCIA avoided that fate because it had leadership in the executive branch. The leadership came from Dean Meador and the rest of the OIAJ, which secured the backing of the DOJ and the president. With that support in place, the FCIA gained congressional leadership in both houses.”).

<sup>122</sup> Dennis DeConcini, *The Federal Courts Improvement Act of 1982: A Legislative Overview*, 14 GEO. MASON U. L. REV. 529, 529 (1992).

<sup>123</sup> *Id.*; see also *id.* at 532 (quoting Dean Erwin Griswold as noting that some areas of law are disproportionately burdened by a lack of uniformity, and that this condition “is especially true in areas where there are a large number of recurring questions, no one of which is of great importance by itself, and most of which are not worthy of review by the Supreme Court of the United States. There are a number of fields in which such questions are concentrated. One of these is . . . that of patents and trademarks.”); Seamon, *supra* note 96, at 556 (“[M]any who thought that inconsistency was a problem also thought that it was a particularly acute problem in patent and tax cases.”).



And in conducting hearings in 1979 evaluating Meador’s proposal, the Subcommittee heard testimony “from all areas of the legal profession.”<sup>124</sup>

Ultimately, it seems that the “regulated parties”—industry and the patent bar, broadly—did not play a dispositive role in the enactment of the FCIA. Despite theoretical predictions that this is the type of issue they ought to be concerned about, they did not organize in any significant way or engage with Congress or the OIAJ on this issue in a particularly involved way. Yet the FCIA nevertheless passed, with overwhelming executive and legislative support.

Admittedly, a statute creating a specialized court is a bit of an odd situation to analyze from a public choice theory perspective. Specifically, the Federal Circuit did not exist before the statute created it. Insofar as statutes usually benefit or harm an *existing* interest group, the FCIA arguably created an interest group—the Federal Circuit—where none previously existed. And even though the Federal Circuit did come to be made up of judges from the former Court of Claims and Court of Customs and Patent Appeals<sup>125</sup> (judges who certainly existed and had an interest in the enactment of the FCIA), at least some of these judges largely avoided advocating for the FCIA throughout the process to avoid any appearance of impropriety.<sup>126</sup>

Additionally, it is surely somewhat of an odd fit to discuss the Federal Circuit as an interest group. As a federal court, it does not possess many of the characteristics we might otherwise ascribe to political actors. For instance, it certainly does not overtly spend money lobbying for its own perpetuation or for Congress to give it greater authority. Yet in many ways the Federal Circuit does lobby for its own existence, through the judges’ judicial and extra-judicial activities<sup>127</sup> and through its posture regarding the regulated industry (in ways that should at least make *the industry* oppose

<sup>124</sup> DeConcini, *supra* note 122, at 530.

<sup>125</sup> Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25 (1982).

<sup>126</sup> See Meador, *supra* note 112, at 609 (“Chief Judge Markey again expressed the view he had stated many times previously that it would be unwise for his court to take any position one way or the other on the pending proposal.” (citing the *Federal Courts Improvement Act of 1979: Hearings on S. 677 and S. 678 Before the Subcomm. on Improvements in Judicial Machinery of the Senate Comm. on the Judiciary*, 96th Cong., 1st Sess. 111 (1979) (statement of Hon. Howard T. Markey, Chief Judge, U.S. Court of Customs and Patent Appeals))).

<sup>127</sup> See, e.g., Todd Ruger, *Appellate Judge Warns of Congressional Overreach on Patent Reform*, THE BLOG OF LEGAL TIMES (Sept. 27, 2013), <http://legaltimes.typepad.com/blt/2013/09/appellate-judge-warns-of-congressional-overreach-on-patent-reform.html>; Tony Dutra, *Current and Former Federal Circuit Chief Judges Defend Patent System Benefit to U.S. Public*, BLOOMBERG BNA (Nov. 27, 2012), <http://www.bna.com/current-former-federal-n17179871184/>.

efforts to eliminate the court).<sup>128</sup> And there is a growing body of scholarship addressing the interests and incentives of government institutions, like the PTO, as interest groups in a very real sense.<sup>129</sup>

### ***B. Present But Disorganized: The Bayh-Dole Act***

Around the same time that Congress and the executive branch were embroiled in debates about appropriate reforms to the federal judiciary, there was also an ongoing debate about the ability of institutions receiving federal funds for research to patent any discoveries resulting from that research. The Bayh-Dole Act of 1980 generally permitted “non-profit organization[s]” (including universities) and “small business firm[s]” to “retain title to any subject invention,” permitting those organizations to file for patents on their subject inventions, except in a few specialized circumstances regarding government-owned facilities, national security, or “exceptional circumstances.”<sup>130</sup> Subsequently, the number of universities with dedicated technology transfer offices (TTOs) skyrocketed,<sup>131</sup> and today the Association of University Technology Managers, which brings together university TTOs for various data-gathering, organizational, and political reasons,<sup>132</sup> is a powerful force for change in this area. Unlike in the case of the creation of the Federal Circuit, the regulated interest group here—university TTOs, essentially—did exist in some form prior to the passage of the Bayh-Dole Act. Yet evidence suggests that TTOs in general had little involvement in the passage of the statute, although public choice theory would predict otherwise. Further, the lobbying activities of industry (which may in some sense be viewed as the real party in interest here) do not clearly provide an alternate explanation for the Act’s passage.

Before the Bayh-Dole Act, the situation facing university technology managers who wanted to patent and commercialize the results

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<sup>128</sup> See, e.g., *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558, 571–72 (Fed. Cir. 2000) (en banc), *vacated*, 535 U.S. 722, 742 (2002) (“Congress contemplated that the Federal Circuit would ‘strengthen the United States patent system in such a way as to foster technological growth and industrial innovation.’ Issues such as the one before us in this case are properly reserved for this court to answer with ‘its special expertise.’”).

<sup>129</sup> See generally, e.g., 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 (2013).

<sup>130</sup> 35 U.S.C. § 202 (2012).

<sup>131</sup> But see *infra* notes 152–160 and accompanying text for arguments that the marginal effect of Bayh-Dole on university technology transfer programs beyond the already-occurring expansion thereof is small.

<sup>132</sup> *AUTM Board of Directors: Mission and Goals*, ASSOC. OF UNIV. TECHNOLOGY MANAGERS (July 22, 2009), [http://www.autm.net/Mission\\_and\\_Goals/9885.htm](http://www.autm.net/Mission_and_Goals/9885.htm).

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of their faculty members' innovation could be described in one word: chaos. In general, the federal government was presumed to have the right to take title to patents stemming from federally funded research at universities. And the government had long recognized that the question of which organization should take title to patents resulting from federally-funded research (the government as grantor or the university as grantee) was complex.<sup>133</sup> By 1979, there were "at least 24 different patent policies in effect in the Federal agencies."<sup>134</sup> Ultimately, the fate of grantees hoping to take title to patents resulting from research was highly dependent on the identity of the agency from which the grant came.<sup>135</sup> Further, these policies were "frequently contradictory from agency to agency (and even sometimes within the same agency) and [] prove[d] to be formidable barriers to organizations interested in participation in Government work."<sup>136</sup>

The complexity of the situation had not gone unnoticed, however. As early as 1963, President Kennedy had issued an executive order intending to bring some uniformity to the situation, recognizing the "need for greater consistency in agency practices in order to further the governmental and public interest in promoting the utilization of federally financed inventions and to avoid difficulties caused by different approaches by the agencies when dealing with the same class of organizations in comparable patent situations."<sup>137</sup> Essentially, though, President Kennedy's order imposed only a superstructural uniformity in which each of the federal grantor agencies placed default ownership of such patents with the federal government, allowing grantees to take title only where "the contractor or grantee successfully completes lengthy waiver procedures justifying why patent rights should be left to the inventor."<sup>138</sup> These waiver procedures (which continued to differ among agencies) were "difficult," and only "in

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<sup>133</sup> See Peter Lee, *Transcending the Tacit Dimensions: Patents, Relationships, and Organizational Integration in Technology Transfer*, 100 CAL. L. REV. 1503, 1512 (2012).

<sup>134</sup> S. Rep. No. 96-480, at 2 (1979).

<sup>135</sup> See, e.g., Jay P. Kesan, *Transferring Innovation*, 77 FORDHAM L. REV. 2169, 2175 n.38 (2009) ("DHEW, for example, had a policy of negotiating IPAs with universities, while the U.S. Department of Defense (DoD) allowed universities to retain title if the universities followed 'approved' patent policies.").

<sup>136</sup> S. Rep. No. 96-480, at 2 (1979).

<sup>137</sup> Memorandum for the Heads of Executive Departments and Agencies, 28 Fed. Reg. 10,943, 10,943 (Oct. 12, 1963).

<sup>138</sup> S. Rep. No. 96-480, at 2 (observing also that "[i]n general, the present patent policies require contractors and grantees to allow the funding agency to own any patentable discoveries made under research and development supported by the Federal Government").

rare cases” did petitions survive the process.<sup>139</sup> It is unsurprising that the system continued to engender discontent.

In December 1965, the Federal Council for Science and Technology established the Committee on Government Patent Policy to examine the impact of President Kennedy’s policy statement and to gather additional information about the situation.<sup>140</sup> The Committee then commissioned Harbridge House to conduct a review of federal patent policy.<sup>141</sup> The review discovered that one variable affecting the commercial utilization of innovations stemming from federally-funded research was “whether or not the contractor or another assignee had exclusive patent rights.”<sup>142</sup> Specifically, the rate of commercialization of patents was much higher when the contractor had taken title to their invention (23.8%) as compared to when the federal government had retained title (13.3%).<sup>143</sup> And so in August 1971, President Nixon issued a new policy statement, in which he

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<sup>139</sup> COUNCIL ON GOVERNMENTAL RELATIONS, *THE BAYH-DOLE ACT: A GUIDE TO THE LAW AND IMPLEMENTING REGULATIONS 2* (1999); *see also* Arti Kaur Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77, 95–96 (1999) (“Although some federal agencies allowed university patenting of federally sponsored research, the process of obtaining the right to patent was generally cumbersome and complex, and thus the number of cases in which patenting occurred was small.”).

<sup>140</sup> Memorandum about Government Patent Policy, 36 Fed. Reg. 16,887, 16,887 (Aug. 23, 1971).

<sup>141</sup> Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1679 (1996).

<sup>142</sup> F.M. Scherer, *The Political Economy of Patent Policy Reform in the United States*, 7 J. TELECOMM. & HIGH TECH. L. 167, 181–82 (2009). Professor Scherer also notes one particularly “extreme” application of the Committee’s general research, in the pharmaceutical context:

[U]p to 1962, drug companies routinely screened new organic molecules synthesized under government grants by academic researchers. However, when the Department of Health, Education, and Welfare (HEW) imposed new reporting requirements that threatened the exclusivity of drug companies’ rights to commercialize molecules found to be therapeutically interesting, such testing ceased abruptly. The moratorium ended in 1968 when HEW changed its policies to allow drug companies exclusive rights on grant-originated molecules they tested.

*Id.* at 181–82. For a more extensive discussion of this particular example, see Eisenberg, *supra* note 141, at 1682–84. In this, like in most other areas of patent law, the pharmaceutical industry seems to be the outlier in terms of the severity of their connection to the phenomenon. Yet the industry’s importance to society suggests that this event may have served as a precipitating factor of the Act.

<sup>143</sup> Eisenberg, *supra* note 141, at 1680. *But see id.* (“[I]t should be noted that eighty-three percent of the contractor inventions included in the Harbridge House data had been funded by DoD under contracts and policies that would have permitted the contractors to retain title if they had so elected.”).

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emphasized that although a “Government-wide policy best serves the public interest,” such a policy must be “flexible” about the ownership of patent rights.<sup>144</sup> President Nixon recommended a revised policy that would give agency heads “additional authority to permit contractors to obtain greater rights to inventions where necessary to achieve utilization.”<sup>145</sup>

Congress soon took action, with the White House proposing a draft bill in August 1976 and the House drafting its own version soon thereafter.<sup>146</sup> Subsequent hearings before the House Committee on Science and Technology and Monopolies Subcommittee of the House Judiciary Committee included testimony from a wide range of individuals and organizations, including representatives of the Committee on Government Patent Policy, representatives of several federal agencies that issue research grants, the Society of University Patent Administrators (SUPA) (the predecessor to AUTM), anti-patent scholars, and the consumer activist chairman of the Federal Trade Commission.<sup>147</sup>

In the end, the Bayh-Dole Act was enacted in December 1980, reversing the presumption that the federal agency grantor would retain title to the inventions resulting from such federal grants and permitting universities and small businesses to take title in such cases, subject to a few exceptions.<sup>148</sup> Since the pre-Bayh-Dole patchwork of federal regulations had engendered confusion and discontent among both federal grantees and the agencies themselves, one of Congress’ purposes in enacting the Act was to “minimize the costs of administering policies in this area,”<sup>149</sup> and by effectively standardizing the reversal of its presumption, Congress was able to do so. Yet Congress had also explicitly stated a series of additional purposes in the statute. Specifically:

It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to

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<sup>144</sup> Memorandum about Government Patent Policy, 36 Fed. Reg. 16,887 at 16,887.

<sup>145</sup> *Id.* at 16,888.

<sup>146</sup> Scherer, *supra* note 142, at 182. The Senate had already made one halting attempt to address this issue, in 1965 introducing a bill that included compromise policies. The bill’s progress, however, was postponed pending the completion of the Committee’s studies. *Id.*

<sup>147</sup> See *Government Patent Policy: The Ownership of Inventions Resulting from Federally Funded Research and Development: Hearing Before the Subcomm. on Domestic and Int’l Scientific Planning and Analysis of the H. Comm. on Sci. and Tech.*, 94th Cong. 12 (1976); *Government Patent Policies: Hearings Before the Subcomm. on Monopoly and Anticompetitive Activities of the Select Comm. on Small Business*, 95th Cong. (Dec. 1977).

<sup>148</sup> 35 U.S.C. § 202 (2012).

<sup>149</sup> 35 U.S.C. § 200.

encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; [and] to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions[.]<sup>150</sup>

The compromises struck in the Act reflect the complexity of these policy goals. For instance, the final goal—ensuring the retention of sufficient rights for the Government—underlies the statute’s grant of march-in rights. Yet the goals of encouraging commercialization and utilization of inventions support the statute’s limiting of these rights to cases in which the patent holder “has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use” or where “action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees.”<sup>151</sup>

Commentary is mixed as to whether the Act succeeded in accomplishing its mission. There is of course general agreement that the absolute number of TTOs has skyrocketed in the decades since 1980,<sup>152</sup> as has the number of patents granted each year to universities,<sup>153</sup> the amount of

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<sup>150</sup> *Id.*

<sup>151</sup> 35 U.S.C. § 203(a)–(b).

<sup>152</sup> See David C. Mowery, Richard R. Nelson, Bhaven N. Sampat, & Arvids A. Ziedonis, *The Growth of Patenting and Licensing by U.S. Universities: An Assessment of the Effects of the Bayh-Dole Act of 1980*, 30 RES. POL’Y 99, 104 (2001) (“[T]he number of universities with technology licensing and transfer offices increased from 25 in 1980 to 200 in 1990.”); see also Rebecca Goulding et al., *Alternative Intellectual Property for Genomics and the Activity of Technology Transfer Offices: Emerging Directions in Research*, 16 B.U. J. SCI. & TECH. L. 194, 201 (2010).

<sup>153</sup> See Rai, *supra* note 139, at 109 (“[F]rom 1980 to 1992, the number of patents granted per year to universities increased from fewer than 250 to almost 2,700.”); see also *Patent Issues in Federally Funded Research: Hearing Before the Senate Judiciary Subcomm. on Patents, Copyrights, and Trademarks*, 103rd Cong. 11 (1994) (statement of Birch Bayh) (summarizing similar data).

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royalties paid to TTOs in licensing fees,<sup>154</sup> and the number of companies spun off of universities.<sup>155</sup> The Bayh-Dole Act is certainly “contemporaneous with a sharp increase in U.S. university patenting and licensing activity.”<sup>156</sup> But David Mowery and others have questioned precisely how much of this growth is attributable to the Act itself, as other factors (like the growth of the biotechnology industry and the increasing willingness of the Supreme Court to permit patents on basic inventions in that field<sup>157</sup>) might have contributed to the growth in such activity in any case.<sup>158</sup> Mowery argues that an “array of developments in academic research, industry and policy thus combined to increase U.S. universities’ activities in technology licensing, and Bayh-Dole, while important, was not determinative,” particularly for universities like Stanford that had already engaged in patenting and licensing activity.<sup>159</sup> Further, it is far from clear that these metrics are the correct ones to determine whether Congress’s objectives regarding commercialization have been met. Although the numbers of patents granted and royalties paid in licensing fees have

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<sup>154</sup> See Ron A. Bouchard, *Balancing Public and Private Interests in the Commercialization of Publicly Funded Medical Research: Is There a Role for Compulsory Government Royalty Fees?*, 13 B.U. J. SCI. & TECH. L. 120, 177 (2007) (“[U]niversity profits have gone from a baseline approaching nil in 1980 to well in excess of \$1.5B by 2007.”); Mowery et al., *supra* note 152, at 104.

<sup>155</sup> See Bouchard, *supra* 154, at 124 (“[I]n FY 2002 US universities brought in approximately \$1B in licensing royalties, filed 6,500 patent applications, executed 3,700 licenses and created over 400 startups.”); ASSOCIATION OF UNIVERSITY TECHNOLOGY MANAGERS, FY 2002 LICENSING SURVEY (2003).

<sup>156</sup> Mowery et al., *supra* note 152, at 103; see also Goulding, et al., *supra* note 152, at 201.

<sup>157</sup> See, e.g., *Diamond v. Chakrabarty*, 447 U.S. 303, 318 (1980); see also Peter Lee, *Interface: The Push and Pull of Patents*, 77 FORDHAM L. REV. 2225 at 2232 n.44 (“[P]assage of the Bayh-Dole Act was not the only catalytic event that spurred greater university patenting. In 1980, the U.S. Supreme Court expansively construed patentable subject matter so as to include many products of the nascent biotechnology industry. . . . In addition, advances in molecular biology revealed a relatively clear path from ‘basic’ discoveries to commercial products, thus enhancing opportunities for university patenting.”); Rebecca S. Eisenberg, *Patents and Data-Sharing in Public Science*, 15 INDUS. & CORP. CHANGE 1013, 1014 (2006).

<sup>158</sup> See Mowery et al., *supra* note 152, at 116; see also Kesan, *supra* note 135, at 2177 (“[T]hese circumstances led to a ‘chicken or the egg’ debate. On one hand, the Bayh-Dole Act might have caused the increase in university patenting; on the other, the demand for the passage of the Bayh-Dole Act could have resulted from increased patenting activity by universities.”).

<sup>159</sup> Mowery et al., *supra* note 152, at 116; see *id.* at 117. But see Goulding, et al., *supra* note 152, at 201 (“[P]atenting by research institutions in the United States was possible and practiced even prior to 1980. The Bayh-Dole Act did not, in fact, change this reality. It did, however, serve the important functions of making the process uniform and easier to implement across governmental funding agencies.”).

increased, most TTOs are either losing money or are barely breaking even on their expenses.<sup>160</sup>

Other commenters have focused more on the conceptual shifts occasioned by Bayh-Dole and the normative desirability of the Act's effects. For instance, Professor Arti Rai emphasizes the Act's effects on the traditional Mertonian norms of scientific research.<sup>161</sup> These norms "promote a public domain of freely available scientific information, independent choice in the selection of research topics, and (perhaps above all) respect for uninhibited scientific invention."<sup>162</sup> Yet the "dramatic increases in patenting activity," "delays in publication," and "restrictions on the sharing of research materials and tools caused by concerns about intellectual property rights" after Bayh-Dole have "undermined" the norms against secrecy.<sup>163</sup> In practice, the Act also affects the "commercial orientation"<sup>164</sup> of universities, with many commentators arguing that it has caused universities to emphasize applied research at the expense of basic research, which has traditionally been seen as the heart of a university's public purpose.<sup>165</sup> Others have expressed concern about the effect of this

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<sup>160</sup> See Kesan, *supra* note 135, at 2181–84, 2188–89; Lorelei Ritchie de Larena, *The Price of Progress: Are Universities Adding to the Cost?*, 43 HOUS. L. REV. 1373, 1431 (2007) ("Universities typically do not make money from their technology-transfer offices once expenses are paid and disbursements are made."). *But see* Thomas A. Massaro, *Innovation, Technology Transfer, and Patent Policy: The University Contribution*, 82 VA. L. REV. 1729, 1734–35 (1996) ("Few institutions are currently generating big dollars from royalties or licenses. . . . But these are relatively unrestricted discretionary funds—perhaps the most difficult moneys to find, yet, the most important in allowing a wise and well-prepared Dean to shape the future of an institution.").

<sup>161</sup> Rai, *supra* note 139, at 88.

<sup>162</sup> *Id.* at 89–90.

<sup>163</sup> *Id.* at 115; *see* Lee, *supra* note 157, at 2233 ("[W]hat are the normative implications of the push of patents? These developments raise the question of whether and to what extent universities should promote particular policy objectives . . . in their technology transfer practices. This question is ultimately a component of a broader inquiry into the proper role of universities in society."). Further, Bayh-Dole was premised on Edward Kitch's "development-oriented" idea that traditional norms of science (those in which patenting is not typical) impeded goals of developing products. However, this idea has often been highly criticized. *See* Rai, *supra* note 139, at 115–21.

<sup>164</sup> Bouchard, *supra* note 154, at 121.

<sup>165</sup> *See, e.g.*, Kesan, *supra* note 135, at 2192; Massaro, *supra* note 160, at 1732 ("It is almost impossible to overestimate the magnitude of change in universities. As an academic physician interested in the business of medicine, I have seen a revolution in our thinking about the nature of our core activity—the generation of new knowledge. Innovation and technology transfer are now more closely linked. This has brought an associated interest in patents, licenses and royalties."); *Bayhing for Blood or Doling Out Cash?*, THE ECONOMIST (Dec. 20, 2005), <http://www.economist.com/node/5327661> ("[The Bayh-Dole Act] makes



change in orientation on the equities of the Act, contending that “the public assumes a majority share of the risks and economic inefficiencies of the current commercialization regime, and that patentee firms and universities retain the lion’s share of the fiscal rewards and economic efficiencies of commercialization.”<sup>166</sup>

Under the traditional public choice theory account, the purpose and structure of the Act suggest that its enactment might have been motivated by the lobbying activities of universities and of already-existing TTOs who faced difficulty navigating the existing nonuniform federal policies regarding patenting. The primary benefits of such a policy would be concentrated among a relatively small, identifiable group of individuals: universities and their TTOs, although other related groups, such as small companies relying on government funding, could benefit as well. Further, the costs to society are not only diffuse, but they can be framed in a public-regarding way,<sup>167</sup> by emphasizing the societal benefits of incentivizing innovation. The regulated parties here, universities and TTOs, certainly existed during the statute’s conception and passage. Further, representatives thereof testified at some of the congressional hearings held during the drafting of the Act. But there is no evidence that the burgeoning technology transfer industry drove the enactment of the statute in a way that is comparable to the industry involvement seen in the copyright space. The testimony at the various congressional hearings of members of Stanford’s then-three-person technology transfer office<sup>168</sup> or of SUPA was surely helpful to the statute’s drafters, but this is not a situation in which

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American academic institutions behave more like businesses than neutral arbiters of truth.”).

<sup>166</sup> Bouchard, *supra* note 154, at 190; *see also id.* at 163; *see generally* Goulding, et al., *supra* note 152.

<sup>167</sup> This is less true in the copyright space. For instance, the public-regarding argument about the statute at issue in *Golan v. Holder*, restoring copyright protection in works that had already been elevated into the public domain, is not easy to make. *See, e.g.*, *Golan v. Holder*, 132 S. Ct. 873, 900 (2012) (Breyer, J., dissenting) (“The statute before us, however, does not encourage anyone to produce a single new work. By definition, it bestows monetary rewards only on owners of old works—works that have already been created and already are in the American public domain. At the same time, the statute inhibits the dissemination of those works . . .”).

<sup>168</sup> *See* Rai, *supra* note 139, at 95 n.102; *see also The University and Small Business Patent Procedures Act: Hearings on S.414 Before the Senate Comm. on the Judiciary*, 96th Cong. 178, at 210 (1979) (statement of Niels Reimers, Manager of Technology Licensing, Stanford University).

universities proposed and drafted the legislation or in which Congress heard testimony only from the universities.<sup>169</sup>

However, there is a real sense in which universities and TTOs are not the relevant parties for public choice theory purposes. Of course universities and TTOs valued their ability to engage in patenting and licensing activity. But public choice theory might also suppose that corporations, those that deal with universities in their licensing activities, would be involved in the enactment of the statute.<sup>170</sup> Industry representatives were certainly included in the various congressional hearings preceding the Act's passage. Further, industrial involvement would explain certain substantive provisions of the statute. For instance, the Act's protections for government are extremely weak.<sup>171</sup> The march-in rights discussed above have never been exercised in the more than thirty years since 1980, and proposed "recoupment"<sup>172</sup> and "reasonable price"<sup>173</sup> provisions were ultimately not included in the text of the Act. The statute

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<sup>169</sup> See, e.g., *Golan*, 132 S. Ct. at 907 (Breyer, J., dissenting) (discussing the statute before the Court and observing that "Congress, with one minor exception, heard testimony only from the representatives of existing copyright holders"). Certainly, the role of the Wisconsin Alumni Research Foundation (WARF) in the passage of the statute must be mentioned. WARF asserts that the language of the Bayh-Dole Act, in the words of Carl Gulbrandsen, tracks "verbatim" the language of the Institutional Patent Agreements negotiated between WARF and the Department of Health, Education, & Welfare. See Carl E. Gulbrandsen, *Bayh-Dole: Wisconsin Roots and Inspired Public Policy*, 2007 WIS. L. REV. 1149, 1157; *WARF & Bayh-Dole*, WISCONSIN ALUMNI RESEARCH FOUNDATION (last visited May 26 2014), <http://www.warf.org/home/about-us/background/history/warf-bayh-dole/warf-and-bayh-dole.cmsx> ("Bayh-Dole is often seen as a codification of the terms and provisions contained in the first IPA between WARF and DHEW."). Although WARF asserts its "leadership role in helping to draft and promote the passage of the Bayh-Dole Act," Gulbrandsen, *supra*, at 1163, I could not find publicly available evidence to support this conclusion.

<sup>170</sup> See ASSOCIATION OF AMERICAN UNIVERSITIES, UNDERSTANDING UNIVERSITY TECHNOLOGY TRANSFER 2 (2011), <http://files.eric.ed.gov/fulltext/ED517264.pdf> ("By enabling corporations to negotiate exclusive licenses of promising technologies, the Act encouraged them to invest in the additional research, development, and manufacturing capabilities needed to bring new products to market.").

<sup>171</sup> See Rai, *supra* note 139, at 148 ("The Act provides that 'exceptional circumstances' must exist before an agency can determine that restriction or elimination of a university's right to seek patents on an invention serves the Act's goals of development and commercialization. Moreover, the determination of 'exceptional circumstances' is subject to an administrative appeals procedure.").

<sup>172</sup> See Bouchard, *supra* note 154, at 174 ("Recoupment would have seen the federal government receive 15% of gross income over \$70,000 and an additional 5% on income in excess of \$1M—up to the amount [of] government contributions under the funding agreement(s).").

<sup>173</sup> *Id.* at 175.

even provides that small businesses, not just nonprofit organizations, may also take title to their inventions qualifying under the Act.<sup>174</sup> Yet the resulting statute is still clearly the product of compromise rather than industry railroading. Industry proposed an amendment that would have extended the Act's provisions to cover large businesses,<sup>175</sup> but the amendment was defeated in the Senate.<sup>176</sup> Only years later did President Reagan, in an executive order, instruct agencies to treat large firms similarly under the Act.<sup>177</sup>

The Bayh-Dole Act thus appears to be a case in which, although the university-industrial complex was certainly present and had views about the proposed statute, it did not drive the Act's creation or passage. Similar to the case of the FCIA, executive reports and memoranda convinced Congress of the need for such reform, and although input from the regulated parties was helpful, it was far from dispositive in propelling the statute through Congress.

### ***C. Present and Organized, But Opposing: The Hatch-Waxman Act***

Congress passed the third and final statute in this series of patent-related interventions, the Hatch-Waxman Act (or, as it is officially known, the Drug Price Competition and Patent Term Restoration Act) in 1984, soon after the Bayh-Dole Act and the FCIA. As its formal name would suggest, the Hatch-Waxman Act contained two main substantive provisions: first, it statutorily created a pathway for approval of generic drugs through the filing of Abbreviated New Drug Applications (ANDAs),<sup>178</sup> and second, it provided for extension of the patent term for new drugs, subject to

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<sup>174</sup> 35 U.S.C. §202(a), (c)(4) (2012). See Rai, *supra* note 139, at 96 n.109; *Government Patent Policy: Hearings Before the Subcomm. on Science, Research and Tech. of the House of Representatives Comm. on Science and Tech.*, 96th Cong. 45–190 (1979) (testimony of witnesses from large and small businesses).

<sup>175</sup> See Rai, *supra* note 139, at 96 n.109; *Government Patent Policy: Hearings Before the Subcomm. on Science, Research and Tech. of the House of Representatives Comm. on Science and Tech.*, 96th Cong. 53–54 (1979) (statement of John Maurer, Patent Counsel at Monsanto, arguing that “patent exclusivity is equally important for research done in universities, small businesses and large businesses. In fact, large businesses are often the only places which have the skill for some types of research and the resources to support long-term innovation. It simply would be self-defeating to limit a sound patent policy to only universities and small businesses.”).

<sup>176</sup> See Eisenberg, *supra* note 141, at 1694.

<sup>177</sup> Memorandum to the Heads of Executive Departments and Agencies: Government Patent Policy, 1983 PUB. PAPERS 248 (Feb. 18, 1983).

<sup>178</sup> 21 U.S.C. § 355 (2012).

limitations on the total period of post-approval protection.<sup>179</sup> Although the Act has certainly inspired litigation between the various industry groups,<sup>180</sup> each of these major provisions has also been critical to continued profitability, with the then-burgeoning generic drug industry exploding after the Act's passage<sup>181</sup> and branded pharmaceutical firms relying heavily on the patent extension provisions to ensure that they are able to extract monopoly rents sufficient to recoup their investments<sup>182</sup> into a given drug. Unlike in either the FCIA or Bayh-Dole cases, the relevant interest groups in this case—the generic drug industry and the branded pharmaceutical industry—were both deeply involved in the Act's passage. The Hatch-Waxman Act thus looks very much like a classic example of public choice theory. Yet as the stakeholder groups were on opposite sides of the issue, the public choice account of the statute is more complex than is typically predicted, and the Act's provisions reflect compromise between the groups.

The road to Hatch-Waxman began decades before its enactment, when Senator Estes Kefauver in 1959 convened a series of hearings on pharmaceutical prices before the Senate Subcommittee on Antitrust and Monopoly. The Subcommittee argued that industry laboratories contributed little social value, and that where the original research had come from outside industry or industry had merely created “me-too” drugs, the high prices charged for these drugs could not be justified.<sup>183</sup> Kefauver

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<sup>179</sup> 35 U.S.C. § 156(c)(3) (2012).

<sup>180</sup> Contentious particularly surrounds “Paragraph IV” certifications in which the generic drug applicant certifies that the patent on which their drug is based “is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.” 21 U.S.C. § 355(b)(2)(A)(iv). The originating manufacturer may then sue the generic applicant for patent infringement. *See* Janssen Pharmaceutica, N.V. v. Apotex, Inc., 540 F.3d 1353, 1355–57 (Fed. Cir. 2008) (summarizing the Paragraph IV system).

<sup>181</sup> *See* Colleen Kelly, *The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond*, 66 FOOD & DRUG L.J. 417, 418 (2011) (“Today, seven out of ten prescriptions in the United States are for generic drugs. As of 2007, of the 12,751 listed drugs in the Orange Book, 10,072 of the listed drugs have generic counterparts. In 2007, brand pharmaceutical sales totaled \$228 billion, while generic pharmaceutical sales totaled \$58.5 billion.”).

<sup>182</sup> *See* Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 151 (2003) (estimating the full cost of developing a new drug at \$802 million). *But see* Donald W. Light & Rebecca Warburton, *Demythologizing the High Costs of Pharmaceutical Research*, 6 BIOSOCIETIES 34, 46 (2011) (estimating the cost of R&D at \$43.4 million per new drug).

<sup>183</sup> *See* William S. Comanor, *The Drug Industry and Medical Research: The Economics of the Kefauver Committee Investigations*, 39 J. BUS. 12, 12 (1966). Pharmaceutical companies opposed this contention, arguing that their laboratories had created, in Comanor's words, “most of the new drugs that [were] extensively utilized” in medical practice. *Id.* at 13.

subsequently proposed a bill requiring mandatory cross-licensing of drug patents, in an attempt to lower drug prices.<sup>184</sup> Ultimately, though, simultaneous societal developments—specifically, the thalidomide tragedy—subverted Kefauver’s bill into one that, for the first time, would require drug companies to prove “substantial evidence”<sup>185</sup> of efficacy and safety prior to receiving FDA approval for their products. The subsequently adopted Drug Amendments of 1962<sup>186</sup> to the Food, Drug, and Cosmetic Act, also known as the Kefauver-Harris Amendment, included only one element from Kefauver’s initial cross-licensing proposal: the requirement that drug labels disclose the generic name for the drug.<sup>187</sup>

Yet the federal government’s subsequent establishment of Medicare and Medicaid in 1965 soon brought the drug pricing issue to the fore once again, as the federal government in its new funding role more directly faced the high costs of prescription drugs than it had previously. The FDA used its flexibility under the 1962 amendments to establish an ANDA pathway for the marketing of generic versions of pre-1962 prescription drugs that had been determined to be effective under the Drug Efficacy Study Implementation (DESI) program, which was designed to examine all pre-1962 drugs and classify them by effectiveness. Under this pathway, generic applicants only needed to show bioavailability and bioequivalence to obtain FDA approval.<sup>188</sup> For drugs approved after 1962, however, the FDA in 1980 could only establish a “paper NDA” pathway to generic approval. Through this “paper NDA” pathway, generic versions of drugs that were generally recognized as safe and effective “based on publicly available data” (typically, scientific literature) could pursue an abbreviated path to approval.<sup>189</sup> But these conditions were met only rarely, and thus this avenue was not commonly pursued.<sup>190</sup> The FDA then drafted a regulation to establish an ANDA process for drugs approved after 1962,<sup>191</sup> and generic

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<sup>184</sup> See *Social Reassessment, Regulation, and Growth: 1960–80*, AMERICAN CHEMICAL SOCIETY (2005), <https://pubs.acs.org/cen/coverstory/83/8325/8325social.html>.

<sup>185</sup> 21 U.S.C. § 355(d) (2012).

<sup>186</sup> Pub. L. No. 87-781, 76 Stat. 780 (1962).

<sup>187</sup> See PETER BARTON HUTT, RICHARD A. MERRILL, & LEWIS A. GROSSMAN, *FOOD AND DRUG LAW: CASES AND MATERIALS* 754 (3d ed., Foundation Press 2007).

<sup>188</sup> 21 C.F.R. § 314.2 (2013).

<sup>189</sup> See Ellen J. Flannery & Peter Barton Hutt, *Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984*, 40 *FOOD DRUG COSM. L.J.* 269, 276 (1985); Elizabeth Stotland Weiswasser & Scott D. Danzis, *The Hatch-Waxman Act: History, Structure, and Legacy*, 71 *ANTITRUST L.J.* 585, 589 (2003).

<sup>190</sup> See Weiswasser & Danzis, *supra* note 189, at 590.

<sup>191</sup> See Flannery & Hutt, *supra* note 189, at 276.

drug companies filed a lawsuit seeking to compel the FDA to establish the proposed ANDA process.<sup>192</sup> Ultimately, the case became moot with the enactment of the Hatch-Waxman Act.<sup>193</sup>

In general, the 1962 amendments required generic pharmaceutical companies seeking to introduce generic versions of drugs approved after 1962 to complete full NDAs and surmount two formidable obstacles before they could market their products: First, generic manufacturers had to wait for the drug patent to expire before even beginning to develop their own generic version. The Federal Circuit in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*<sup>194</sup> had explicitly held that “taking, during the life of a patent, the statutory and regulatory steps necessary to market, after the patent expired, a drug equivalent to a patented brand name drug” constituted “a violation of the patent laws in the guise of ‘scientific inquiry.’”<sup>195</sup> And second, generic drug companies had to conduct the full panoply of FDA-mandated clinical trials on their generic version of the originator molecule. Both of these obstacles contributed substantially to the significant lags then observed between the expiration of a patent on a given drug and the approval of a generic version of that drug. Thus, although generic drugs certainly existed in the 1970s, their access to the market for post-1962 drugs was significantly restricted.

At the same time, the corrosive impact of the 1962 amendments on the effective patent life of pharmaceuticals had become evident.<sup>196</sup> With the addition of the effectiveness requirement, each additional day post-patent grant that companies spent conducting studies to prove efficacy was an additional day taken from the manufacturer’s exclusivity. Moreover, studies showed that this effect was not trivial. One study concluded that, between 1966 and 1979, the effective post-approval life of a patent had declined from 13.6 years to 9.5 years.<sup>197</sup> Admittedly, the requirement that generic manufacturers wait for patent expiration before beginning development of their own versions “resulted in a *de facto* extension of the

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<sup>192</sup> See Kelly, *supra* note 181, at 420 n.36 (citing *Nat’l Ass’n of Pharm. Mfrs., Inc. v. Heckler*, 83 Civ. 4817 (WCC) (S.D.N.Y)).

<sup>193</sup> See Flannery & Hutt, *supra* note 189, at 420.

<sup>194</sup> 733 F.2d 858 (Fed. Cir. 1984).

<sup>195</sup> *Id.* at 860, 863.

<sup>196</sup> See, e.g., Weiswasser & Danzis, *supra* note 189, at 588.

<sup>197</sup> Alan D. Lourie, *Patent Term Restoration*, 66 *J. PAT. & TRADEMARK OFF. SOC’Y* 526, 527 (1984); H.R. Rep. No. 98-857 (Pt. I), at 17 (1984); *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1357 (Fed. Cir. 2003).

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patent term,” as such development took a “substantial amount of time,”<sup>198</sup> but the problem was still perceived as acute.

In the 97th Congress, bills were introduced in both the House and the Senate that would have restored patent terms, but that would have avoided addressing the generic drug issue entirely. Although the Senate bill, S. 255, passed that chamber in July of 1981,<sup>199</sup> the House bill died in Committee after hearings on the subject were conducted.<sup>200</sup> In the next term, the House marked up the bill and drafted a clean version, which was successfully reported out of committee. In September 1982, H.R. 6444 was then brought up on the suspension calendar, which requires a majority of two-thirds of that chamber to pass a given bill. H.R. 6444 received a simple majority of the vote, but it failed to achieve the required two-thirds margin of victory.<sup>201</sup> It is noteworthy that during this session of Congress, the hearings conducted by those in support of the patent term restoration bill were counterbalanced by hearings sponsored by Representative Henry Waxman and then-Representative Al Gore, “opponents of patent term legislation.”<sup>202</sup>

In the 98<sup>th</sup> Congress, however, Henry Waxman introduced H.R. 3605, a bill that would balance patent term restoration for branded pharmaceuticals with ANDAs for drugs receiving FDA approval after 1962. After “extensive negotiation[]”<sup>203</sup> between representatives of the generic and originator pharmaceutical firms, the Hatch-Waxman Act passed unanimously in the House and by voice vote in the Senate<sup>204</sup> before being signed into law.<sup>205</sup>

Hatch-Waxman was thus “the product of compromise” between branded pharmaceutical firms and generic manufacturers.<sup>206</sup> Congress’

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<sup>198</sup> *Warner-Lambert Co.*, 316 F.3d at 1357; *see also* *Eli Lilly & Co v. Medtronic, Inc.*, 496 U.S. 661, 670 (1990) (referring to the *Bolar* case and noting that “the combined effect of the patent law and the premarket regulatory approval requirement was to create an effective extension of the patent term”).

<sup>199</sup> Patent Term Restoration Act of 1981, S. 255, 97th Cong (1981).

<sup>200</sup> Patent Term Restoration Act of 1981, H.R. 1937 97th Cong. (1981).

<sup>201</sup> H.R. Rep. No. 98-857 (Pt. II), at 3; *see also* Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187, 188 (1999).

<sup>202</sup> H.R. Rep. No. 98-857 (Pt. II), at 3.

<sup>203</sup> *Id.* at 4.

<sup>204</sup> Scherer, *supra* note 142, at 198.

<sup>205</sup> Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, 1598–99 (1984).

<sup>206</sup> *Abbott Laboratories v. Young*, 920 F.2d 984, 991 (D.C. Cir. 1990) (Edwards, J., dissenting) (“The Act emerged from Congress’ efforts to balance two conflicting policy objectives: to induce name-brand pharmaceutical firms to make the investments necessary

dueling objectives are stated clearly not only in the title of the Act itself, but also in the “relatively sparse”<sup>207</sup> legislative history on the subject:

The purpose of Title I of the bill is to make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962. . . . The purpose of Title II of the Bill is to create a new incentive for increased expenditures for research and development of certain products which are subject to premarket government approval. The incentive is the restoration of some of the time lost on patent life while the product is awaiting pre-market approval.<sup>208</sup>

The Act provides market exclusivity and patent term restoration incentives to branded pharmaceutical firms, while simultaneously establishing a safe harbor for pre-patent expiration generic development<sup>209</sup> and permitting generic drug companies to employ the data generated by the originator applicants. In a broad sense, this compromise seems to have effectuated increased generic production and increased research in the branded pharmaceutical space.<sup>210</sup>

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to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market.”); *see also, e.g.*, *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1358 (Fed. Cir. 2003) (“The Hatch-Waxman Act was accordingly a compromise between two competing sets of interests: those of innovative drug manufacturers, who had seen their effective patent terms shortened by the testing and regulatory processes; and those of generic drug manufacturers, whose entry into the market upon expiration of the innovator’s patents had been delayed by similar regulatory requirements.”); Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 356 (2007) (referring to the Act as a “legislative compromise[]”); Kelly, *supra* note 181, at 417 (“The Act was a compromise designed to balance the competing interests of research-based pharmaceutical companies . . . and generic drug manufacturers . . .”).

<sup>207</sup> Flannery & Hutt, *supra* note 189, at 271; *see also* Mossinghoff, *supra* note 201, at 187 (“There is a paucity of legislative history on the Hatch-Waxman Act.”).

<sup>208</sup> H. Rep. No. 98-857 (Pt. I), at 14–15.

<sup>209</sup> 35 U.S.C. § 271(e)(1) (2012) (“It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.”). The Act’s legislative history on this provision references the *Bolar* case by name, stating that it explicitly intended to overturn the ruling in the case. H. Rep. No. 98-857 (Pt. II), at 18.

<sup>210</sup> WENDY H. SCHACHT & JOHN R. THOMAS, *THE HATCH-WAXMAN ACT: A QUARTER CENTURY LATER*, CONGRESSIONAL RESEARCH SERVICE (2011) (noting that although just 35% of brand-name drugs had generic counterparts in 1984, nearly all brand-name drugs



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Of course, Hatch-Waxman has been subject to gaming of various kinds, most notably around “reverse payment settlements” between originator firms and generics manufacturers.<sup>211</sup> The Act grants a 180-day exclusivity period as an incentive to the first generic manufacturer who files and prevails in a Paragraph IV certification, in which the generic applicant avers that the patent on which the original drug is based is invalid or not infringed. However, this exclusivity period is only triggered either when a court rules that the patent is invalid or not infringed or when the generic drug is first marketed. As such, originator firms that settle with the Paragraph IV first filers prior to judgment may forestall the entrance of other generic competition by avoiding triggering the exclusivity period. These settlements have the potential to “exclude entry for longer than the expected litigation exclusion period, which would have reflected the often significant likelihood that the patent holder would have lost.”<sup>212</sup> In its 2012 Term, the Supreme Court held that this practice is subject to antitrust scrutiny under the rule-of-reason test.<sup>213</sup>

Like the other statutes examined previously in this Article, public choice theory predicts that the Hatch-Waxman Act would be primarily motivated by interest group activity. Indeed, because the Act targets an even smaller number of companies than does either the FCIA or Bayh-Dole (which apply broadly across technologies), the public choice collective action problem would seem to be even more exaggerated here. That is, the pharmaceutical and generics industries should have little or no problem coming together to lobby for this statute (as its benefits would be even more concentrated), while the diffuse public will be unable to prevent its enactment. Admittedly, the issue of patent terms for pharmaceuticals is likely of higher salience to the public than is judicial reform or university patenting, and thus we might expect consumer groups to oppose that portion of the legislation. Yet the inclusion of the generic drug pathway in the enacted statute should placate consumer groups, particularly where the House Report on the subject concluded that the availability of generic drugs

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have such counterparts today); *but see* Mossinghoff, *supra* note 201, at 187 (“[Hatch-Waxman] was not a good deal [for the pharmaceutical industry], unless one believed that FDA was going to go forward with its plans to implement abbreviated new drug applications (ANDAs) through regulation.”).

<sup>211</sup> See C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1560–61 (2006).

<sup>212</sup> Einer Elhauge & Alex Krueger, *Solving the Patent Settlement Puzzle*, 91 TEX. L. REV. 283, 284–85 (2012).

<sup>213</sup> *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2237 (2013).

for originator products approved after 1962 would save American consumers \$920 million over twelve years.<sup>214</sup>

Given the strength of this public choice theory prediction, it is therefore not surprising that the Hatch-Waxman Act strongly resembles the situation presented by the enactment of the various copyright laws, in that its passage seems to be primarily the product of interest group lobbying and negotiation.<sup>215</sup> Yet the interest group compromise aspect of the Act's passage is intriguing. Specifically, the branded pharmaceutical industry was unable to obtain a statute solely focused on patent term restoration. Further, because the originator and generic firms had opposing viewpoints on the ultimate statute, a process of negotiation ensued beyond any that would have needed to occur in the copyright context. The situation here is thus basically consistent with public choice theory when industry is conceived of broadly, but when the regulated parties are examined more closely, the situation becomes more complicated.

### III. EXPLANATIONS AND APPLICATIONS

The foregoing analysis suggests that the standard public choice theory account of legislative enactment does not typically hold in the patent law space. Examining three major patent-related statutes of the last several decades, none of the histories surrounding their enactments quite match the situation observed in copyright law, in which the regulated industries have repeatedly colluded to pass copyright term extensions or other laws that strengthen their rights, such as the DMCA. Instead, the history behind legislative enactments in patent law reveals a more complex taxonomy of interest group involvement. In some cases, like with the FCIA, the relevant institution essentially does not even exist at the time the statute is passed, and joint executive-legislative cooperation propels the bill through the process. In cases like the Bayh-Dole Act, the regulated parties existed and their voices were considered in the lead-up to the Act's passage, but there is little historical evidence of a determinative role in the enactment of the statute. Moreover, the statute contains a range of concessions whose existence is inconsistent with the significant involvement predicted by public choice theory. In still other cases, like the Hatch-Waxman Act, industry is clearly the primary driver of the legislation, but the presence of industry groups on both sides of the Act leads to compromise. Yet in all three cases, a traditional public choice theory story explaining the enactment of the statute can be told—it simply lacks a grounding in reality.

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<sup>214</sup> H.R. REP. NO. 98-857, at 17 (1984).

<sup>215</sup> See *supra* notes 42–48 and accompanying text.

The remainder of this Article seeks to answer some of the questions posed by these case studies. In particular, this Part considers all three statutes together and identifies factors that might explain their enactment even in the absence of strong interest group pressure. It also suggests factors that might differentiate legislative enactments in the patent area, where the standard interest group account does not hold, from enactments in copyright law, where the account does hold. This Part then elaborates on one example of how consumer groups might use the insights developed in this Article to their advantage. Finally, this Part considers potential implications for public choice theory and intellectual property scholarship.

### *A. Explanations for Patent Legislation*

Given that something more than pure interest group willpower was needed in each of the above cases to drive the passage of the statute in question, it is first important to determine what factor or factors provided the additional activation energy needed before enactment. There are at least four potential factors to consider, and although the relationships between them are complex, they may have the potential to work synergistically to drive legislative action.

*Historical Context.* — First and perhaps most obviously, the examples described in the previous Part may be direct results of the particular historical circumstances surrounding their enactment. All three statutes percolated through Congress and the executive branch at nearly the same time. In the post-World War II period, the advent of the National Science Foundation<sup>216</sup> in 1950 and growth of the National Institutes of Health had “brought the U.S. federal government into extensive technological cooperation with private industry and universities.”<sup>217</sup> But by the time of the Cold War, concerns about the United States’ ability to compete in the global market were at their height.<sup>218</sup> American policymakers were conscious of “the success of the Ministry of International Trade and Industry (‘MITI’) in coordinating the industrial strategy of Japan. Political and economic leaders everywhere were looking to see how they could encourage MITI-like sources of direction for

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<sup>216</sup> The National Science Foundation’s establishment is codified at 42 U.S.C. § 1861 (2012).

<sup>217</sup> Scherer, *supra* note 142, at 180.

<sup>218</sup> See Gulbrandsen, *supra* note 169, at 1149 (“At the time, the United States was suffering from a slide into industrial irrelevance in an increasingly global marketplace.”); see also Meador, *supra* note 112, at 615 (“There was growing concern that the United States might be lagging behind other industrial nations and that steps should be taken to induce more innovation.”).

industrial strategy but without the invasiveness of central planning agencies.”<sup>219</sup> Although the United States already had a “robust scientific infrastructure,” the idea was to “encourage an appropriate hand-off of scientific breakthroughs to the production and commercial sectors.”<sup>220</sup>

Relatedly, in 1978 President Carter had “launched a major domestic policy review on industrial innovation” through the Advisory Committee on Industrial Innovation, which made a series of recommendations about alterations to innovation policies.<sup>221</sup> Among the review’s ultimate recommendations were a Bayh-Dole-like suggestion that “commercial rights to government-supported research be transferred to the private sector”<sup>222</sup> as well as a Hatch-Waxman-like suggestion of “patent term restoration for pharmaceuticals and any other product that required regulatory review,”<sup>223</sup> a proposal supported by the Reagan Administration.<sup>224</sup>

Taking a further step back and considering the enactment of these statutes in light of the broader legislative and regulatory climate, beyond that relating to innovation alone, is similarly instructive. Specifically, these statutes were enacted against a larger backdrop of deregulation and privatization in issues regarding common carriers and public utilities.<sup>225</sup> For instance, the Airline Deregulation Act of 1978<sup>226</sup> aimed to “encourage, develop, and attain an air transportation system which relies on competitive market forces to determine the quality, variety, and price of air services.”<sup>227</sup> Regulation of these industries, which included railroads, airlines, and

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<sup>219</sup> Massaro, *supra* note 160, at 1730; *see also id.* at 1731 (“[O]ne of the more well-known examples of the discontinuity is the video cassette recorder. Ampex and one or two other American firms developed the basic concepts. Japanese firms then refined the concepts, took their product to the consumer market, and subsequently blew the American manufacturers out of the water on their way to achieving world dominance in the personal electronics industry.”).

<sup>220</sup> Massaro, *supra* note 160, at 1731.

<sup>221</sup> Mossinghoff, *supra* note 201, at 188; *see, e.g.*, UNITED STATES DEP’T OF COMMERCE, ADVISORY COMMITTEE ON INDUSTRIAL INNOVATION, FINAL REPORT (1979).

<sup>222</sup> Eisenberg, *supra* note 141, at 1689.

<sup>223</sup> Mossinghoff, *supra* note 201, at 188; *see also* H.R. REP. NO. 98-857 (Pt. II) at 3 (“Patent owners began to complain that the period of federal government regulatory review eroded the effective market life of their patents. This view was first formally voiced by President Carter’s Advisory Committee on Industrial Innovation.”).

<sup>224</sup> Mossinghoff, *supra* note 201, at 188.

<sup>225</sup> Merrick B. Garland, *Deregulation and Judicial Review*, 98 HARV. L. REV. 505, 507–08 (1985).

<sup>226</sup> Airline Deregulation Act of 1978, Pub. L. No. 95-504, 92 Stat. 1705 (codified as amended in scattered sections of 49 U.S.C.).

<sup>227</sup> *Id.*

electric companies,<sup>228</sup> was of course more stringent than general regulation of intellectual property.<sup>229</sup> Yet given the contemporaneous nature of the debates over deregulation, the economic thinking behind these deregulatory impulses was surely in the minds of lawmakers in both the executive and legislative branches as they drafted these patent statutes, each of which has the effect of giving more power to private entities.

The particular historical context of the time surely played some role in the enactment of the FCIA, Bayh-Dole Act, and Hatch-Waxman Act. What is unclear, however, is how large a role the historical context played. Daniel Meador suggests that the FCIA's "confluence with what was referred to as 'industrial innovations proposals'" from President Carter "carried [the Act] forward in the House, at least initially."<sup>230</sup> But how attributable this momentum was to the mood among Congressmen for ensuring American competitiveness or deregulating industry and how much to their respect for the considered proposals from the President is not clear.

*Legislative Entrepreneurship.* — Second, certain policy problems may provide particularly robust opportunities for legislative entrepreneurship,<sup>231</sup> in which Congressmen "invest time, staff, and other resources to acquire knowledge of particular policy areas, draft legislation addressing issues in those areas, and shepherd their proposals through the legislative process by building and maintaining coalitions."<sup>232</sup> As Daniel Meador phrased this concept in the executive branch context, "the extent to which the attorney general is successful in warding off improper political intrusions depends more than anything else on the character of the person holding the office."<sup>233</sup> From an economic perspective (and analogously to the logic underlying public choice theory), individual legislators should rarely if ever be incentivized to bear the costs of such investment themselves in any given policy area, as opposed to free riding on the efforts of other Congressmen. However, empirical evidence<sup>234</sup> suggests that legislators often are sufficiently motivated to advocate for change in patent-related areas, such that interest group pressures take a backseat to concerns

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<sup>228</sup> Kearney & Merrill, *supra* note 225, at 1327.

<sup>229</sup> For instance, although the government is the gatekeeper for the issuance of patents, it does not (generally) then tell patentees how much to charge for their goods or services.

<sup>230</sup> Meador, *supra* note 112, at 615.

<sup>231</sup> Robert A. Katzmann, *Making Sense of Congressional Intent: Statutory Interpretation and Welfare Policy*, 104 *YALE L.J.* 2345, 2361 (1995) (reviewing R. SHEP MELNICK, *BETWEEN THE LINES: INTERPRETING WELFARE RIGHTS* (1994)).

<sup>232</sup> GREGORY WAWRO, *LEGISLATIVE ENTREPRENEURSHIP IN THE U.S. HOUSE OF REPRESENTATIVES 2* (2001).

<sup>233</sup> Meador, *supra* note 85, at 539.

<sup>234</sup> See generally WAWRO, *supra* note 232.

about the public interest or reelection prospects.<sup>235</sup> Henry Waxman's central role in many of the most important health-related legislation of the 1980s and 1990s, beyond even the cases discussed above, is certainly an example of this phenomenon.<sup>236</sup>

*Interest Group Alignment.* — One factor potentially distinguishing statutory change in the copyright context from statutory change in the patent field is the character and positions of the various interest groups. In the copyright context, the content creators are still essentially monolithic.<sup>237</sup> The RIAA, MPAA, and other related organizations have quite similar views about the kind and amount of protection they would like to receive for their members. Their ability to stand united behind a given protection-increasing measure functionally increases the pressure on Congress and thus the likelihood that the measure will become law.<sup>238</sup> But interest groups in patent law are more heterogeneous, with their perspectives on patent law dividing along (and even within) technological lines. Pharmaceutical companies “rely heavily on the patent system to maximize the return on their considerable investment in new product development,” due to “the nature of small molecule chemistry and considerable expense of drug development,” while software firms “have less interest in long patent terms, as product cycles and dubious incentive function of patents make patents more likely to serve as obstacles than to provide incentives for innovation.”<sup>239</sup> Empirical studies have borne out this divergence,<sup>240</sup> but

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<sup>235</sup> At least one study of the House of Representatives argued that without legislative entrepreneurship, “it is doubtful that the House could pass legislation.” *Id.* at 2.

<sup>236</sup> See generally HENRY WAXMAN, *THE WAXMAN REPORT: HOW CONGRESS REALLY WORKS* (2009) (discussing Representative Waxman's involvement in the passage of the Ryan White Act, Orphan Drug Act, and Nutrition Labeling and Education Act, among others); see also *id.* at xii (“The other guys always have more money. That's why Congress is so important. Run as it should be, it ensures that no special interest can ever be powerful enough to eclipse the public interest.”).

<sup>237</sup> See, e.g., Paul J. Heald, *American Corporate Copyright: A Brilliant, Uncoordinated Plan*, 12 J. INTELL. PROP. L. 489, 489 (2005).

<sup>238</sup> To be sure, the views of the RIAA, MPAA, and other organizations are not precisely identical, and the character of the statute (see *infra*) has a key role to play in this area. Negotiation may still be required, Litman, *Legislative History*, *supra* note 42, at 862, but the parties in the copyright space are still far closer than are the parties in the patent space.

<sup>239</sup> Morriss & Nard, *supra* note 48, at 168 (2011); see also WILLIAM M. LANDES & RICHARD A. POSNER, *THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW* 312 (2003) (“Many highly progressive, research-intensive industries, notably including the computer software industry, do not rely heavily on patents as a method of preventing free riding on inventive activity.”).

<sup>240</sup> See Wesley M. Cohen, Richard R. Nelson, & John P. Walsh, *Protecting Their Intellectual Assets: Appropriability Conditions and Why US Manufacturing Firms Patent (or Not)* (2000) (NBER Working Paper 7552) (surveying different industries and finding

admittedly, it appears to be a relatively recent development<sup>241</sup> and thus it cannot explain why the lack of such a conflict earlier in the twentieth century did not lead to more patent-protective legislation at that time. As an additional note, the fact that a given interest group is present or absent plays a critical role here: a statute establishing a formally absent interest group will likely never be explained on strong public choice grounds.

*Statutory Character.* — A second factor distinguishing the patent and copyright contexts is the character and appearance of each statute. Specifically, the copyright statute contains many technology- and situation-specific rules and exceptions, whereas the majority (although certainly not all<sup>242</sup>) of the patent statute is written in more general terms that formally apply across technologies.<sup>243</sup> As Jessica Litman puts it, the copyright statute “seems on its face to have been drafted primarily for the benefit of people with ready access to copyright counsel. It is long, complicated, counterintuitive and highly specific.”<sup>244</sup> Professors Dan Burk and Mark Lemley opine that the “bloated, impenetrable” Copyright Act “reads like the tax code.”<sup>245</sup> Burk and Lemley note the comparative simplicity of the patent statute<sup>246</sup> and encourage patent law to avoid adopting the model used by the copyright statute, as “[t]echnology-specific patent legislation will encourage rent-seeking by those who stand to benefit from favorable legislation.”<sup>247</sup> Of course, the Hatch-Waxman Act is one such technology-specific statute.

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that the pharmaceutical industry relies more heavily on patent rights than do other industries).

<sup>241</sup> Morriss & Nard, *supra* note 48, at 168 (“[I]n the late eighteenth and much of the nineteenth century, there were no such distinct industry-specific positions on patent law.”).

<sup>242</sup> See, e.g., Burk & Lemley, *supra* note 49, at 1637 & n.218 (listing sections).

<sup>243</sup> *But see id.* at 1577 (“[D]espite the appearance of uniformity, patent law is actually as varied as the industries it seeks to foster.”).

<sup>244</sup> Litman, *Technological Change*, *supra* note 42, at 23; see also Jessica Litman, *The Exclusive Right to Read*, 13 CARDOZO ARTS & ENT. L.J. 29, 34 (1995) (“The current copyright statute weighs in at 142 pages.”).

<sup>245</sup> Burk & Lemley, *supra* note 49, at 1638.

<sup>246</sup> *Id.* at 1637. In fact, Burk and Lemley ascribe the patent statute’s simplicity at least in part to the interest group conflict articulated above. *Id.* (“Patent law has some balance today in part because different industries have different interests, making it difficult for one interest group to push through changes to the statute.”). The mechanism of action behind their supposition, however, is not clear. Burk and Lemley do not explain how the interest group conflict in patent law prevents one interest group from enacting an interest-group-specific protectionist measure like those seen in the context of copyright. They do, though, explain why an expenditure of time on such efforts might be wasteful, given the pace of technological progress.

<sup>247</sup> *Id.* at 1637; see also *id.* (“Industry-specific legislation is much more vulnerable to industry capture.”).

The fact that public choice theory appears to hold weakly where the statute is phrased in general terms does not necessarily require that public choice theory will hold strongly where a statute is phrased in technology-specific terms. Yet, assuming that the various industry groups will be unable to convert the generally phrased patent statute into one more closely resembling the situation-specific copyright statute,<sup>248</sup> these two factors might explain why there has been more legislative activity in copyright law as compared with patent law. Particularly when considered together, it seems intuitive that protectionist measures in a context of monolithic interest groups and technology-specific statutes would both arise and succeed in their passage more often than in a context of sharp divisions within interest groups and a generally phrased statute. Instead, though, interest group conflict over an issue and the precise character of a given statute may create room for political activity of various kinds, as described above.

The foregoing is not merely an empty exercise in speculation: the four factors identified herein present testable hypotheses. Although historical context is admittedly difficult to assess during a given moment in time, retrospective examinations of various patent statutes might seek to explain the process of their enactments as artifacts of a particular national mood. The actions of Henry Waxman and other like-minded Congressmen also lend support to the legislative entrepreneurship factor. It is similarly unclear whether this factor may be predicted in advance, however—that is, we might be able to predict that different industries would take different perspectives on a proposed bill, but we might not be able to predict that any given (or even any) legislator would latch on to and promote that same bill. But the presence or absence of legislative entrepreneurship can at the very least be identified retrospectively. The confluence of the third and fourth factors might be studied in a comparative manner, as I alluded to above. Specifically, we would expect to see fewer, less extensive statutes enacted that achieve IP-protectionist purposes in fields where interest groups have diverging viewpoints about the substantive merits of any changes to the statute, particularly where the statute is framed in general terms that would force these incongruous interests to compromise, as compared to fields where interest groups are essentially united in their views and even then have the additional opportunity to customize their protection to their specifications, minimizing the need for negotiation and compromise. Given the pace of copyright expansion over the past thirty years as compared to the pace of patent expansion, these factors seem to be based in reality.

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<sup>248</sup> This may be a significant assumption. See *infra* notes 266–267.



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The Leahy-Smith America Invents Act<sup>249</sup> (AIA) may present one such example for retrospective (though nearly contemporaneous) consideration of these factors. From a historical perspective, the financial crisis and resurging fears about America's global competitiveness may have helped catalyze the passage of the AIA, particularly where the interventions of patent scholars, industry, and a few Congressmen had failed previously. The general character of the legislation as largely procedural and as applying across industries, as well as the observed fault lines within and across industries, may have similarly helped. At any rate, it appears that the AIA was the result of considered, thoughtful legislative action conducted in dialogue with the executive and judiciary, rather than of slavish adherence to interest groups.<sup>250</sup>

From a predictive standpoint, another potential example might be the case of patent trolls. Although efforts to curtail what practicing entities view as trolls' abusive litigation practices have popped up in both the legislative and executive branches over the past decade or even more, attention to the issue may be reaching a critical mass. President Obama has announced several executive orders designed to ameliorate the situation,<sup>251</sup> but they are not sufficient to solve it. Congressmen have proposed a number of bills aiming to deter trolls, such as the Saving High-Tech Innovators from Egregious Legal Disputes Act (SHIELD)<sup>252</sup> or the Patent Abuse Reduction Act,<sup>253</sup> and one passed the House in December 2013 with wide bipartisan support.<sup>254</sup> None have yet become law, however, and in May 2014 Senator Leahy removed the issue of troll reform from the congressional agenda.<sup>255</sup> Still, here, the above four conditions would seem to be met, and thus legislative entrepreneurship might provide a sufficient

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<sup>249</sup> Pub. L. No. 112-29, 125 Stat. 284 (2011) (to be codified in scattered sections of 35 U.S.C.).

<sup>250</sup> See generally Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part I of II*, 21 FED. CIR. B.J. 435 (2011); Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part II of II*, 21 FED. CIR. B.J. 539 (2011).

<sup>251</sup> Edward Wyatt, *Obama Orders Regulators to Root Out "Patent Trolls,"* N.Y. TIMES, June 4, 2013, <http://www.nytimes.com/2013/06/05/business/president-moves-to-curb-patent-suits.html>.

<sup>252</sup> Saving High-Tech Innovators from Egregious Legal Disputes Act, H.R. 6245, 112th Cong. (2012).

<sup>253</sup> Patent Abuse Reduction Act, S. 1013, 113th Cong. (2013).

<sup>254</sup> Edward Wyatt, *House Bill Raises Bar for Suits Over Patents*, N.Y. TIMES, Dec. 5, 2013, <http://www.nytimes.com/2013/12/06/business/house-bill-raises-bar-for-suits-over-patents.html>.

<sup>255</sup> Edward Wyatt, *Legislation to Protect Against "Patent Trolls" Is Shelved*, N.Y. TIMES, May 21, 2014, <http://www.nytimes.com/2014/05/22/business/legislation-to-protect-against-patent-trolls-is-shelved.html>.

catalyst to push a helpful law through Congress. Troll litigation harms consumers as well as practicing entities, most obviously by preventing consumers from accessing new products when start-ups are the target of the suits<sup>256</sup> or by leading to increased prices when established companies externalize their litigation costs. Although the software and hard technology industries have generally come out against trolls, other technological sectors where troll litigation is comparatively rare at this time (like biotechnology) may be indifferent, and powerful trolls will exert (and have exerted<sup>257</sup>) their own pressure on the other side of the law.

Other questions regarding these factors still remain to be answered. Their effects should be isolated from each other and quantified, their interactions examined, and their prospective prediction capabilities assessed. Determining their relative contributions to legislative action or inaction would bolster the predictive power of public choice analysis.

### ***B. Applying Systemic Irregularities to Achieve Patent Reform***

Part I of this Article presented Professor Amy Kapczynski's contention that there is an "emerging countermobilization" to the strengthening of IP rights that has occurred over the last few decades.<sup>258</sup> This countermobilization has not yet included the enactment of IP-weakening legislation by the United States Congress, and at least some scholars have questioned whether such efforts would even be possible.<sup>259</sup> But this Article is more optimistic, suggesting a way forward for those seeking to affirmatively make change and weaken patent rights where they result in the most negative societal consequences.<sup>260</sup> By determining the valence of each of the four factors above in a given situation, advocates may be better able to target their interventions.

Specifically, for the most effective results, advocates should target their intervention in the political process to situations involving proposed IP-weakening provisions in which 1) the contemporary context reflects

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<sup>256</sup> David Segal, *How a Typical Patent Battle Took an Unexpected Turn*, N.Y. TIMES, July 13, 2013, <http://www.nytimes.com/2013/07/14/business/how-a-typical-patent-battle-took-an-unexpected-turn.html>.

<sup>257</sup> See, e.g., Andrew Ramonas, *Intellectual Ventures CEO Warns of Premature IP Reform*, BLOG OF LEGAL TIMES (Sept. 12, 2013, 03:33 PM), <http://legaltimes.typepad.com/blt/2013/09/intellectual-ventures-ceo-warns-of-premature-ip-reform.html>.

<sup>258</sup> Kapczynski, *supra* note 51, at 820.

<sup>259</sup> See Benkler, *supra* note 14, at 196.

<sup>260</sup> This Article's insights into related efforts in the copyright space, unfortunately, will be less helpful due to the valence of factors two and three in that context.

concern about dangers to consumers or businesses, particularly those stemming from overprotection,<sup>261</sup> 2) feelings about the provision differ amongst interest groups, 3) the proposed provision is a general one affecting large swathes of industry, and 4) a motivated legislator will not only support the legislation but also steward its passage through Congress. The combination of the first three factors will effectively “make room” for legislative entrepreneurship and public interest groups to prevail. As noted in the previous Section, legislation altering the ways in which nonpracticing entities proceed with litigation may be a ripe target for the involvement of consumer advocates.

Advocates should be realistically optimistic about the potential opportunities this theory creates for consumer groups to have their voices heard by Congress. It would be naïve to suggest that industry would somehow, magically, be unable to prevent the weakening of their IP, or that consumers would find it easy in any absolute sense to drive such legislation through Congress. Ultimately, the FCIA and Bayh-Dole Acts were both pro-patent statutes, even though they were constructed with relatively little input from the relevant interest groups involved.

### ***C. Implications for Public Choice Theory and Intellectual Property Scholarship***

The above case study analysis also has implications for scholarship in public choice theory and intellectual property. From a public choice theory standpoint, the recognition that public choice analysis should be deployed along a spectrum of interest group representation, in which interest groups are categorized not only by their presence or absence but also by their level of involvement in the legislation, can improve the precision with which public choice analyses are conducted. In particular, the category of statutes involving absent interest groups is woefully underrepresented in the literature.<sup>262</sup> Yet statutes creating entirely new interest groups are or at least should be among the most interesting, from a scholarly perspective, and these statutes would benefit from greater attention in the literature.

This Article also has implications for the debate over public choice theory and the appropriate scope of judicial review in the context of

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<sup>261</sup> See generally Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 *SCIENCE* 698 (1998); Note, *Diagnostic Method Patents and Harms to Follow-On Innovation*, 126 *HARV. L. REV.* 1370 (2013).

<sup>262</sup> See *supra* notes 74–78.

intellectual property legislation.<sup>263</sup> If judges should be engaged in higher levels of scrutiny when examining statutes that appear to be simple protectionism, then the appropriate scope of review of copyright statutes may be quite different than the scope of review of patent statutes. As one example, judicial expansion of the fair use doctrine might be justified, but perhaps judges should be more circumspect in examining similar defensive doctrines in patent law.

Finally, an issue that deserves much more attention than I am able to give it in this Article is the potential involvement of the executive in this area of law. Admittedly, executive involvement should be invoked cautiously. It is possible that various industry stakeholders have made the rational choice not to commandeer the legislative process, anticipating public criticism, and have instead attempted to secure concessions through the passage of follow-on regulations to these various statutes. One such example of this would be President Reagan's 1983 extension of the Bayh-Dole Act to large businesses by executive order.<sup>264</sup>

But the potential for an engaged Office of the Chief Economist at the PTO or for the Office of Science and Technology Policy to be an additional, public-spirited source of policy should not be overlooked. Clearly, the executive branch played at least some role in the passage of each statute analyzed above, and it played a significant role in the FCIA and Bayh-Dole contexts. Industry and Congress are not the only relevant actors anymore, and although the executive branch has historically served largely as a source of information about potential problems worthy of legislative action, it can do more. This Article is far from the first to suggest a broader policymaking role for the executive in the patent arena,<sup>265</sup> but it does provide examples of ways in which the executive and Congress might engage in productive policy dialogue.

#### IV. CONCLUSION

The foregoing analysis has challenged the conventional wisdom in the intellectual property literature. I have argued that public choice theory cannot explain the enactment of several important patent-related statutes. To be sure, this analysis is far from complete. Certain pseudo-patent statutes like the Semiconductor Chip Protection Act of 1984<sup>266</sup> or the Plant

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<sup>263</sup> See *supra* notes 22–24.

<sup>264</sup> See *supra* note 177.

<sup>265</sup> See, e.g., Burstein, *supra* note 25.

<sup>266</sup> Pub. L. No. 98-620, 98 Stat. 3347 (codified at 17 U.S.C. §§ 901–914 (2012)).

## THE NEW MODEL OF INTEREST GROUP REPRESENTATION IN PATENT LAW

Variety Protection Act of 1970<sup>267</sup> and individual patent extension laws<sup>268</sup> suggest that Congress is certainly capable of protecting particular industries. But the statutes that are most often referred to as expanding patentees' rights—the FCIA, the Bayh-Dole Act, and the Hatch-Waxman Act—cannot be so easily explained by public choice analysis. In categorizing interest group activity in the patent space and inductively establishing particular factors that might explain the pattern of legislation observed in this area, this Article sought to provide insight for consumers and scholars alike. For consumers looking to counter the seemingly inexorable slide toward ever-increasing patent protections of various kinds, this taxonomy and list of factors might have predictive value in permitting them to concentrate lobbying efforts in areas where they might have the greatest potential of actually effecting change. And for scholars of public choice theory and intellectual property law, this analysis suggests not only refinements to the public choice analysis, but also a new way to think about the legislative process for patent scholars.

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<sup>267</sup> Pub. L. No. 91-577, 84 Stat. 1542 (1970) (codified as amended in scattered sections of 7 and 28 U.S.C.).

<sup>268</sup> See generally Richard M. Cooper, *Legislative Patent Extensions*, 48 FOOD & DRUG L.J. 59 (1993).