

## PATENT CONFLICTS

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*Patent policy is typically thought to be the product of the Patent and Trademark Office, the Court of Appeals for the Federal Circuit, and, in certain instances, the Supreme Court. This simple topography, however, understates the extent to which outsiders can shape the patent regime. Indeed, a wide range of administrative actors can influence patent policy through the exercise of their regulatory authority and administrative power.*

*Although interventions into patent policy by nonpatent agencies predate the First World War, the patent office and the Federal Circuit have resisted attempts at regulation by outsiders, and the authority for such agencies to take patent-related action has rarely been clearly articulated. As a result, outside agencies sometimes avoid regulation. In other cases, nonpatent agencies pursue a policymaking process that is costly, inefficient, and requires resort to Congress or the Supreme Court. This is true even where patent-related regulation is critical to achieving an agency's clear mandate. This dynamic has the striking effect of shifting authority from nonpatent agencies to patent policymakers, thereby replacing a particular regulatory design with a patent's generic innovation-inducing incentive.*

*This article offers a novel description of the ways in which nonpatent agencies intervene in patent policy. In particular, it examines agency responses to conflicts between patent and other regulatory aims, uncovering a relative preference for complacency ("inaction") and resort to outside help ("indirect action") over regulation ("direct action"). The article thus offers agencies new options for facing patent conflict, including an oft-overlooked theory of agency authority for patent-related regulation. Such intervention and regulation by nonpatent agencies can be more efficient, and may give rise to a more context-sensitive patent regime that is better aligned with other regulatory goals.*

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## INTRODUCTION

Albert Einstein, a famous former patent clerk, was known to have described the patent office as a “worldly cloister.”<sup>1</sup> Nearly a century later, that description still seems apt. The patent office lies at the crossroads of vast and varied innovations in almost every field of inquiry, yet it can also evoke images of monastic patent examiners, removed from the practical uses of these new discoveries, attempting to interpret their strictures through application documents. Other administrative agencies, by contrast, regularly encounter patents in their applied contexts—and these agencies frequently find such patents to be in conflict with their own regulatory aims.

Consider, for example, the Federal Communications Commission (FCC). A cornerstone of the FCC’s mandate has been to ensure that the nation’s communications systems are used to protect the safety of life and property.<sup>2</sup> In service of this goal, the Commission recently issued a rule requiring that cellular phones automatically provide their current location to 911 operators,<sup>3</sup> concluding that the new standard could save thousands of lives annually.<sup>4</sup> Patent litigation, however, has unexpectedly threatened to interrupt the implementation of the regulation while promising to delay future 911 improvements.<sup>5</sup> Patent owners have alleged that several parties infringed their patents as a direct consequence of

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<sup>1</sup> WALTER ISAACSON, *EINSTEIN: HIS LIFE AND UNIVERSE* 78 (2007) (quoting a letter dated December 12, 1919 from Albert Einstein to his friend, Michele Besso).

<sup>2</sup> 47 U.S.C. § 151 (2012) (“[F]or the purpose of promoting safety of life and property through the use of wire and radio communications . . . there is created a commission to be known as the ‘Federal Communications Commission’ . . .”).

<sup>3</sup> That is, the rule requires the cell phone to provide its present location, as opposed to, for example, the billing address of the subscriber. See 47 C.F.R. § 20.18(h) (2008).

<sup>4</sup> See *Wireless E911 Location Accuracy Requirements, Third Further Notice of Proposed Rulemaking*, 29 FCC Rcd. 2374, 2388 (2014) (suggesting that further improvements could help save 10,120 lives).

<sup>5</sup> *Petition of Telecommunication Systems, Inc. for Declaratory Ruling and/or Rulemaking, Wireless E911 Location Accuracy Requirements*, FCC Docket No. 11-117 (filed July 24, 2012) (on file with author).

implementing the FCC's rule, and have sought injunctions that would prevent the purported infringers from carrying out the agency's mandate.<sup>6</sup> That is, a single set of patent rights undermines the agency's core responsibility to protect public safety.

This is a problem of a general form. Patent rights and policies collide with regulatory goals in contexts as varied as biotechnology, border control, communications, environmental protection, and tax.<sup>7</sup> The consequences of such conflict are significant. While a patent rule will typically establish a balance between patent owners and potential infringers, the effect is much more pronounced in areas of regulatory overlap. The choice between patent and an outside field of regulation establishes priority between bodies of law and shifts authority between policymaking institutions. Patent conflicts thereby operate both within the patent regime's home territory of innovation, as well as in non-innovation-specific policy domains, such as public safety, national defense, and competition.

Despite their importance, agency responses to such clashes vary widely. In some examples, the nonpatent agency does nothing at all: The FCC, for example, seems to have concluded that it does not hold the authority to require patent owners to license the patents implicated by the new 911 standards. In other instances, an agency will regulate only indirectly, through resort to Congress or the Supreme Court: The National Institutes for Health (NIH), for example, enlisted the support of the White House and the Department of Justice to oppose the Patent and Trademark Office (PTO) and seek Supreme Court review of DNA-related patents. Finally, nonpatent authorities sometimes, but sparingly, directly assert jurisdiction to regulate patent-related matters within the scope of their own authority: The Federal Trade Commission (FTC), for example, has targeted anticompetitive assertions of patent rights under its general mandate to sanction unfair methods of competition.

Nonpatent agencies thereby wield important—but only inconsistent— influence over the development of the patent regime. Where an agency declines to assert jurisdiction, a patent—or a general patent policy—can take on outsized influence relative to the nonpatent agency's existing policy design. For instance, the patents implicated in the FCC's 911 regulations have, by the FCC's inaction,

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<sup>6</sup> *E.g.*, Zoltar Satellite Systems, Inc.'s Opposition to Sanyo Defendants' Motion to Transfer to the Northern District of California at 3, *Zoltar Satellite Sys. v. LG Elecs. Mobile Comm'ns Co.*, 402 F. Supp. 2d 731 (E.D. Tex. 2005) (No. 2:05-CV-215 LED), 2005 WL 4143096 ("Zoltar charges that Sanyo and the other Defendants have willfully infringed and are continuing to willfully infringe [several patents] by [making and selling] cellular telephones . . . and equipping them with location features including E-911 as mandated by the FCC."); *see also* Zoltar Satellite Systems, Inc.'s Complaint for Patent Infringement at 6, *Zoltar Satellite Sys.*, 402 F. Supp. 2d 731 (No. 2:05-CV-215 LED), 2005 WL 1539665 (seeking injunction).

<sup>7</sup> *See infra* Table 1; Index.

assumed precedence over the standards promulgated by the Commission. The significant, and perhaps surprising, result of such agency inaction is to render the patent system's incentive to innovate a relatively more important catalyst for achieving the public safety goals embodied in the FCC's rule. And where agencies seek assistance from the courts or from Congress, the policymaking process may forfeit the agency's comparative advantages in expedience and expertise.

Despite the frequency, breadth, and importance of patent-nonpatent clashes, they have received only occasional scholarly attention. This article offers a novel account of such interagency interactions, drawing from a study of a varied set of conflicts between patent and other fields of regulatory law. Furthermore, this article examines questions of regulatory authority for nonpatent agencies' patent-related policies. Stated simply: What can (and what should) an agency do when a patent or a patent policy stands in the way of its regulatory aims? This study thus builds in part on previous work that has engaged in deep examinations of the particular relationships between a specific agency and a patent institution, such as the PTO or the Court of Appeals for the Federal Circuit,<sup>8</sup> and extends it to offer an integrated account of the varied ways in which nonpatent agencies approach patent matters.<sup>9</sup>

I argue that the default tendency to prioritize patent can undermine the policy choices of various nonpatent agencies, often without careful consideration of the consequences. Even when agencies take some action in response, they often prefer to act through Congress or the courts. But this imposes an "intolerable regulatory burden . . . one which [Congress] sought to escape by delegating administrative functions" to the agencies.<sup>10</sup> I therefore offer to expand the menu of options available to agencies in response to patent conflicts. In particular, where an alleged lack of jurisdiction has impeded direct agency action, I suggest reviving and expanding a theory of regulatory authority that would grant nonpatent agencies the ability to regulate patents that obstruct an objective. And where

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<sup>8</sup> E.g., Arti Rai, *Patent Validity Across the Executive Branch: Ex Ante Foundation for Policy Development*, 61 DUKE L.J. 1237, 1241 (2012) (exploring relationship between the PTO and the NIH) [hereinafter Rai, *Patent Validity*]; John F. Duffy, *The Federal Circuit in the Shadow of the Solicitor General*, 78 GEO. WASH. L. REV. 518, 519 (2010) (comparing the Federal Circuit and the Justice Department's Office of the Solicitor General).

<sup>9</sup> See Rai, *Patent Validity*, *supra* note 8, at 1240 (noting that "scholars have generally failed to explore the influence exercised by [agencies with more specialized expertise]" on patent litigation, and going on to explore this dynamic through the lens of DNA-related patents); Kali N. Murray, *The Cooperation of Many Minds: Domestic Patent Reform in a Heterogeneous Regime*, 48 IDEA 289, 293–94 (2008) (noting that "[s]tudies of agencies administering patent law have typically focused on the judicial oversight of *one* particular agency," and going on to study the relationship of other agencies, such as the FTC and the International Trade Commission, to patent).

<sup>10</sup> *United States v. Midwest Video Corp.*, 406 U.S. 649, 665 n.23 (1972).

agencies might turn to the courts or to Congress to effect change in patent doctrine, I argue instead in favor of an interagency approach towards patent adjudication at the PTO, and in patent policymaking more broadly, to help ensure that the policies implemented by primary patent policymakers are responsive to the input of outside agencies. Together, these options may yield results more consistent with a preferred approach to “the interaction of [federal] laws that bear on the same subject:” to the greatest extent possible, avoid allowing “one federal statute to preclude the operation of another,” and instead give effect to both.<sup>11</sup>

This Article proceeds in three Parts. The first sets the stage for patent conflicts through the microcosm of the clash between patent and antitrust, and focuses particularly on the institutional development and resolution of the specific policy conflict at the heart of the Supreme Court’s decision in *FTC v. Actavis*.<sup>12</sup> In particular, I examine the various ways in which the policy positions of two primary institutions of patent policy—the PTO and the Federal Circuit—curtailed the authority of the FTC to pursue anticompetitive conduct related to pharmaceutical patents. As the Part describes, the FTC eventually succeeded in restoring its authority to sanction this conduct, but only after multiple failed attempts at winning Supreme Court review and billions of dollars in consumer loss during the intervening years.

The second Part develops the larger phenomenon—beyond antitrust—of conflict between the regulatory aims of various administrative agencies and patent. In some cases, the conflict is between patent’s innovation-inducing goal and some competing regulatory imperative, such as public safety; the FCC’s new 911 standards provide an example of such conflict. In others, the clash regards competing visions of innovation; this is illustrated, for example, through the patent office’s practice of granting tax-strategy patents, and the Internal Revenue Service’s (IRS) desire to dampen innovation for tax-reduction strategies.<sup>13</sup>

This Part offers a new taxonomy for the various forms of agency responses to both such conflicts. In the first category of agency response, nonpatent regulators take no action to address the conflicting patent or patent policy. But where an agency does not act in the face of a patent conflict, it often falls short of its regulatory goals, or it is dependent on the patent mechanism to achieve its mandate. In the second category, nonpatent agencies seek assistance from Congress or the Supreme Court to fulfill a regulatory aim. But, as noted, resort to the Court or to Congress can be inefficient and inconsistent with the rationale for

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<sup>11</sup> *Pom Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2236–2238 (2014); *see also id.* at 2238 (allowing such preclusion “show[s] disregard for the congressional design” where the regulatory regimes can instead be made complementary).

<sup>12</sup> 133 S. Ct. 2223 (2013).

<sup>13</sup> *See infra* text accompanying note 114 (describing competing visions for innovation policy in the context of DNA-related patents).

delegating authority to the agency in the first instance. In a third category of agency response, nonpatent agencies rely on their existing authority to issue patent-related regulations. Such regulation avoids the problems of inconsistency and inefficiency described above, and may better balance the nonpatent agency's objective with the more general, and thus less tailored, incentive created by the patent laws. These three categories of responses to conflicting patents and patent policies can be simply and generally characterized as inaction, indirect action, and direct action. This taxonomy, along with the examples described in the first and second Parts, is summarized in *Table 1*.

*Table 1.*

Response Category	Agency
Inaction	FCC (911-related patents)
	EPA (emission control technology patents)
Indirect Action: <i>Supreme Court</i>	FTC (Hatch-Waxman Act)
	NIH (DNA patentability)
Indirect Action: <i>Congress</i>	IRS (tax strategy patentability)
	Department of the Navy (airplane patents)
Direct Action	FCC (network element patents)

Given the costs associated with common modes of addressing (and avoiding) conflict—inaction and indirect action—the article's third Part expands the toolkit available to nonpatent agencies. First, to the extent that a perceived lack of agency jurisdiction yields agency inaction, I argue that a congressional command to carry out a specific mandate carries with it the inherent authority to regulate patents implicated by the rule. That is, an agency may issue a patent-related regulation if it is "reasonably ancillary to the effective performance" of its existing statutory mandates, even if the agency lacks patent-specific authority.<sup>14</sup> Second, I argue in favor of greater policy coordination across the Executive Branch, and therefore offer some initial suggestions for improving cross-agency policymaking. In particular, I focus on the ability of nonpatent agencies to leverage newly-instituted patent review procedures in order to influence patent policy decisions.

The article's third Part concludes with a description of the considerations that may inform a nonpatent agency's decision to intervene. In particular, consistent with the observation that "patent law is technology-neutral in theory,

<sup>14</sup> *United States v. Sw. Cable Co.*, 392 U.S. 157, 178 (1968). *Southwestern Cable*, the theory of ancillary authority that it supports, and the applicability of such authority to instances of patent conflict, are described *infra* Part III.A.1.

[but] technology-specific in application,”<sup>15</sup> I argue that the intervention of outside agencies provides a legal basis for industry- and context-specific patent tailoring that draws upon an outside agency’s specialized expertise. Thus, when nonpatent agencies have a part to play, the resulting regime may better account for the broader “matrix into which patent cases fit.”<sup>16</sup>

## I. INTRODUCING PATENT CONFLICTS

The intersection of patent and antitrust provides a familiar terrain for the exploration of patent conflicts. The competing scopes of intellectual property rights and the antitrust laws have proved to be fertile grounds for research and legal development,<sup>17</sup> as scholars have long wrestled with the scope of a patent’s exception to the antitrust laws. Some have argued that the monopoly grant of a patent is absolute, while others have suggested exclusions that may be enforceable in antitrust.<sup>18</sup> In an important work on this relationship, Louis Kaplow hypothesized the effect of two “extreme doctrinal regimes” that could dictate the resolution of conflict between the patent and antitrust laws.<sup>19</sup> In one, the antitrust laws might “reign supreme,” with the practical effect of rendering any action by a patentee that violates the antitrust laws illegal, regardless of whether the action might be authorized by the patent’s right to exclude.<sup>20</sup> Alternatively, the patent laws might be thought to have absolute priority over the antitrust laws, thereby granting a patentee permission to use her patent to engage in anticompetitive behavior, so long as such behavior is within the patent’s scope.<sup>21</sup>

The Supreme Court penned the latest chapter to this long-running policy conflict in *FTC v. Actavis*, holding that agreements to settle infringement litigation that merely preserve—without extending—a patent’s term are subject to antitrust

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<sup>15</sup> Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1577 (2003).

<sup>16</sup> Rochelle Cooper Dreyfuss, *The Federal Circuit: A Case Study in Specialized Courts*, 64 N.Y.U. L. REV. 1, 54 (1989) [hereinafter Dreyfuss, *Case Study*].

<sup>17</sup> See, e.g., Louis Kaplow, *The Patent-Antitrust Intersection: A Reappraisal*, 97 HARV. L. REV. 1813 (1984); Martin J. Adelman, *Property Rights Theory and Patent-Antitrust: The Role of Compulsory Licensing*, 52 N.Y.U. L. REV. 977 (1977); see generally WARD S. BOWMAN, JR., *PATENT AND ANTITRUST: A LEGAL AND ECONOMIC APPRAISAL* (1973).

<sup>18</sup> Compare *FTC v. Actavis*, 133 S. Ct. 2223, 2231 (2013) (“[I]t would be incongruous to determine antitrust legality by measuring the . . . anticompetitive effects [of a settlement of pharmaceutical patent litigation] solely against patent law policy . . .”), with *id.* at 2238 (Roberts, C.J., dissenting) (“A patent carves out an exception to the applicability of antitrust laws.”).

<sup>19</sup> Kaplow, *supra* note 17, at 1818.

<sup>20</sup> *Id.*

<sup>21</sup> *Id.*



scrutiny.<sup>22</sup> That is, settlement agreements consistent with a patent's ostensible scope may nevertheless be illegal under the antitrust laws. The rule, as applied in *Actavis*, seems sensible: The agreements at issue arose under the Hatch-Waxman Act, which offers a "special incentive" for challenging weak pharmaceutical patents that inhibit competition.<sup>23</sup> The settlement agreements had the dual effect of shielding the weak patent from attack while simultaneously preserving the challenger's statutory incentive, thereby harming other competitors and reducing consumer welfare.<sup>24</sup> The FTC's targeted enforcement thus gave rise to a standard that is responsive to the particular innovation and competition needs of the pharmaceutical sector, and that is sensitive to the industry's governing regulatory regime.<sup>25</sup>

This particular clash provides a useful lens for viewing conflicts between patent policy and other fields of regulatory law more generally.<sup>26</sup> The competing policy aims of the patent and antitrust laws have sometimes put the PTO and the FTC at cross-purposes. Indeed, as described below, the litigation strategy that eventually provided the impetus for the Supreme Court's decision in *Actavis* provides more than just another illustration of the competing goals of the patent and antitrust laws. The case also highlights the institutional conflict between the agencies charged with giving effect to these clashing policies.

As the rest of this Part describes, the primary agents of patent policy—the PTO and the Federal Circuit—strongly resisted the possibility that antitrust scrutiny might apply within the scope of a patent's exclusionary grant. Such reticence may not be surprising, as the PTO and Federal Circuit have long been

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<sup>22</sup> 133 S. Ct. at 2227. The Supreme Court has long held that agreements that effectively extend a patent's term may be illegal under the antitrust laws. *See, e.g.,* *United States v. Singer Mfg.*, 374 U.S. 174, 196–97 (1963) (It is "well settled that the possession of a valid patent or patents does not give the patentee any exemption from the provisions of the Sherman Act beyond the limits of the patent monopoly."); *but cf. Kimble v. Marvel Ent.*, 135 S. Ct. 781 (2014) (mem.) (granting certiorari to review question whether royalty agreements that extend beyond the life of a patent should continue to be *per se* illegal).

<sup>23</sup> *Actavis*, 133 S. Ct. at 2228–29.

<sup>24</sup> *Id.* at 2234–37. (describing anticompetitive effects).

<sup>25</sup> *See* C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1617 ("[A] court can resolve pay-for-delay settlements in the pharmaceutical industry—a set of cases of great theoretical significance and practical importance—without reconsidering the relationship of antitrust and patent generally.').

<sup>26</sup> For other examples of the clash between patent and antitrust, compare *Brulotte v. Thys Co.*, 379 U.S. 29 (1964), with *Kimble*, 135 S. Ct. 781 (granting certiorari to determine whether to overrule *Brulotte*), and compare *Henry v. A.B. Dick Co.*, 224 U.S. 1 (1912), with *Motion Picture Patents Co. v. Universal Film Manufacturing Co.*, 243 U.S. 502 (1917) (overruling *A.B. Dick*). *See also* ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, *PATENT LAW AND POLICY: CASES & MATERIALS* (6th ed. 2013).

charged with exercising their authority to champion the aims of the patent laws at the expense of other regulatory goals.<sup>27</sup> The effect of such policymaking is striking: By elevating patent policy over competition regulation, the PTO and the Federal Circuit shift regulatory power to the patent laws while simultaneously constraining the ability of competition regulators to target conduct harmful to competition. Restoring this balance required several years, multiple petitions for a writ of certiorari, and a restructuring of alliances across the Executive Branch, during which time consumers suffered billions of dollars in losses.<sup>28</sup>

#### A. CONFLICT: PATENT POLICY AND FTC AUTHORITY

The Patent and Trademark Office has not traditionally held policy-setting authority comparable to most modern administrative agencies. The first lasting patent administration system—established shortly after the nation’s founding—set a strong precedent in favor of the judicial administration of patent policy.<sup>29</sup> Thus, when Congress introduced a gatekeeping system of patent examination in 1836, the statute left the agency charged with its administration without any significant policymaking authority.<sup>30</sup> Since then, the structure of patent examination has “remained largely unchanged.”<sup>31</sup> As a result, the PTO’s primary institutional role is to adjudicate patent applications and issue patents accordingly.

The PTO, however, occasionally offers policy guidance through the scope of litigation, given the importance of the judiciary in the development of patent policy.<sup>32</sup> For example, the litigation strategy that eventually culminated in the

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<sup>27</sup> See, e.g., Dreyfuss, *Case Study*, *supra* note 16, at 54 (noting likelihood that Federal Circuit will “overemphasize the need to reward inventors” and “undervalue the interest of competitors”); *but see infra* notes 292–295 and accompanying text (noting changes at the PTO that suggest it has moderated its stance more recently).

<sup>28</sup> See, e.g., FED. TRADE COMM’N, *PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS* (2010); see also Hemphill, *supra* note 25, at 1557.

<sup>29</sup> See Patent Act of 1793, ch. 11, § 1, 1 Stat. 318; see also Michael Burstein, *Rules for Patents*, 52 WM. & MARY L. REV. 1747, 1764 (2011) (It is “unsurprising that the courts would retain most of this [policymaking] role under the [1793] regime.”).

<sup>30</sup> Patent Act of 1836, ch. 357, § 7, 5 Stat. 117, 119–20.

Specifically, the newly-constituted patent office was endowed with the authority to examine patent applications to verify their novelty and utility. However, other than the power to prescribe procedures for the patent application and examination process, the patent office had practically no substantive authority. Indeed, if an application was found to have met the standards for patentability, the Patent Commissioner was statutorily obligated to issue the patent. *Id.* This standard continues to govern the PTO’s administrative authority.

<sup>31</sup> Burstein, *supra* note 29, at 1761.

<sup>32</sup> See, e.g., U.S. PATENT & TRADEMARK OFFICE, *PERFORMANCE AND ACCOUNTABILITY REPORT FISCAL YEAR 2013 38–39* (“The USPTO strongly influences IP law and policy through domestic litigation, both as a party and as an *amicus curiae* . . . .”); U.S. PATENT & TRADEMARK OFFICE,

*Actavis* decision included several distinct antitrust cases across the country. Among these was *Schering-Plough Corp. v. FTC*.<sup>33</sup> As was true with several cases prior to the Supreme Court's decision in *Actavis*,<sup>34</sup> the FTC (or the private antitrust plaintiff) lost: The Eleventh Circuit concluded that the test for legality did not hinge on antitrust's usual standard—the “rule of reason”<sup>35</sup>—but rather upon “the extent to which the agreements exceed th[e] scope” of the patent.<sup>36</sup> According to the court, the only salient question under antitrust law was the ostensible scope of the grant under the patent laws. The FTC sought Supreme Court review of the decision. But because the FTC's petition for a writ of certiorari was submitted under its independent litigation authority, the Court asked the Solicitor General to offer its views on the case.

After consulting with the Patent and Trademark Office,<sup>37</sup> the Solicitor General recommended that the Supreme Court deny the petition for certiorari, arguing that “the statutory right of patentees to exclude competition within the scope of their patents[] would potentially be frustrated by a rule of law that subjected patent settlements involving reverse payments to automatic or near-

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PERFORMANCE AND ACCOUNTABILITY REPORT FISCAL YEAR 2006 47 (similar) [hereinafter *2006 PTO Annual Report*].

<sup>33</sup> 402 F.3d 1056 (11th Cir. 2005).

<sup>34</sup> *But see In re K-Dur Antitrust Litig.*, 686 F.3d 197, 218 (3d Cir. 2012) (ruling for the FTC and giving rise to a circuit split leading to Supreme Court review in *Actavis*). Although the courts of appeals often ruled against the FTC or private antitrust plaintiffs, their decisions, in contrast to the Federal Circuit's decision discussed *infra*, exhibited a notable amount of consternation at the result the courts sometimes felt compelled to reach. *See, e.g., Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 808–810 (D.C. Cir. 2001) (affirming dismissal on procedural grounds, but noting anticompetitive effects); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 221–232 (2d Cir. 2006) (Pooler, J., dissenting); *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908–09 (6th Cir. 2003) (sanctioning patent-related conduct because it reached outside the patent's formal scope). In addition to these cases, the Eleventh Circuit had, before deciding *Schering-Plough*, crafted a more comprehensive test that required “consideration of the scope of the exclusionary potential of the patent, the extent to which these provisions of the [a]greements exceed that scope, and the anticompetitive effects thereof[]” and directed courts to consider “the likelihood of [the patent holder] obtaining such protections” through their settlement agreement. *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1312 (11th Cir. 2003). On remand, the plaintiff won. *See In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279 (S.D. Fla. 2005).

<sup>35</sup> *See, e.g., Leegin Creative Leather Prods. v. PSKS, Inc.*, 551 U.S. 877 (2007) (“The rule of reason is the accepted standard for testing whether a practice restrains trade in violation of § 1 [of the Sherman Act]”)

<sup>36</sup> *Schering-Plough*, 402 F.3d at 1065–66 (citation omitted).

<sup>37</sup> *2006 PTO Annual Report*, *supra* note 32, at 47 (“[T]he USPTO gave input to the Solicitor General's Office, and the Solicitor General's Office in turn filed a brief recommending against *certiorari*.”); *see also* Brief for the United States as Amicus Curiae at 1, *FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2006) (No. 05-273), 2006 WL 1358441 (recommending against granting certiorari).

automatic invalidation.”<sup>38</sup> This recommendation was consistent with the PTO’s general position (at that time) that “competition regulators” be “cautious in assuming that Congress automatically intends the distinctive policies of antitrust laws to trump those underlying the intellectual property system.”<sup>39</sup> To be sure, the Solicitor General’s amicus brief also highlighted a number of factual conditions that militated against Supreme Court review in *Schering-Plough*. But to the extent the distinct submissions by agents of the government conflict on policy grounds, they express a clash between the institutions of the patent and antitrust laws.<sup>40</sup>

This difference is indicative of the then-prevailing visions of innovation policy held at the FTC and the PTO. For example, the PTO argued in a hearing held by the FTC that “suspicion” of patent rights by “competition regulators” would “interfer[e] with these market-based incentives to innovation.”<sup>41</sup> By contrast, the FTC report that emerged from those hearings sharply suggested that the PTO and the Federal Circuit would “benefit from much greater consideration

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<sup>38</sup> Brief for the United States, *supra* note 37, at 10–11.

<sup>39</sup> Fed. Trade Comm’n, *Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy*, Public Hearing, at 23 (Feb. 6, 2002) (statement of James E. Rogan, Dir., U.S. Patent & Trademark Office) available at [http://www.ftc.gov/sites/default/files/documents/public\\_events/competition-ip-law-policy-knowledge-based-economy-hearings/020206ftc.pdf](http://www.ftc.gov/sites/default/files/documents/public_events/competition-ip-law-policy-knowledge-based-economy-hearings/020206ftc.pdf).

<sup>40</sup> The Solicitor General’s position has previously been framed as a consequence of disagreement between the FTC and the DOJ’s Antitrust Division. However, the recommendation in the amicus brief may be better explained by the input of the PTO. That is, the Solicitor General’s position is more suggestive of disagreement between patent and competition regulators (the FTC and the PTO), rather than of conflict between two different antitrust enforcement agencies (the FTC and the DOJ). Compare Gregory Dolin, *Reverse Settlements as Patent Invalidity Signals*, 24 HARV. J.L. & TECH. 281, 310 (2011) (suggesting that the Solicitor General’s brief was evidence of “a very different approach” at the Antitrust Division), and Harry First, *Controlling the Intellectual Property Grab: Protect Innovation, Not Innovators*, 38 RUTGERS L.J. 365, 391–92 (2007) (*Schering-Plough* provides a “clear example of the difference between the . . . Justice Department [Antitrust Division] and the FTC . . .”), with Brief for the United States, *supra* note 37, at 8 (“[S]uch settlements may pose a risk of restricting competition . . . to the detriment of consumers.”), and David L. Meyer, *We Should Not Let the Ongoing Rationalization of Antitrust Lead to the Marginalization of Antitrust*, 15 GEO. MASON L. REV. 1175, 1186 (2008) (originally presented at the George Mason Univ. Law Ann. Symposium, October 31, 2007) (noting that courts “went too far in giving holders of patents of uncertain validity carte blanche to enter agreements restraining competition under the guise of a patent settlement.”); see also C. Scott Hemphill, *An Aggregate Approach to Antitrust*, 109 COLUM. L. REV. 629, 661 & n.131 (2009) (citing this evidence of “convergence” between FTC and DOJ).

<sup>41</sup> Fed. Trade Comm’n, *Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy*, Public Hearing, at 23–24 (Feb. 6, 2002) (statement of James E. Rogan, Dir., U.S. Patent & Trademark Office) available at [http://www.ftc.gov/sites/default/files/documents/public\\_events/competition-ip-law-policy-knowledge-based-economy-hearings/020206ftc.pdf](http://www.ftc.gov/sites/default/files/documents/public_events/competition-ip-law-policy-knowledge-based-economy-hearings/020206ftc.pdf).

and incorporation of economic insights” in their attempts “to find the proper balance between patent and competition law.”<sup>42</sup>

Indeed, the FTC’s efforts to define an appropriate border between patent and antitrust were directed not only at the PTO, but were also aimed at the Federal Circuit.<sup>43</sup> But as it did with the PTO, the FTC found its efforts frustrated before the specialized appellate court.

The Court of Appeals for the Federal Circuit is generally considered to be “the most important expositor of the substantive law of patents.”<sup>44</sup> That is, the substantive policymaking authority that the PTO lacks has been located instead at the Federal Circuit. That policymaking authority was once diffused across the judiciary, but concerns regarding inconsistent adjudications and concomitant forum shopping caused Congress to consolidate appellate patent jurisdiction within a single court, noting that several benefits would flow from the “centralization of patent appeals,” including uniformity and expertise.<sup>45</sup> Critics, however, have argued that the Federal Circuit’s narrow emphasis on patent law has caused it to “overemphasize the need to reward inventors” while simultaneously “undervalu[ing] the interest of competitors.”<sup>46</sup> Thus, the Federal Circuit, as the PTO before it, has been charged with espousing a policy view that favors patent at the expense of broader competition policies.

This tendency manifested in *In re Ciprofloxacin Hydrochloride Antitrust Litigation*,<sup>47</sup> one of the cases preceding the Supreme Court’s decision in *Actavis*. Although antitrust litigation is typically appealed to a regional court of appeals rather than to the Federal Circuit, portions of *In re Ciprofloxacin* were transferred to the Federal Circuit because they included state-law claims that were preempted

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<sup>42</sup> FED. TRADE COMM’N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY 17 (2003).

<sup>43</sup> *See id.*

<sup>44</sup> Burstein, *supra* note 29, at 1757 (2011); *see also* Ryan Vacca, *Acting Like an Administrative Agency: The Federal Circuit En Banc*, 76 MO. L. REV. 733, 734 (2011); Craig Allen Nard, *Legal Forms and the Common Law of Patents*, 90 B.U. L. REV. 51, 53 (2010); Arti K. Rai, *Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform*, 103 COLUM. L. REV. 1035, 1041 (2003) (“Congress has delegated policymaking responsibility in patent law to the judiciary.”) [hereinafter Rai, *Facts and Policy*].

<sup>45</sup> H.R. REP. NO. 97–312, at 23 (1981); S. REP. NO. 97–275, at 6 (1981) (the act benefits from “the selective benefit of expertise in highly specialized and technical areas”) (citation omitted). But there are downsides to such expertise and uniformity. *See, e.g., infra* notes 262–265 and accompanying text.

<sup>46</sup> Dreyfuss, *Case Study, supra* note 16, at 54.

<sup>47</sup> 544 F.3d 1323 (Fed. Cir. 2008).

by federal patent law.<sup>48</sup> But the Federal Circuit's opinion in *Ciprofloxacin* did more than adjudicate the questions arising under the federal patent laws: In stark contrast to the court's accepted practice of applying regional circuit law to pendent nonpatent claims, including antitrust claims,<sup>49</sup> the Federal Circuit developed its own line of jurisprudence to hold that the patent laws trumped antitrust.<sup>50</sup>

Notably, the Federal Circuit explicitly rejected the arguments advanced by the FTC in its amicus brief to the court. The FTC primarily argued that the patent laws do not "immunize from antitrust scrutiny any agreement by a patent holder . . . to pay a potential rival to abandon competition . . . so long as the exclusionary terms are within the nominal scope of the patent."<sup>51</sup> Rejecting this contention, the Federal Circuit held flatly that a "settlement is not unlawful if it serves to protect that to which the patent holder is legally entitled."<sup>52</sup>

Such a ruling assumes the answer to the question presented, as the scope of the "legal[] entitle[ment]" is precisely the operative issue.<sup>53</sup> Does the patent necessarily include an exception from the antitrust law? As the vast literature considering the competing scopes of patent and antitrust suggests, the answer to this question is not as obvious as the Federal Circuit intimated.<sup>54</sup> Indeed, because the PTO often grants patents later deemed invalid,<sup>55</sup> the FTC's amicus brief argued that a rule favoring "antitrust immunity" would "misconstru[e] the policies and

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<sup>48</sup> Ark. Carpenters Health & Welfare Fund v. Bayer AG, 604 F.3d 98, 103 n.10 (2d Cir. 2010) ("Because the [state law] *Walker Process* [antitrust] claims are preempted by patent law, we transferred the indirect purchaser plaintiffs' appeal to the Federal Circuit . . . ." (citation omitted)).

<sup>49</sup> E.g., *Cygnus Therapeutics Sys. v. Alza Corp.*, 92 F.3d 1153, 1161 (Fed. Cir. 1996); *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 875 (Fed. Cir. 1985) ("We must approach a federal antitrust claim as would a court of appeals in the circuit of the district court whose judgment we review.").

<sup>50</sup> *Ciprofloxacin*, 544 F.3d at 1333 (determining antitrust legality solely by whether the agreements were consistent with "exclusionary zone of the patent").

For evidence that the Federal Circuit developed its own line of jurisprudence, rather than follow regional circuit precedent, compare *id.* at 1332 (describing "the law of the Second Circuit"), with *id.* at 1333–1337 (developing its own rationale for prioritizing patent law over antitrust and eventually "agree[ing]" with other circuits, including the Second Circuit (rather than *applying* the law of the Second Circuit)). An alternative theory is that patent law itself compels the antitrust result—but if that were true, then all such cases (including, for example, *Schering-Plough*) should have fallen within the Federal Circuit's appellate jurisdiction. That these varied appeals were instead heard by several circuits, see *supra* note 34, suggests that the Federal Circuit developed its own rule of antitrust law (rather than apply an rule of patent law).

<sup>51</sup> Corrected Brief of Amicus Curiae Federal Trade Commission, In Support of Appellants and Urging Reversal at 14, *Ciprofloxacin*, 544 F.3d 1323 (No. 2008-1097), 2008 WL 644394.

<sup>52</sup> *Ciprofloxacin*, 544 F.3d at 1337.

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

<sup>54</sup> See, e.g., Adelman, *supra* note 17, at 977–78 ("The appropriate scope of [patent] rights . . . has long been a matter of some dispute . . .").

<sup>55</sup> Corrected Brief of Amicus Curiae Federal Trade Commission, *supra* note 51, at 19–20.

incentives” designed to promote innovation and competition in the pharmaceutical industry.<sup>56</sup> In contrast to the approaches of other circuits that seemed to struggle to reconcile allegations of anticompetitive effect with the patent’s statutory grant,<sup>57</sup> the Federal Circuit was fairly dismissive of the FTC’s argument, holding flatly that “any adverse anticompetitive effects within the scope of [a] patent c[an] not be redressed by antitrust law.”<sup>58</sup>

Thus, by understating the particular competition (and related access-to-health) policies that inhabit the Hatch-Waxman Act, the Federal Circuit concluded that the exclusionary potential of a patent—even of a patent that is likely invalid—subsumes any inquiry under the antitrust laws.<sup>59</sup> Indeed, the Federal Circuit’s opinion in *Ciprofloxacin* is representative of a pro-patent and formalistic bent that has sometimes been described as characteristic of these primary institutions of patent law.<sup>60</sup> The practical effect of the policies propped by the PTO and the Federal Circuit was to elevate the patent laws over competition enforcement, and thereby prevent the FTC from sanctioning anticompetitive conduct in the pharmaceutical industry.

## B. RESOLUTION: SUPREME COURT REVIEW

The development of the patent-antitrust jurisprudence at the PTO and the Federal Circuit contrasts sharply with the Supreme Court’s decision in *FTC v. Actavis*.<sup>61</sup> Although the Office of the Solicitor General supported the PTO in its opposition to the FTC’s petition for certiorari in *Schering-Plough*,<sup>62</sup> it reversed course (under a new administration) in *Actavis*. Indeed, the petition for certiorari in *Actavis* was jointly filed by the FTC and the Solicitor General,<sup>63</sup> and was far more

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<sup>56</sup> *Id.* at 14.

<sup>57</sup> See the cases cited *supra* note 34.

<sup>58</sup> *Ciprofloxacin*, 544 F.3d at 1333.

<sup>59</sup> See *id.* at 1336.

<sup>60</sup> See, e.g., Peter Lee, *Patent Law and the Two Cultures*, 120 YALE L.J. 2, 27 (2010); Rochelle Cooper Dreyfuss, *In Search of Institutional Identity: The Federal Circuit Comes of Age*, 23 BERKELEY TECH. L.J. 787, 809 (2008) (Federal Circuit engages in a form of legal reasoning that is “more characteristic of . . . the nineteenth century than the twenty-first.”); Rai, *Facts and Policy*, *supra* note 44, at 1106–07; see also Hon. Timothy B. Dyk, *Ten Prescriptions for What Ails Patent Law*, 17 STAN. TECH. L. REV. 345, 350 (2014) (“Examination would be easier in some cases if there were more bright-line rules in patent law.”).

<sup>61</sup> 133 S. Ct. 2223 (2013).

<sup>62</sup> See Brief for the United States as Amicus Curiae at 10–11, *FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2006) (No. 05-273), 2006 WL 1358441.

<sup>63</sup> According to the briefs filed with the Supreme Court, attorneys for both the FTC and the Office of the Solicitor General contributed to the petition of certiorari. The government’s brief on the merits of the case included attorneys from the FTC, as well as two divisions of the Department of Justice—the Office of the Solicitor General as well as the Antitrust Division. See Petition for a

solicitous of the FTC's prior position regarding the legality of settlements under the Hatch-Waxman Act. Where the Solicitor General once argued that the rights of patent holders could be "frustrated by a rule of law that subjected patent settlements involving reverse payments to automatic or near-automatic invalidation,"<sup>64</sup> it now argued that the "correct approach" was "to treat reverse-payment agreements as presumptively anticompetitive."<sup>65</sup>

Although Supreme Court did not adopt the government's proposed presumption, the decision in *Actavis* clearly rejects the notion that antitrust legality is to be measured "solely against patent law policy."<sup>66</sup> That is, in contrast to the Federal Circuit's recursive conclusion that a patent's legal entitlement includes, by definition, antitrust immunity, the Supreme Court made clear that "the 'scope of the patent monopoly'" is to be defined by *both* "patent and antitrust policies."<sup>67</sup>

While the Supreme Court's decision was critically important to the FTC's authority to target particular patent-related conduct harmful to competition, the extended policy and institutional conflict had significant and important costs. Eight years separated the FTC's decision to seek certiorari in *Schering-Plough* and the Supreme Court's decision in *Actavis*, and the consumer loss resulting from anticompetitive settlement practices during that time exceeded \$25 billion.<sup>68</sup>

Thus, while the possibility of nondeferential Supreme Court review is an important consequence of vesting patent policymaking authority within the judiciary, its effectiveness is limited, both by its bandwidth for important patent-related cases as well as by the efficiency with which those matters present to Court. To be sure, the Court has been increasingly active in patent-related matters,<sup>69</sup> and, as in *Actavis* and other cases, the incidence of interagency conflict may signal to that Supreme Court that review is warranted.<sup>70</sup> But these recent developments notwithstanding, Supreme Court review is an uncertain prospect at best, and is bundled with the significant costs of delay. The Supreme Court has decided less

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Writ of Certiorari, *FTC v. Watson Pharms., Inc.* 133 S. Ct. 787 (No. 12-416), 2012 WL 4750283; Brief for the Petitioner, *Actavis*, 133 S. Ct. 2223 (No. 12-416), 2013 WL 267027.

<sup>64</sup> Brief for the United States as Amicus Curiae, *supra* note 37, at 10–11.

<sup>65</sup> Petition for a Writ of Certiorari at 21–22, *FTC v. Actavis*, 133 S. Ct. 2223 (2013) (No. 12-416), 2012 WL 4750283; *see also id.* at 21 n.6 (acknowledging shift in position).

<sup>66</sup> 133 S. Ct. 2223, 2231 (2013).

<sup>67</sup> *Id.*

<sup>68</sup> FED. TRADE COMM'N, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 8 (2010) (estimating annual loss of \$3.5 billion dollars).

<sup>69</sup> *See, e.g.*, Timothy R. Holbrook, *Explaining the Supreme Court's Interest in Patent Law*, 3 IP THEORY 62, 62–63 (2013) ("Starting in around 2000, the Supreme Court became active, if not even hyperactive, in patent law.").

<sup>70</sup> As described *infra* note 126 and accompanying text, the petition for certiorari in a case regarding the patentability of isolated DNA explicitly highlighted a conflict between the PTO and the Department of Justice, and argued that such conflict made Supreme Court review necessary.



than 50 patent-related cases—of which *Actavis* is one—since the inception of the Federal Circuit<sup>71</sup> while the Federal Circuit decides over 500 patent cases in a single term.<sup>72</sup> All of this is to suggest that the decision in *Actavis* to police the boundary between patent and antitrust, and between the agencies charged with the exposition of these regimes, is an extraordinary event<sup>73</sup>—one that was a decade in the making, and involved the PTO, the FTC, the Department of Justice, several circuit courts including the Federal Circuit, and, finally, the Supreme Court.

## II. PATENT CONFLICTS AND AGENCY RESPONSES

The specific context of Hatch-Waxman litigation highlights several problems that can result from conflict between patent and other fields of regulation. And such conflict is not limited to the interaction of patent and antitrust. To the contrary, such clashes extend across several other areas of law, including communications, tax, environmental protection, and national defense. Although nonpatent agency responses to these conflicts vary significantly, they can be classified (and are discussed below) in three general categories: in some cases, agencies do nothing at all; in other cases, including *Actavis*, agencies seek the assistance of the Supreme Court or Congress; or, finally, agencies may directly address the conflict patent or policy themselves.<sup>74</sup>

The effects of each conflict are particularly acute because they present in overlapping regulatory space.<sup>75</sup> In a standard setting, a rule favoring patent holders merely alters the balance between potential patent owners and potential infringers (or other downstream users). But in the *Actavis* context, for example, the policies advanced by the PTO and accepted by the Federal Circuit had the distinct effect of shifting authority between institutions and entire bodies of law.

The choice of agency response to a clashing patent or policy thus has important implications for the competing administrative agency and its regulatory goals. In *Actavis*, the need for Supreme Court review had the striking effect of constraining the ability of competition regulators to pursue anticompetitive

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<sup>71</sup> See generally Lisa Larrimore Ouellette, *Supreme Court Patent Cases*, WRITTEN DESCRIPTION BLOG <http://writtendescription.blogspot.com/p/patents-scotus.html> (last visited July 2014).

<sup>72</sup> See ADMIN. OFFICE OF THE U.S. COURTS, STATISTICAL TABLES FOR THE FED. JUDICIARY, tbls. B-7, B-8 (June 2013).

<sup>73</sup> See Rebecca S. Eisenberg, *The Supreme Court and the Federal Circuit: Visitation and Custody of Patent Law*, 106 MICH. L. REV. FIRST IMPRESSIONS 28, 28 (2007) (likening the Supreme Court's relationship to patent law as that of a "a non-custodial parent who spends an occasional weekend with the kids" while analogizing the Federal Circuit to the "custodial parent").

<sup>74</sup> See *supra* Table 1; *infra* Index. With the exception of the Hatch-Waxman Act example discussed in Part I, all of the examples noted in Table 1 are described at length in this Part.

<sup>75</sup> See Jody Freeman & Jim Rossi, *Agency Coordination in Shared Regulatory Space*, 125 HARV. L. REV. 1131, 1135–36 (2012).

conduct during the intervening period, resulting in billions of dollars of consumer loss. Likewise, as described below, agency inaction and indirect action can have lasting effects on nonpatent policies. In total, the cumulative effect of these policy conflicts and the agency responses that have followed is a patent regime that has been influenced by an unexpectedly large network of actors—but one that also seems unprincipled, unpredictable, and inefficiently formed.

#### A. INACTION

The most straightforward agency response to a patent that impedes a regulatory objective is inaction. Faced with a patent or patent policy that blocks a regulatory goal, the agency may simply decide to stand down. The Food and Drug Administration (FDA), for example, has repeatedly declined to review assertions by pharmaceutical companies that certain products incorporate particular patents, citing a lack of substantive authority. This regulatory approach, however, has substantial deleterious effects on competition in the pharmaceutical industry.<sup>76</sup> Likewise, the FCC's response to patents essential to implementing its 911-related standards, and the Environment Protection Agency's (EPA) treatment of patented emission control technology, provide further examples of this approach.

##### 1. Public Safety Patents and the FCC

As noted in the Introduction, the FCC has required that cellular phones automatically provide their current location to 911 operators.<sup>77</sup> Despite the critical importance of these improvements to 911 systems, they have been delayed,<sup>78</sup> and an important contributing factor has been the potential for patent infringement liability for the telephone companies that are subject to the regulations.<sup>79</sup> Indeed, patent owners have plainly asserted that these companies infringe their patents as

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<sup>76</sup> This example is discussed at greater length *infra* notes 204–218 and accompanying text.

<sup>77</sup> That is, the rule requires the cell phone to provide its present location, as opposed to, for example, the billing address of the subscriber. See 47 C.F.R. § 20.18(h) (2008); see also Wireless E911 Location Accuracy Requirements, *Second Report and Order*, 25 FCC Rcd. 18,909 (2010).

<sup>78</sup> See Brian Fung, *Calling 911 from Your Cellphone in D.C.? Good Luck Getting First-Responders to Find You*, WASH. POST (July 10, 2014), <http://www.washingtonpost.com/blogs/the-switch/wp/2014/07/10/calling-911-from-your-cell-phone-in-d-c-good-luck-getting-first-responders-to-find-you/>.

<sup>79</sup> Telephone Interview with Tim Lorello, Senior Vice President, Telecommunications Systems, Inc. (Feb. 20, 2015); see also, e.g., Petition of Telecommunication Systems, Inc. for Declaratory Ruling and/or Rulemaking, Wireless E911 Location Accuracy Requirements, FCC Docket No. 11-117 (filed July 24, 2012) (on file with author).

a direct consequence of following the FCC's rules.<sup>80</sup> Furthermore, the patent holders have sought injunctions against the alleged infringers, which have had the practical effect of delaying—or blocking altogether—the deployment of technology essential to the regulation.<sup>81</sup>

In response, Telecommunications Systems, Inc. (TCS) (an agent of some of the telephone companies at issue) petitioned the FCC “to require that current [enhanced 911 systems] and [next-generation 911 systems] patents be licensed subject to [reasonable and nondiscriminatory] terms.”<sup>82</sup> That is, the telephone companies are seeking the ability to pay a reasonable royalty for the use of patented technology in connection with the FCC's regulation without the threat of patent litigation, infringement liability, and, most importantly, an injunction. But in reply, commenters have rebuffed the argument that the FCC has the authority to implement such a mandatory licensing requirement.<sup>83</sup> Even commenters “sympathetic” to the “general concepts presented in TCS's petition” have argued that the Commission “lacks authority” to do anything more than to consider the existence of patents and patent policies in its rulemaking process—that is, to consider whether it should avoid adopting a rule because of the possibility of obstructive patents.<sup>84</sup> If such patents are granted or become known only at a later date, however, the Commission is purportedly without authority to regulate in response. Thus, while the FCC has the authority to require “voice service provider[s] to provide 9-1-1 and enhanced 9-1-1 service” that meet Commission

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<sup>80</sup> *E.g.*, Zoltar Satellite Systems, Inc.'s Opposition to Sanyo Defendants' Motion to Transfer to the Northern District of California at 3, *Zoltar Satellite Sys. v. LG Elecs. Mobile Commc'ns Co.*, 402 F. Supp. 2d 731 (E.D. Tex. 2005) (No. 2:05-CV-215 LED), 2005 WL 4143096 (“Zoltar charges that Sanyo and the other Defendants have willfully infringed and are continuing to willfully infringe [several patents] by [making and selling] cellular telephones . . . and equipping them with location features including E-911 as mandated by the FCC.”).

<sup>81</sup> *E.g.*, Zoltar Satellite Systems, Inc.'s Complaint for Patent Infringement at 6, *Zoltar Satellite Sys.* 402 F. Supp. 2d 731 (No. 2:05-CV-215 LED), 2005 WL 1539665 (seeking injunction).

<sup>82</sup> Petition of Telecommunication Systems, *supra* note 5, at 2–3. The petition also asks the FCC to invoke 28 U.S.C. § 1498, discussed *infra* notes 162–169 and accompanying text, by confirming that any patent infringement that results from the implementation of these standards is “for the United States.” That is, TCS asks the FCC to bear the costs of any infringement concomitant to the implementation of the agency's new 911 standards.

<sup>83</sup> *See, e.g.*, Opposition of Qualcomm, Inc. to Telecommunication Systems, Inc.'s Petition for Declaratory Ruling and/or Rulemaking, FCC Docket No. 11-117 (filed Mar. 25, 2013); Comment of Cassidian Communications, Public Safety and Homeland Security Bureau Seeks Comment on Petition for Declaratory Ruling and/or Rulemaking Filed by Telecommunication Systems, Inc., FCC Docket No. 11-117 (filed Mar. 22 2013) (on file with author).

<sup>84</sup> *See generally* Comments of the Nat'l Emergency Number Ass'n, Facilitating the Deployment of Text-to-911 and Other Next Generation 911 Applications, Framework for Next Generation 911 Deployment, FCC Docket No. 11-153 (filed Dec. 2011) (on file with author).

standards,<sup>85</sup> these commenters suggest that this authority does not extend to require the licensing of patents that impede the ability to achieve this objective.

The FCC has taken no action in response to TCS's petition. Indeed, some evidence of the FCC's apparent view of its own authority might be found in other recent rulemakings. In setting standards to enable the "transmi[ssion of] emergency alerts" via cellular phone,<sup>86</sup> the Commission noted the importance of patent licensing to the fulfillment of the statutory objective. But it nevertheless explicitly concluded that imposing a requirement that patent holders commit to such licensing was "outside the scope" of its regulatory authority.<sup>87</sup>

Thus, while the FCC has declined to take a public position on the competing claims regarding its authority in the 911 context, its inaction on this petition and its statements in similar rulemakings are consistent with a view that it lacks the authority to regulate. The petition has remained pending for over two years, during which time the FCC has taken no substantive action.<sup>88</sup> Despite claims that patent infringement litigation will continue to plague the implementation of improvements to the nation's 911 system, including the Commission's latest proposal to implement a "text to 911" system,<sup>89</sup> the FCC has refrained from taking any patent-related regulatory action that would vindicate these public safety mandates.

The costs of the FCC's inaction are potentially significant. Nationwide, the Commission estimates that improved location-accuracy standards could save thousands of lives.<sup>90</sup> Even though some have argued that the Commission's public

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<sup>85</sup> New and Emerging Technologies 911 Improvement Act of 2008, Pub. L. No. 110-283, § 6, 122 Stat. 2620, 2620.

<sup>86</sup> 47 U.S.C. § 1201(a) (2012).

<sup>87</sup> Commercial Mobile Alert System, *First Report and Order*, 23 FCC Rcd. 6144, 6160 (2008); cf. Universal Encryption Standard for Satellite Cable Programming, *Report*, 5 FCC Rcd. 2710, 2711 (1990) (noting a patent holder's "contention, supported by legal analysis, that the Commission has no authority to compel patent licensing," but making "no finding on [the Commission's] authority to regulate" such licensing).

<sup>88</sup> The only official FCC action seems to be a Public Notice that seeks comment on the petition. See Public Notice, Docket No. 11-117 (Feb. 22, 2013).

<sup>89</sup> Reply Comments of Competitive Carriers Association at 8, *Facilitating the Deployment of Text-to-911 and Other Next Generation 911 Applications*, FCC Docket No. 11-153 (filed May 5, 2014) (warning that patent litigation will hold-up implementation of proposed text-to-911 rules); see also Press Release, Fed. Comm'ns Comm'n, FCC Adopts Rules to Promote Widespread Text-to-911 Availability (Aug. 8, 2014), available at [https://apps.fcc.gov/edocs\\_public/attachmatch/DOC-328755A1.pdf](https://apps.fcc.gov/edocs_public/attachmatch/DOC-328755A1.pdf).

<sup>90</sup> See Wireless E911 Location Accuracy Requirements, *Third Further Notice of Proposed Rulemaking*, 29 FCC Rcd. 2374, 2388 (2014).

safety standards should trump a patent's right to exclude,<sup>91</sup> the FCC has yet to take any patent-related action in the 911 or mobile emergency alert context. The result of such inaction is that patent law's preference for property rules has impeded progress towards the FCC's standards, and has thereby made the patent system's general incentive to innovate a relatively more important catalyst for public safety improvements than the FCC's own direct authority to require the achievement of prescribed public safety standards.<sup>92</sup>

## 2. Emission Control Technology Patents and the EPA

While FCC action may have been stymied by claims that it lacks the authority to issue patent-related regulation, other agencies, in rare instances, have clear jurisdiction to issue such orders.<sup>93</sup> Section 308 of the Clean Air Act, for example, explicitly authorizes the grant of a compulsory license for patents deemed necessary to comply with an EPA standard.<sup>94</sup> That is, where a patent's exclusionary right could impede the adoption of a clean air standard, the EPA may seek to convert the patent's property right into a simple liability rule.<sup>95</sup> But despite this explicit authority, the EPA has abstained from ever invoking it, even in cases where it may seem obvious to at least consider its applicability.

In 1992, the EPA considered regulating certain chemical emissions from existing dry cleaners.<sup>96</sup> In the course of its analysis, however, the EPA noted that one class of devices that could control toxic emissions was patented, and that these patents had deterred other vendors from selling competing devices (and thereby also dampened the likelihood of there being enough supply to meet the potential addressable market that new regulations would create). Concerned that the

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<sup>91</sup> See *supra* notes 82 and accompanying text; see also Jacob S. Sherkow, *Patent Infringement as Criminal Conduct*, 19 MICH. TELECOMM. & TECH. L. REV. 1, 24 (2012) [hereinafter Sherkow, *Criminal Conduct*].

<sup>92</sup> It is possible that, on net, the value to future innovation outweighs the public safety gains that might be incurred by requiring licensing. But that would be a reason for the FCC to decline to exercise its authority, not to determine that such action was outside its regulatory scope. Cf. Commercial Mobile Alert System, *First Report and Order*, 23 FCC Rcd. 6144, 6160 (2008).

<sup>93</sup> In addition to the example described in this section, see 42 U.S.C. § 2183 (2012) (granting similar authority to the Atomic Energy Commission).

<sup>94</sup> 42 U.S.C. § 7608 (2012); see also 40 C.F.R. § 95.1 *et seq.* (2015); Mandatory Patent Licenses Under Section 308 of the Clean Air Act, 59 Fed. Reg. 67,636, 67,636 (Dec. 30, 1994) (codified at 40 C.F.R. pt. 95).

<sup>95</sup> Specifically, the statute outlines a particular process necessary for the grant of a mandatory license. 42 U.S.C. § 7608.

<sup>96</sup> National Emission Standards for Hazardous Air Pollutants for Source Categories: Perchloroethylene Emissions from Dry Cleaning Facilities, 57 Fed. Reg. 45,363, 45,363–69 (proposed Oct. 1, 1992) (codified at 40 C.F.R. pt. 63); see also *Comment Sought on Two Unregulated Sources of Dry Cleaning Perchloroethylene Emissions*, 23 ENV'T REP. (BNA) 1542 (October 9, 1992).

proposed rules “could give rise to a monopoly market for hamper enclosures,” thereby trapping dry cleaners between deploying costly technology and facing EPA enforcement action, the Agency found itself “inclined to conclude that control of [toxic chemical] emissions . . . is not achievable within the meaning of the Act.”<sup>97</sup>

Notably, the EPA’s analysis completely overlooks the possibility of exercising its authority under Section 308 of Clean Air Act. Despite the fact that the proposed regulations “fall squarely within the scope of the statute’s compulsory license provision,” the EPA seems to have missed the possibility of exercising that authority to give effect to the statute’s goals.<sup>98</sup> Indeed, were the EPA to have exercised this authority, it would have known the precise rate that dry cleaners would have had to pay to implement the control technology, and could have avoided hypothesizing about the costs of the standard.

Thus, as in the FCC example, the price of inaction is significant. The EPA’s decision to regard a patented technology as unavailable is inconsistent with its own statutory authority, and further undermines Congress’s policy design. By declining to give effect to the policy embodied in the compulsory license provision, the development and adoption of clean air technology is contingent on the patent system’s general incentive to innovate, rather than on the EPA’s own standards. And to the extent that the patent system is not tailored to environmental protection technologies,<sup>99</sup> “the environment does not receive the full level of protection Congress envisioned when it enacted the statute.”<sup>100</sup>

## B. INDIRECT ACTION

In contrast to the decisions of the FCC and the EPA to abstain from regulation, several agencies have taken indirect action in response to a patent conflict. That is, these agencies have not refrained entirely from trying to resolve the conflict posed by patent, but neither have they regulated under their own authority. Instead, the examples described below highlight examples of agencies enlisting the support of outside actors—most notably the Supreme Court and Congress—to resolve the clash. The FTC’s approach in *Actavis*, described above,<sup>101</sup> provides one such example of such indirect action. Like the FCC, the FTC found itself faced with claims that its authority could not reach inside a patent’s ostensible scope. Unlike the FCC, however, the FTC enlisted the support of allies across the Executive Branch and won Supreme Court support for the view that patents are not categorically immune from antitrust scrutiny. That is, the FTC

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<sup>97</sup> National Emission Standards, 57 Fed. Reg. at 45,367.

<sup>98</sup> Paul Gormley, *Compulsory Patent Licenses and Environmental Protection*, 7 TUL. ENVTL. L.J. 131, 142 & nn.54–55 (1993).

<sup>99</sup> See Burk & Lemley, *supra* note 15, at 1577–78.

<sup>100</sup> Gormley, *supra* note 98, at 143.

<sup>101</sup> See *supra* Part I.

indirectly (*i.e.*, with Supreme Court and other Executive Branch assistance) gave effect to its view of its authority to sanction anticompetitive conduct. As described below, similar examples are found across agencies as varied as the NIH, IRS, and Department of the Navy.

### 1. DNA Patents and the NIH

An especially important example of indirect action arises in the context of the PTO's practice of granting patents for isolated DNA molecules—that is, “a DNA molecule excised from the genome and separated from its cellular environment.”<sup>102</sup> The question whether such molecules satisfied the Patent Act's basic requirement of patentability under Section 101 mimics, in many ways, the institutional conflict that gave rise to the Supreme Court's decision in *Actavis*. In both instances, a nonpatent agency disagreed with a position of the PTO and the Federal Circuit, and would eventually ally with the Solicitor General to seek—and win—Supreme Court review of the patent policy decision.

In 1995, the NIH, under the leadership of a new director, decided to withdraw its applications to patent certain gene fragments, known as “expressed sequence tags” (ESTs).<sup>103</sup> The newly-installed director noted that this decision was motivated by a concern that “patent clutter”—or the problem of overlapping and vague or speculative patent claims—“might well restrict progress” in genomic research.<sup>104</sup> That is, the NIH's position was informed by the “view . . . that widespread patenting of ESTs w[ould] pose some fairly serious problems.”<sup>105</sup>

But as Arti Rai has explained, the NIH's new tack was met with resistance at the PTO. In that same year, the PTO issued new guidelines “that were widely seen as lowering the utility threshold” for applications seeking to patent ESTs.<sup>106</sup> In response, the NIH warned that the PTO's new guidelines “would chill genomics research.”<sup>107</sup> But even as the NIH expressed its concerns with the PTO's new standard, the NIH claimed to have only little authority over the matter, noting that

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<sup>102</sup> Brief for the United States as Amicus Curiae in Support of Neither Party at 3, *Ass'n for Molecular Pathology v. Myriad Genetics*, 133 S. Ct. 2107 (2013) (No. 12-398), 2013 WL 390999.

<sup>103</sup> See Rai, *Patent Validity*, *supra* note 8, at 1249–1251. The ESTs at issue were found to be “associated with neurological function and disease.” *Id.* at 1249.

<sup>104</sup> Harold Varmus, *Government*, in *INTELLECTUAL PROPERTY RIGHTS AND RESEARCH TOOLS IN MOLECULAR BIOLOGY: SUMMARY OF A WORKSHOP HELD AT THE NAT'L ACAD. OF SCIS.*, FEB. 15–16, 1996, 66, 68 (Nat'l Res. Council ed., 1997) (quotation marks omitted).

<sup>105</sup> *Id.*

<sup>106</sup> Rai, *Patent Validity*, *supra* note 8, at 1251.

<sup>107</sup> *Id.*

the question of “what is legal” under the patent laws would ultimately depend on “decisions from either the judiciary or the Patent and Trademark Office.”<sup>108</sup>

Despite the NIH’s limited view of its own ability to influence patent policy, it continued to engage the PTO in a dialogue regarding the proper standard for the patentability of gene fragments. After a public back-and-forth between the agencies, as well as a behind-the-scenes “formal and informal discourse,” the PTO eventually offered some amendments to its standard for patentability. To be sure, the “NIH was not entirely happy” with the PTO’s new guidelines, but it nevertheless did offer some light praise for moving in a welcome direction.<sup>109</sup>

These new guidelines, however, concerned only two of the core patentability criteria. They defined what it meant for a patent to have utility under the Patent Act,<sup>110</sup> and they clarified how an application could meet the “written description” requirements of a patent.<sup>111</sup> The NIH’s successful, if not extended, exercise of soft intrabranch power,<sup>112</sup> foreshadowed the higher-stakes conflict in *Association for Molecular Pathology v. Myriad* regarding the question whether any isolated DNA molecule, including ESTs, could constitute patentable subject matter in the first instance.<sup>113</sup>

As noted above, the question whether isolated DNA molecules could satisfy the Patent Act’s Section 101 standard mirrors the tale preceding *Actavis*. The primary distinction between the examples is the underlying policy concern: *Actavis* implicated the conflict between antitrust and patent; *Myriad*, on the other hand, concerned balancing the PTO’s position to allow patents over “isolated DNA molecules,” against the rest of the Executive Branch’s belief that genomic research would benefit by “dissipating the shadow of infringement liability to the greatest extent possible.”<sup>114</sup> That is, this interagency dispute centered on competing visions of innovation policy itself (even if only for the narrower context of biotechnology).

In 2010, the PTO defended its practice of granting patents claiming isolated DNA molecules before the federal courts. In particular, the PTO argued that “isolated genes are chemicals” and such chemicals comprise patentable subject

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<sup>108</sup> Varmus, *supra* note 104, at 69.

<sup>109</sup> Rai, *Patent Validity*, *supra* note 8, at 1254–55 & n.71. Indeed, the higher threshold requirement for the patentability of gene fragments has, according to some commentators, aided in avoiding a severe anticommons problem in genomic research. *Id.* at 1255–56 & n.78.

<sup>110</sup> 35 U.S.C. § 101 (2012) (inventions must be “useful”)

<sup>111</sup> 35 U.S.C. § 112 (2012).

<sup>112</sup> See, e.g., J.R. DeShazo & Jody Freeman, *Public Agencies as Lobbyists*, 105 COLUM. L. REV. 2217, 2288–92, 2298–2300 (2005); Freeman & Rossi, *supra* note 75, at 1157.

<sup>113</sup> 133 S. Ct. 2107 (2013) (interpreting the scope of 35 U.S.C. § 101).

<sup>114</sup> Arti K. Rai, *Biomedical Patents at the Supreme Court: A Path Forward*, 66 STAN. L. REV. ONLINE 111, 114–15 (2013) [hereinafter Rai, *Path Forward*] (quotation marks omitted).



matter because their status as “isolated” renders them different from their state “as they are found in nature.”<sup>115</sup> The court, however, invalidated the patent claims, holding the molecules unpatentable under Section 101.<sup>116</sup>

On appeal to the Federal Circuit, the Department of Justice intervened and reversed the position asserted by the PTO at the district court. In its amicus brief, the government “acknowledge[d]” that its position was “contrary to the longstanding practice of the [PTO], as well as the practice of . . . government agencies that have . . . sought and obtained patents for isolated genomic DNA.”<sup>117</sup> Despite this past practice, however, the Department of Justice noted that the case “prompted the United States to reevaluate” this earlier conclusion.<sup>118</sup>

That the Executive Branch revisited the prior policy position, however, need not imply that all agencies had reached consensus, as the PTO “remained firmly behind its policy.”<sup>119</sup> Indeed, the PTO is noticeably absent from the Department of Justice’s amicus briefs to the Federal Circuit,<sup>120</sup> and some judges even suggested

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<sup>115</sup> Memorandum of Law in Support of Defendant United States Patent and Trademark Office’s Motion for Judgment on the Pleadings and in Opposition to Plaintiffs’ Motion for Summary Judgment at 20–24, *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181 (S.D.N.Y. 2010) (No. 09 Civ. 4515), 2009 WL 5785024. This distinction is important because products of nature have long been held to be unpatentable. *See, e.g., Diamond v. Chakrabarty*, 447 U.S. 303, 313 (1980) (“[T]he relevant distinction [for patentability questions] [i]s not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions.”).

<sup>116</sup> *Ass’n for Molecular Pathology*, 702 F. Supp. 2d at 229 (concluding that the “challenged composition claims are directed to unpatentable products of nature”).

<sup>117</sup> Brief for the United States as Amicus Curiae in Support of Neither Party at 18, *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011) (No. 2010-1406), 2010 WL 4853320.

<sup>118</sup> *Id.*

<sup>119</sup> Sandra S. Park, *Gene Patents and the Public Interest*, 15 N.C. J.L. & TECH. 519, 526 (2014).

<sup>120</sup> *See Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1357–58 (Fed. Cir. 2012) (Bryson, J., dissenting). The dissent is unusually candid about the possible intrabranch conflict:

[W]hatever force the PTO’s views on the issue of patent eligibility may have had in the past has, at the very least, been substantially undermined by the position the government has taken in this case. The Department of Justice has twice filed a brief on behalf of the United States in this court taking the position that Myriad’s gene claims (other than the cDNA claims) are not patent-eligible. Although the PTO did not “sign” the brief on either occasion and we are left to guess about the status of any possible continuing inter-agency disagreements about the issue, the Department of Justice speaks for the Executive Branch, and the PTO is part of the Executive Branch, so it is fair to conclude that the Executive Branch has modified its position from the one taken by the PTO in its 2001 guidelines and, informally, before that.

*Id.*

that it might have been appropriate for the PTO to file a separate brief dissenting from the position taken by the Department of Justice.<sup>121</sup>

The consolidated—if not consensus—view of the Executive Branch notwithstanding, the Federal Circuit reversed the decision of the district court and held the patents valid.<sup>122</sup> In particular, the Federal Circuit seemed to set aside the government’s official position that “patents on isolated but otherwise unmodified DNA would significantly impair the public’s ability to study and make use of genomic DNA,”<sup>123</sup> and instead offered its own policy justifications for granting and sustaining such patents.<sup>124</sup> That is, the Federal Circuit adopted the position consistent with the PTO’s vision for innovation policy, and (as in *In re Ciprofloxacin*) rejected the policy arguments of competing Executive Branch agencies.<sup>125</sup>

Having lost before the Federal Circuit, the plaintiffs sought review at the Supreme Court. Notably, the petition for certiorari highlighted the institutional clash and even argued that “the conflicting views of the PTO and the Department of Justice” proved the need for Supreme Court review.<sup>126</sup> The Court granted the petition for certiorari and, as before, the Department of Justice argued against

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<sup>121</sup> *Hear Oral Argument at 30:18–31:38, Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303 (Fed. Cir. 2013), available at [http://oralarguments.ca9.uscourts.gov/Audiomp3/2010-1406\\_7202012.mp3](http://oralarguments.ca9.uscourts.gov/Audiomp3/2010-1406_7202012.mp3) (questioning whether “the views of the United States” represent the “views of the Department of Commerce and, in particular, the PTO” and noting other cases, including *Tennessee Valley Authority v. Hill*, 437 U.S. 153 (1978), “in which different agencies have taken different positions” through “dissenting brief[s]”).

<sup>122</sup> *Ass’n for Molecular Pathology*, 689 F.3d at 1308–09 (“On the merits, we reverse the district court’s decision that Myriad’s composition claims to isolated DNA molecules cover patent-ineligible products of nature under § 101 . . .” (quotation marks omitted)).

<sup>123</sup> Brief for the United States as Amicus Curiae in Support of Neither Party at 10, *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303 (Fed. Cir. 2012) (No. 2010-1406), 2012 WL 2884115.

<sup>124</sup> *Ass’n for Molecular Pathology*, 689 F.3d at 1324–25 (noting that “patents on life-saving material and processes, involving large amounts of risky investment, would seem to be precisely the types of subject matter that should be subject to the incentives of exclusive rights” but conceding that was not “what this case was about” and was a “policy question[] best left to Congress”); see also *id.* at 1347 (Moore, J., concurring) (“Th[e] long-term policy of protecting isolated DNA molecules has resulted in an explosion of innovation in the biotechnology industry, an industry which . . . depends on patents to survive.”); Brief for the United States as Amicus Curiae in Support of Neither Party at 11, *Ass’n for Molecular Pathology v. Myriad Genetics*, 133 S. Ct. 2107 (2013) (No. 12-398), 2013 WL 390999 (noting that the “court of appeals also suggested that factors specific to the biotechnology industry supported a narrow view of the product-of-nature exception to patent-eligibility”).

<sup>125</sup> *In re Ciprofloxacin*, 544 F.3d 1323 (Fed. Cir. 2008), is discussed in greater detail *supra* Part I.A.

<sup>126</sup> Petition for a Writ of Certiorari at 21, *Myriad Genetics*, 133 S. Ct. 694 (2012) (mem.) (No. 12-398), 2012 WL 4502947.

patentability. Thus, to the chagrin of the PTO, the Office of the Solicitor General argued against the validity of the very patents that the patent office had granted. The Supreme Court's decision in *Myriad* adopted the government's position that isolated and unmodified gene fragments were "products of nature" and therefore unpatentable.<sup>127</sup>

All told, nearly two decades after the NIH first withdrew its applications to patent particular ESTs, the agency's position that gene-related patents (including ESTs) could "restrict" research progress had reached its apex.<sup>128</sup> But the NIH's success depended on Supreme Court review that was made possible only through a collection of allies across the Executive Branch, including the White House and the Department of Justice,<sup>129</sup> among others<sup>130</sup> that were willing to cross the PTO and the Federal Circuit.

## 2. Tax Strategy Patents and the IRS

As the FTC and the NIH turned to the Supreme Court for assistance in resolving patent conflicts, other agencies, including the IRS, have relied on congressional intervention. Consider the PTO's practice of granting patents over "tax strategies," or business methods intended to reduce an entity's tax liability. Such tax strategy patents were "apparently welcom[ed]" by the PTO beginning in 2003, and the agency created an entire sub-classification of patents dedicated to such methods.<sup>131</sup> In less than a decade, the PTO had granted over 100 such patents—yielding over 150 further applications for other tax reduction strategies.<sup>132</sup>

These patents, however, were not universally well-received. In 2006, the IRS noted several "concerns . . . regarding the patenting of tax advice or tax strategies,"<sup>133</sup> including the possibility that the patent gave a veneer of legality to

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<sup>127</sup> *Myriad Genetics*, 133 S. Ct. at 2109.

<sup>128</sup> Varmus, *supra* note 104, at 66, 68.

<sup>129</sup> See Rai, *Path Forward*, *supra* note 114, at 114.

<sup>130</sup> See generally DEP'T OF HEALTH & HUMAN SERVS., SEC'YS ADVISORY COMM. ON GENETICS, HEALTH, & SOCIETY, GENE PATENTS AND LICENSING PRACTICES AND THEIR IMPACT ON PATIENT ACCESS TO GENETIC TESTS (2010) [hereinafter 2010 HHS GENE PATENT REPORT]; see also Park, *supra* note 119, at 526 (noting the critical role that the plaintiff played in helping to instigate the policy shift inside the government).

<sup>131</sup> Andrew A. Schwartz, *The Patent Office Meets the Poison Pill: Why Legal Methods Cannot Be Patented*, 20 HARV. J.L. TECH. 333, 346 & n.90 (citing U.S. PATENT & TRADEMARK OFFICE, U.S. PATENT CLASSIFICATION 705/36T (creating a subclass within 705/36T dubbed "Tax Strategies"))

<sup>132</sup> E.g., 157 CONG. REC. S1201 (daily ed. Mar. 3, 2011) (over 130 patents granted and over 150 applications pending as of February 2011).

<sup>133</sup> AJCA Modifications to the Section 6011 Regulations, 71 Fed. Reg. 64,488, 64,490 (proposed Nov. 2, 2006).

the tax strategy,<sup>134</sup> and that the patents effectively fenced-off access to features of federal law.<sup>135</sup> These problems were compounded by the inability of the accounting community to challenge the validity of these patents in court, who feared that to do so would implicate their confidentiality obligations.<sup>136</sup> This gave rise to a circular dynamic wherein PTO precedent favored granting applications that claimed tax avoidance strategies, and such patents would go unchallenged, thereby giving rise to further applications for such patents.<sup>137</sup> Altogether, the IRS was concerned that PTO's practice of granting such patents offered an additional incentive to discover new ways of avoiding taxes, and impeded the effective administration of tax policy.<sup>138</sup>

The agency, however, seemed to lack a vehicle by which to challenge the applications for and grants of tax strategy patents at the PTO.<sup>139</sup> So it attempted instead to engineer its own novel solution to the problem: Rather than directly proscribe the patentability of tax strategies (which it lacked authority to do), the IRS proposed regulations that would drastically devalue such patents. In

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<sup>134</sup> In particular, the IRS was concerned that that “[a] patent for tax advice or a tax strategy might be interpreted by taxpayers as approval by the IRS and Treasury Department,” and, as a result, the agency would face added difficulty in “obtain[ing] information regarding tax avoidance transactions.” Patented Transactions, 72 Fed. Reg. 54,615, 54,615 (proposed Sept. 26, 2007).

<sup>135</sup> In general, organizations of tax and accounting professionals voiced concerns that patents over tax strategies effectively seek to monopolize features of the law, thereby “limit[ing] taxpayers’ ability to fully use tax law interpretations intended by Congress.” 157 CONG. REC. S1199 (daily ed. Mar. 3, 2011). Furthermore, these patents were seen as tantamount to a private tax, as they practically imposed a royalty, paid to a private party, for paying one’s taxes in a manner consistent with law. See 153 CONG. REC. H10,273 (daily ed. Sept. 7, 2007) (statement of Rep. Boucher). Indeed, unbeknownst to the PTO, some of the patents seemed to be based upon guidance provided by the IRS itself. See Jack Cathey, et al., *Tax Patents Considered*, J. ACCOUNTANCY, July 2007, at 40–41 (U.S. Patent No. 7,149,712 “covers a strategy . . . [that] was approved by the IRS in 1989 in Letter Ruling 9009047 and addressed favorably by the IRS in 1997 in Technical Advice Memorandum 9825001.”); see also 157 CONG. REC. S1199 (daily ed. Mar. 3, 2011) (noting a patent that “resembles the facts and results” of an IRS ruling that predates the application date of a tax strategy patent).

<sup>136</sup> See 157 CONG. REC. S1199 (“[T]ax professionals . . . may be unable, as a practical matter, to challenge the validity of TSPs as being obvious or lacking novelty, due to their professional obligations of client confidentiality.”).

<sup>137</sup> Cf. Jonathan Masur, *Patent Inflation*, 121 YALE L.J. 470, 473–75 (2011) (describing a similar but distinct circular dynamic causing “patent inflation”).

<sup>138</sup> See Patented Transactions, 72 Fed. Reg. at 54,615 (citing concerns regarding “effective tax administration”).

<sup>139</sup> See 157 CONG. REC. S1199 (“The IRS is not involved in the USPTO’s consideration of a TSP application.”).

The IRS might have considered urging the PTO to reconsider its guidelines, see *supra* Part II.B.1, or it might have considered reexamination, see *infra* Part III.A.3. I have found no evidence to suggest that the IRS considered either option.

particular, the IRS proposed creating a new class of “reportable transactions” that required the disclosure of royalty payments made for the use of patented tax strategies.<sup>140</sup> These rules insinuated that such returns—and the tax reduction strategies employed therein—would be subject to increased scrutiny. Because such scrutiny is costly, the IRS effectively threatened to alter the cost-benefit analysis for a tax strategy patent applicant; under the rules, there would be less value in seeking to monetize tax advice through a patent (as opposed to trade secret, for example), thus limiting the adverse effects caused by the proliferation of such patents.<sup>141</sup>

Critically, several holders of tax strategy patents responded to the IRS’s proposal with arguments that the rules were beyond the IRS’s reach. One commenter, for example, argued that the “apparent [attempt] to undermine . . . the value of a patented transaction could be equated to an attempt by the Treasury Department to regulate patents themselves, an act entirely within the constitutional province of Congress . . . .”<sup>142</sup> Indeed, the IRS shelved its proposed direct regulation.

The matter moved to Congress instead. The America Invents Act, a comprehensive patent reform statute enacted in 2011,<sup>143</sup> “effectively ban[ned] tax strategy patents.”<sup>144</sup> But even Congress’s intervention was incomplete: the new patent statute only applies prospectively,<sup>145</sup> thereby leaving untouched the

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<sup>140</sup> Patented Transactions, 72 Fed. Reg. at 54,615. IRS regulations requiring the disclosure of “reportable transaction[s]” have been developed “as a means of providing greater transparency . . . so that it can better assess the validity of innovative tax planning methods . . . .” Linda M. Beale, *Tax Patents: At the Crossroads of Tax and Patent Law*, 2008 U. ILL. J. TECH. & POL’Y 107, 124.

<sup>141</sup> See *supra* notes 134–135 and accompanying text (describing adverse effects). To be sure, if the problems associated with tax strategy patents were to persist under a trade secret regime, the proposed regulation would have had no effect. But trade secrets do not carry the imprimatur of the government in the way that the IRS feared patents did, and tax strategies that are independently-invented are not typically actionable under trade secret, thereby reducing the concern that a single entity could monopolize features of the law.

<sup>142</sup> Comments of Analect at 2, Patented Transactions, 72 Fed. Reg. 54,615 (proposed Sept. 26, 2007) (on file with author); see also Comments of Wealth Transfer Group, Patented Transactions, 72 Fed. Reg. 54,615 (proposed Sept. 26, 2007) (“It is important to recall that a patent is a constitutionally protected property right. As a result, it should be the policy of all agencies of the United States Government to preserve the value of such a right . . . .”) (on file with author).

<sup>143</sup> Leahy-Smith America Invents Act, Pub. L. No. 122-29, 125 Stat. 284 (2011) [*hereinafter* the America Invents Act].

<sup>144</sup> Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part I of II*, 21 FED. CIR. B.J. 435, 502 (2012) (discussing the provision of the America Invents Act, *supra* note 143, at § 14, that banned tax strategy patents).

<sup>145</sup> See 157 CONG. REC. S1368 (“[T]he bill does not apply on its face to the 130-plus tax patents already granted”); but see *id.* (“[I]f someone tries to enforce one of those patents in court by

hundreds of previously granted tax strategy patents that motivated the IRS to seek out a regulatory solution in the first instance. In short, the IRS found its authority to limit the untoward effects of tax strategy patents strongly challenged—and a (partial) resolution to problems posed by such patents was achieved only when Congress took action, half a decade after the agency first noted the problems associated with the PTO's policy and practice.

### 3. Airplane Patents and the Department of the Navy

Congress has also played a critical role in ensuring that agencies themselves have access to patented or patent-incorporating goods. That is, where a patent's right to exclude might be employed to prevent a government agency from procuring necessary equipment — such as military equipment — agencies have relied on congressionally-approved threats of confiscation to purchase or condemn patented goods.

Indeed, the confiscation strategy dates to one of the earliest examples of patent conflict: the threat of airplane patents to undermine the availability of military aircraft in the months prior to the nation's entry into World War I. The growing inability of the navy to fulfill its orders for warplanes eventually caused the government to force airplane manufacturers into an industry-wide patent cross-licensing agreement, thereby ensuring that the threat of injunctions between competing companies did not impede the production of airplanes critical to the nation's looming war effort.<sup>146</sup>

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demanding that a taxpayer provide a fee before using it to reduce their taxes, I hope a court will consider this [bill's] language and policy determination and refuse to enforce the patent as against public policy.”).

Even if a court would “refuse to enforce the patent as against public policy,” *id.*, that may not resolve the IRS's concern that the very existence of the patent “might be interpreted by taxpayers as approval” of the tax-reduction method. *See* Patented Transactions, 72 Fed. Reg. at 54,615.

<sup>146</sup> *See, e.g.,* MICHAEL HELLER, THE GRIDLOCK ECONOMY: HOW TOO MUCH OWNERSHIP WRECKS MARKETS, STOPS INNOVATION, AND COSTS LIVES 30–32 (2008). Other authors dispute this traditional account of the Manufacturers' Aircraft Association. Compare Ron D. Katznelson & John Howells, *The Myth of the Early Aviation Patent Hold-Up—How a U.S. Government Monopsony Commandeered Pioneer Airplane Patents* [ssrn] (Sept. 14, 2013) (asserting no hold-up problem, and arguing that the patent pool was coerced by a government monopsony to establish favorable pricing terms), with Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 890–91 (1990) (“[T]he Wright patent significantly held back the pace of aircraft development in the United States.”). Regardless of whether the government's actions were motivated by an actual hold-up problem or by a convenient excuse to reduce military expenditures, the *fact* of the indirect intervention remains undisputed.

Among the primary challenges for early aviation inventors was to develop a system for “lateral control” that enabled aircraft to remain stable and on-course in the face of rough winds and variable atmospheric conditions. The Wright Brothers were the first, in 1906, to patent a system that achieved this goal.<sup>147</sup> Importantly, the Wrights claimed that their patent covered not only their particular system, but also almost any solution to the general problem of lateral control. Subsequent litigation would validate the Wrights’ view of their patent’s scope:<sup>148</sup> Judge Hand, among others, agreed that the Wrights’ patent covered the prevailing alternative at the time and granted injunctions to bar airplane manufacture by competitors.<sup>149</sup>

Critically, these rulings gave the Wright Brothers effective control over “a key technology that was essential to the development and manufacture of any new aircraft.”<sup>150</sup> The Wrights’ vast power over the manufacture of nearly all modern aircraft threatened to hold up the manufacture of airplanes by competitors:<sup>151</sup> In the December of 1916, the Wright Brothers expressly threatened litigation against any airplane manufacturer that did not have a license for their patent.<sup>152</sup>

Shortly thereafter, the Assistant Secretary of the Navy, Franklin D. Roosevelt, reported difficulty fulfilling airplane orders, as “companies would not expend any money on their [manufacturing] plants for fear that suits brought against them would force them out of business.”<sup>153</sup> The highly litigious

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<sup>147</sup> In particular, the Wright Brothers patented a system of pulleys “warped” the left and right wings in proportionally opposite directions so as to allow the airplane to roll or “bank.” Furthermore, the system integrated with the rudder so that the banked turn would neither take the plane off course nor destabilize the plane. See Katznelson & Howells, *supra* note 146; see also Joe Nocera, Op-Ed., *Greed and the Wright Brothers*, N.Y. TIMES, Apr. 19, 2014, at A17.

<sup>148</sup> The relevant procedural history is somewhat lengthy. Two district court decisions, *Wright Co. v. Herring-Curtiss Co.*, 177 F. 257 (C.C.W.D.N.Y. 1910) and *Wright Co. v. Paulhan*, 177 F. 261, 266 (C.C.S.D.N.Y. 1910) (Hand, J.) (“The use of such ailerons is an obvious equivalent . . .”), were initially inclined towards finding infringement and issued preliminary injunctions that were reversed by the Second Circuit in *Wright Co. v. Herring-Curtiss Co.*, 180 F. 110 (2d Cir. 1910) and *Wright Co. v. Paulhan*, 180 F. 112 (2d Cir. 1910), respectively. In later cases that relied on different claims, the lower court maintained its broad interpretation of the patent’s scope and similarly found infringement, and this time the Second Circuit affirmed. *Wright Co. v. Herring-Curtiss Co.*, 211 F. 654 (2d Cir. 1914).

<sup>149</sup> See *supra* note 148. The alternative solution consisted of applying ailerons, or flaps, to the aircraft’s wings. Using an aileron obviates the need to warp the entire wing; instead, the plane needs only to direct the left and right flaps to achieve a similar effect. See *supra* note 147 (describing the Wrights’ system).

<sup>150</sup> Dustin R. Szakalski, *Progress in the Aircraft Industry and the Role of Patent-Pools and Cross-Licensing Agreements*, 15 UCLA J. L. TECH. 1, 5 (2011).

<sup>151</sup> For a dissenting view, see generally Katznelson & Howells, *supra* note 146.

<sup>152</sup> *Pooling of Patents: Hearing Before the H.R. Comm. on Patents on H.R. 4523*, 74th Cong. 4 (1935) (statement of Brigadier General William Mitchell).

<sup>153</sup> *Mfgs. Aircraft Ass’n v. United States*, 77 Ct. Cl. 481, 483–84 (1933).

environment,<sup>154</sup> including the constant threat of injunctions against active aircraft manufacturers, resulted “in a general demoralization of the entire trade.”<sup>155</sup> Most importantly, this decline in aircraft manufacturing output occurred against the backdrop of World War I. “Just when the [armed] services wanted more airplanes than ever before—when it looked as if the United States would inevitably be drawn into the war in Europe—the nascent American aircraft industry faced an impasse.”<sup>156</sup>

In response to this dearth of necessary military aircraft, the Secretary of War and the Secretary of the Navy enlisted Congress’s support for the confiscation of the several patents, including the Wrights’ patent that obstructed the domestic manufacture of warplanes. One month before the United States officially entered World War I,<sup>157</sup> Congress passed an appropriations bill that included \$1,000,000 for the “condemnation” of any “patents . . . necessary to the manufacture and development of aircraft in the United States.”<sup>158</sup> It was against this backdrop—the credible threat of condemnation—that eleven aircraft manufacturers, including Wright-Martin and chief rival Curtiss-Burgess, agreed to cross-licensing terms in negotiations supervised by military officials. These licensing terms, which fell under the auspices of the Manufacturers’ Aircraft Association (MAA), were vastly different than those that were previously available in a market where fees were once negotiated against the backdrop of threats of litigation and injunctions. Where royalties for a *single* patent might have once exceeded \$1,000, the price for a MAA license, which covered *all* patents necessary for aircraft manufacture, was set at \$200.<sup>159</sup>

The scheme worked. The navy was able to fulfill its demands for aircraft<sup>160</sup> despite the apparent opposition of the Commissioner of Patents.<sup>161</sup> But doing so

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<sup>154</sup> *Pooling of Patents: Hearing*, *supra* note 152, at 4.

<sup>155</sup> *Mfgs. Aircraft Ass’n*, 77 Ct. Cl. at 484.

<sup>156</sup> ALEX ROLAND, NAT’L AERONAUTICS & SPACE ADMIN. (NASA), MODEL RESEARCH: THE NASA HISTORY SERIES (vol. 1, 1985), available at <http://history.nasa.gov/SP-4103/contents.htm>.

<sup>157</sup> The United States officially declared war on April 6, 1917.

<sup>158</sup> Act of Mar. 4, 1917, Pub. L. 64-391, ch. 180, 39 Stat. 1168, 1169 (providing appropriations for naval services).

<sup>159</sup> *Mfgs. Aircraft Ass’n*, 77 Ct. Cl. at 487; see also *id.* at 484 (“Prior to the time the arrangement hereinafter mentioned was agreed upon and placed in operation, one airplane manufacturer, who had made a considerable number of airplanes, was paying a royalty of \$1,000 an airplane for the use of only one of the patents.”).

<sup>160</sup> *Id.* at 514 (“The purpose of the plan, which was carried out in practice, was to enable the Government to fulfill its needs for airplanes . . .”); see also HELLER, *supra* note 146, at 31 (Warplane manufacturing resumed “en masse”).

<sup>161</sup> The Commissioner of Patents seems to have resisted the scheme deployed by the Departments of War and the Navy to ensure the manufacture of warplanes. For example, the Commissioner was a strong advocate for the right of a patent holder to, in contrast to the design of the MAA,



required the credible threat, backed by a congressional appropriation, of confiscation.

Furthermore, the year after the instantiation of the MAA, then-Assistant Secretary Roosevelt persuaded Congress to pass a statute allowing government contractors to infringe patents, limiting the patent holder's remedy to damages against the United States.<sup>162</sup> That is, the amended law (codified at 28 U.S.C. § 1498<sup>163</sup>) excludes the possibility of obtaining an injunction against the United States or its contractors,<sup>164</sup> and thereby limits a patent holder's remedy to "reasonable and entire compensation" for such use.<sup>165</sup> Stated succinctly, the available remedy might be said to simply amount to "just compensation."<sup>166</sup>

Since its enactment, the statute has been repeatedly invoked to ensure access to patented and patent-incorporated goods and processes.<sup>167</sup> In the wake of the anthrax bioterrorism scare that followed shortly after the attacks on September 11,

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"say what the resale price of his patent should be," and even publicly opposed the adoption of antitrust's Clayton Act, which specifically targeted "patented" devices. See L.W. Moffett, *A Big Handicap to Industry: How an Antiquated System of Patent Laws Puts a Brake on Progress—Other Examples of Governmental Inefficiency*, 56 IRON TR. REV. 557, 558 (1915).

While the Commissioner of Patents does not appear to have made any statement directly opposing the creation of the MAA, there are some clues suggestive of his opposition. The Commissioner resigned his post shortly after the creation of the MAA, citing a desire to return private practice, see *Patent Office Loses Ewing: Commissioner is to Resume the Practice of Law in New York City*, WASH. POST, Aug. 14, 1917, at 8, but soon thereafter rejoined the administration when given the opportunity to lead the "Munitions Patent Board," which was charged with ensuring that both the Army and the Navy paid fair and appropriate compensation for the use of patented military technology. See *Joint Army and Navy Munitions Patent Board: Hearing on Sundry Civil Appropriation Bill for 1920 Before the Subcomm. of the H. Comm. on Appropriations*, 65th Cong. 1256–60 (1919) (statement of Thomas Ewing).

Furthermore, the MAA was shepherded through the National Advisory Committee of Aeronautics (NACA) (a precursor to NASA). See ROLAND, *supra* note 156, at ch. 2. While the Commissioner of Patents initially supported the creation of NACA, *id.* at ch. 1, he was increasingly absent from its proceedings as the Committee's mission disclaimed any desire to "promote patented devices" and seemed to support attempts to "break the Wright patent." *Id.* at ch. 1 & n.47.

<sup>162</sup> Sean M. O'Connor, *Taking, Tort, or Crown Right?: The Confused Early History of Government Patent Policy*, 12 J. MARSHALL REV. INTELL. PROP. L. 145, 188 (2012).

<sup>163</sup> The statute provides a cause of action in the United States Court of Federal Claims "[w]henever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license . . . ." 28 U.S.C. § 1498(a) (2012). The "or for" clause includes actions taken by private contractors for the government.

<sup>164</sup> See the line of cases beginning with *Crozier v. Fried. Krupp Aktiengesellschaft*, 224 U.S. 290 (1912), for the contours of the rule against injunctive relief under the government use statute.

<sup>165</sup> 28 U.S.C. § 1498(a).

<sup>166</sup> U.S. CONST. amend V.

<sup>167</sup> See generally O'Connor, *supra* note 162.

2001, the Department of Health and Human Services (HHS) used the leverage provided by Section 1498 to secure access to the antibiotic ciprofloxacin (sold under the brand Cipro).<sup>168</sup> More recently, the government has invoked the statute to indemnify private actors using patented processes while acting in a “quasi-governmental” border control capacity.<sup>169</sup>

### C. DIRECT ACTION

Where patent law conflicts with other areas of regulatory law, some agencies have abstained from any patent-related action, while others have sought the assistance of Congress or the Supreme Court. One further category remains: Agencies might choose to directly address, under existing authority, the blocking patent or policy. But such examples are somewhat sparse. Even where the FTC attempted to directly address competition problems created by patent litigation settlement practices under the Hatch-Waxman Act, its enforcement efforts were stymied by the Federal Circuit and the PTO, forcing it to seek the help of the Supreme Court and others across the Executive Branch.<sup>170</sup> Despite their rarity,

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<sup>168</sup> Specifically, HHS compelled Bayer to sell its patented antibiotic treatment at significantly cheaper rates. HHS used the leverage provided by 28 U.S.C. § 1498 and the threat of a compulsory license to force Bayer to drastically cut the price of the drug for an emergency supply. Compare Edmund L. Andrews & Keith Bradsher, *A Nation Challenged: CIPRO; U.S. Says Bayer Will Cut Costs of Its Anthrax Drug*, N.Y. TIMES (Oct. 24, 2001), <http://www.nytimes.com/2001/10/24/business/a-nation-challenged-cipro-us-says-bayer-will-cut-cost-of-its-anthrax-drug.html> (noting the government “won a major price concession from Bayer A.G. for its anthrax medicine, Cipro, after the administration threatened to buy generic alternatives instead.”), and Ralph Nader & James Love, *Letter to Tommy G. Thompson, Secretary of Health and Human Services*, WASH. POST., Oct. 18, 2001 (on file with author), and Press Release, Senator Charles E. Schumer, *Schumer: New Cipro Source Could Dramatically Increase Supply* (Oct. 16, 2001), available at [https://web.archive.org/web/20020113003136/http://schumer.senate.gov/SchumerWebsite/pressroom/press\\_releases/PR00728.html](https://web.archive.org/web/20020113003136/http://schumer.senate.gov/SchumerWebsite/pressroom/press_releases/PR00728.html), with Isaac Igwe, *The WTO and Public Health, Access to Essential Medicine in HIV/AIDS: The Developing Countries Perspectives*, in INTERNATIONAL LAW, CONVENTIONS AND JUSTICE 255, 269 n.6 (David A. Frenkel, ed., 2011) (“Bayer was robbed of their patent exclusivity in Cipro drugs and patent law was weakened . . .” (citation omitted)).

Coincidentally, the pharmaceutical at issue here is the same as the one at the center of *In re Ciprofloxacin Antitrust Litigation*, 544 F.3d 1323 (Fed. Cir. 2008), discussed *supra* Part I.A.

<sup>169</sup> *Iris Corp. v. Japan Airlines Corp.*, 769 F.3d 1359, 1362 (Fed. Cir. 2014) (“[T]he government has clearly provided its authorization or consent because . . . [Japan Airlines] cannot comply with its legal obligations without engaging in the allegedly infringing activities.”); see also Brief for the United States as Amicus Curiae at 6–14, *Iris Corp.*, 769 F.3d 1359 (No. 2010-1051), 2014 WL 808951 (stating government’s position that it, and not Japan Airlines, should be liable for damages related to electronic passport patents).

<sup>170</sup> See *supra* Part I.A. In other examples, however, the FTC has proved somewhat more successful in using its authority to sanction anticompetitive patent-related behavior. See *infra* note 187 and accompanying text.

examples of direct regulation do exist.<sup>171</sup> Indeed, the FCC's apparent conclusion that it lacks the authority to require the licensing of those patents implicated by its 911 standards,<sup>172</sup> sharply contrasts with the FCC's lengthy history of regulating patents and other intellectual property rights,<sup>173</sup> including those implicated by the Telecommunications Act of 1996.

### 1. Network Element Patents and the FCC

As noted above, the FCC has refrained from taking patent-related action in some recent proceedings, concluding that such regulation is "outside the scope" of its authority.<sup>174</sup> But despite the FCC's reluctance to issue rules requiring licensing for patents essential to its public safety objectives, earlier proceedings regarding the implementation of the Telecommunications Act of 1996 provide an important example of the authority of nonpatent agencies to issue patent-related regulation.

In order to promote competition in the telecommunications market, the Telecommunications Act required established, or "incumbent," providers to allow new competitors to offer service over their existing facilities. Stated simply, any new company could offer telephone service to consumers without building its own network of copper telephone wires. The upstart could instead pay to use an incumbent's existing infrastructure at a "just, reasonable, and nondiscriminatory" rate.<sup>175</sup>

One of the many disputes to arise out of the implementation of this new statutory obligation involved a dispute between MCI (a new competitor) and Bell

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<sup>171</sup> In addition to the examples described here and in note 187, see John M. Golden & Hannah J. Wiseman, *The Fracking Revolution: Shale Gas as a Case Study in Innovation Policy*, 64 EMORY L.J. 955, 987, 1008 (2015) ("FERC made [the Gas Research Institute (GRI)] indifferent to [intellectual property] royalties by subtracting any royalties from FERC funding; this ensured that GRI focused on technology diffusion as much as possible . . . ." (quoting JASON BURWEN & JANE FLEGAL, AM. ENERGY INNOVATION COUNCIL, UNCONVENTIONAL GAS EXPLORATION & PRODUCTION 5 (2013) (some alterations in original))).

<sup>172</sup> See *supra* Part II.A.

<sup>173</sup> Revised Patent Procedures of the Federal Communications Commission, 3 F.C.C.2d 24, 24–25 (1961) ("Whenever it appears that the patent structure is or may be such as to indicate obstruction of the service to be provided under the technical standards promulgated by the Commission, this fact will be brought to the Commission's attention for early consideration and appropriate action."); *Advanced Television Systems, Fourth Report and Order*, 11 FCC Rcd. 17,771, 17,794 (1996). The latter proceeding is discussed in more detail *infra* notes 282–286 and accompanying text.

<sup>174</sup> *Commercial Mobile Alert System, First Report and Order*, 23 FCC Rcd. 6144, 6160 (2008); see also Part II.A.1.

<sup>175</sup> 47 U.S.C. §§ 251(c)(3) (2012); see also 47 U.S.C. §§ 252(d)(1), 259(a).

Atlantic (an incumbent) in Virginia. MCI complained that if it leased “elements in [Bell Atlantic’s] network, as the Act gives it the right to do, it will be exposed to potential intellectual property infringement claims.”<sup>176</sup> Indeed, a critical feature of MCI’s claim was that the grant of injunctive relief under the intellectual property laws would have prevented the new competitor from offering service, thereby frustrating the aims of the new communications statute.

MCI demanded that Bell Atlantic extend its existing rights in the intellectual property inherent to the network to include the new competitors that were embraced by the new statute.<sup>177</sup> The Fourth Circuit agreed,<sup>178</sup> and, in a concurrent rulemaking proceeding, the FCC adopted similar reasoning, imposing a similar obligation on every incumbent provider.<sup>179</sup> This decision followed on an earlier, but separate set of rules adopted by the FCC for an analogous requirement, in which the Commission similarly concluded that giving effect to the Telecommunications Act’s sharing requirement “required mandatory licensing, subject to the payment of reasonable royalties,” where there was no other alternative.<sup>180</sup>

The process leading to the Commission’s conclusions was contentious. In its petition, MCI asked the Commission to go much further than it did: MCI asked the Commission to “quickly and decisively hold that . . . intellectual property rights are not implicated in the sale of unbundled elements” at all.<sup>181</sup> By contrast, BellCore, an affiliate of incumbent Bell companies, argued that the Commission

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<sup>176</sup> *AT&T Commc’ns of Va., Inc. v. Bell-Atl. Va., Inc.*, 197 F.3d 663, 670 (4th Cir. 1999).

<sup>177</sup> *Id.* at 671. As a practical matter, this meant that Bell Atlantic would have to renegotiate its licenses with third-party rights holders to include its lessees.

<sup>178</sup> *Id.* Under the statute’s requirement to offer access on a “nondiscriminatory” basis, Bell Atlantic was required to cover the new competitors that had rights to use its infrastructure.

<sup>179</sup> *See, e.g.*, *Petition of MCI for Declaratory Ruling that New Entrants Need Not Obtain Separate License or Right-To-Use Agreements Before Purchasing Unbundled Elements*, 15 FCC Rcd. 13,896, 13,901 (2000). Although the FCC’s rule followed shortly *after* the Fourth Circuit’s decision in *AT&T Communications of Virginia*, the rulemaking proceeding actually began with MCI’s petition filed in 1997. *See* *Petition of MCI for Declaratory Ruling*, FCC Docket No. 96-98 (filed Mar. 14, 1997) (on file with author); *see also* Press Release (unofficial), *Fed. Commc’ns Comm’n, Federal Communications Commission Takes Action to Clarify Intellectual Property Rights Obligations of Incumbent Local Telephone Carriers*, (Apr. 27, 2000) (2000 WL 489691) (FCC Order is consistent with “the Fourth Circuit, . . . [which] held that Section 251(c)(3) imposes an obligation on incumbent LECs to use their best efforts to renegotiate modifications to intellectual property licenses to provide nondiscriminatory access to network elements on the same terms and conditions that incumbent LECs enjoy.”).

<sup>180</sup> *Implementation of Infrastructure Sharing Provisions in the Telecommunications Act of 1996, Report and Order*, 12 FCC Rcd. 5470, 5500–01, 5504–05 (1997); *see also* *AT&T Reply Comments* (on file with author) (noting similarity between the two proceedings).

<sup>181</sup> *Petition of MCI for Declaratory Ruling at 7*, FCC Docket No. 96-98 (filed Mar. 14, 1997) (on file with author).

lacked the authority “to nullify the exclusive right of a patent owner . . . to exclude others from using [its] invention.”<sup>182</sup> While the Commission agreed that it could not nullify incumbent or third-party patent rights, it nevertheless determined that it could require mandatory licensing.<sup>183</sup> That is, while the FCC conceded the validity of the intellectual property claims at issue, it regulated those rights to ensure they did not undermine the statutory scheme.

The contrast to more recent FCC proceedings is stark. In 911 and emergency alert regulation, the Commission concluded that mandatory licensing fell outside its jurisdiction. But in its implementation of the Telecommunications Act,<sup>184</sup> the Commission leveraged authority nominally directed at physical infrastructure to convert a patent into a simple right to compensation. Stated simply, the FCC’s patent-related regulations, the first of which came within one year of the passage of the Act, helped to prevent patent holders from blocking the implementation of the new competitive scheme.

### III. TOWARD PATENT CONFLICT RESOLUTION

The choice of agency response to a clashing patent or policy has important implications for the competing regulatory goal. Where a patent impedes progress toward an agency’s goal, agency inaction has the practical effect of undermining that regulatory objective. Contrastingly, relying on the Supreme Court or on Congress to resolve such a policy clash shifts the matter from an expert agency to a generalist body, and may have the further effect of delaying resolution.

But inaction and indirect action routed through the courts and Congress are not the only options available to nonpatent agencies. Indeed, at least one example described above suggests a path forward: the FCC’s direct regulation of the patent rights embedded in network elements subject to the 1996 Telecommunications Act. Indeed, direct regulation by agencies is consistent with the general rationale supporting agency delegation in the first instance: the efficient and expert

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<sup>182</sup> Comments of BellCore (on file with author); *see also* Implementation of Infrastructure Sharing Provisions, *supra* note 180, at 5502 (quoting Southwestern Bell, another incumbent, who filed comments to a similar effect).

<sup>183</sup> *See* Petition of MCI for Declaratory Ruling, *supra* note 179, at 13,901; *see also* Implementation of Infrastructure Sharing Provisions, *supra* note 180, at 5504–05.

Indeed, the Commission went so far as to allocate the costs of obtaining these licenses. Finding that the incumbents were in a better position to negotiate licenses from third-parties, the FCC required incumbents, rather than the new competitors, to negotiate licenses that covered all potential users of the intellectual property rights at issue. Petition of MCI for Declaratory Ruling, *supra* note 179, at 13,902–03.

<sup>184</sup> *See* 47 U.S.C. § 251(c)(3) (2012) (requiring incumbents to provide “nondiscriminatory access to network elements on an unbundled basis”).

administration of a specific policy mandate. Furthermore, much like the Supreme Court's decision in *Actavis*,<sup>185</sup> the FCC's regulations aim to balance their own regulatory aims with the competing interests of the patent regime. Thus, this part of the article considers the lessons from the examples described above and focuses on new possibilities and guiding principles for patent conflict resolution.

#### A. OPTIONS FOR PATENT CONFLICT RESOLUTION

Several new possibilities for addressing patent conflict can be drawn from the shadows of the examples described above. One follows directly from the FCC's implementation of the Telecommunications Act, and provides for further direct exercises of agency power to efficiently and expertly resolve such policy clashes. In particular, it offers a general theory of patent-oriented regulatory jurisdiction to overcome the common objection that agencies lack any authority to issue patent-related rules and orders.

The direct exercise of agency authority, however, may not always be an adequate response. This is especially so where a nonpatent agency's objection is to a general question of patent policy. The authority to decide such matters is generally vested within the judiciary or the PTO, and so outside agency authority alone is likely an incomplete legal basis for policy resolution. Thus, indirect action may be the best (and perhaps the only) mechanism for resolving regulatory clashes with patent policy. That is not to say, however, that existing paradigms for indirect action cannot be improved upon. Rather than turn to the courts or to Congress in the first instance, more robust models of Executive Branch coordination can promote forms of indirect action that retain an agency's comparative advantages in expertise and expedience, and perhaps even better reflect the totality of Congress's regulatory programs.

##### 1. Direct Agency Authority

The ability of an agency to take direct action on patents that impede progress toward a policy objective hinges on that agency's authority to regulate. Some agencies, most notably the EPA, have express statutory authority to regulate patents that implicate their mandates.<sup>186</sup> Other agencies have occasionally found such authority to inhere to existing statutory mandates: Intrinsic to the FCC's authority to require access to elements of communications networks is the

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<sup>185</sup> See *supra* notes 66–67 and accompanying text.

<sup>186</sup> But the EPA has declined to invoke this authority, even where it seems clearly applicable. See *supra* Part II.A.2.

authority to mandate the licensing of implicated patent rights. The FTC has similarly concluded that its broad mandate to target “unfair methods of competition” allows it to sanction anticompetitive patent practices.<sup>187</sup>

But in several cases, agencies have faced stiff challenges to their regulatory authority. Comments to the FCC, for example, argued that the Commission “lacks authority” to require the mandatory licensing of patents implicated by its 911 standards.<sup>188</sup> These arguments have apparently proved persuasive: In contrast to earlier proceedings, the FCC has avoided regulation in the face of such claims. Likewise, comments to proposed IRS regulations regarding tax-strategy patents argued that only Congress could enact the rules that the agency sought to impose.<sup>189</sup>

A revived theory of an oft-overlooked source of agency authority can overcome claims that agencies necessarily lack the authority to issue patent-related regulations. Importantly, shifting focus away from the more procedural issue of whether an agency has authority to regulate can allow nonpatent agencies to engage the question whether complete enforcement of the patents at issue are, on net, in the public interest—particularly given the competing regulatory aim.

Generalizing from successful assertions of existing authority, most notably the FCC’s regulation of network element patents,<sup>190</sup> agencies can be found to hold inherent authority to issue patent-related rules in service of existing statutory mandates. The basis for such regulation borrows from the doctrine of “ancillary authority,” which resides predominantly in communications law.<sup>191</sup> Ancillary authority grants an agency the ability to issue rules and orders that are “reasonably ancillary to the effective performance” of its statutory mandates, even if the agency otherwise lacks the explicit authority to promulgate the proposed regulation.<sup>192</sup> Such jurisdiction derives from the Supreme Court’s decision in

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<sup>187</sup> Robert Bosch GmbH, 155 F.T.C. 713, 739 (2013) (denying availability of injunctive relief for standards-essential patents); *see also* Negotiated Data Solutions LLC, 2008 WL 4407246, at \*6 (F.T.C. Sept. 22, 2008) (N-Data attempted to rescind a licensing offer that a previous patent owner had made as part of a standard setting process); Union Oil Co. of Cal., 138 F.T.C. 1, 39–40 (2004) (Unocal was alleged to have manipulated a state agency’s standard setting process to incorporate its patented technology); *but see* Rambus, Inc. v. FTC, 522 F.3d 456, 462 (D.C. Cir. 2008) (unsuccessful FTC claim under § 2 of the Sherman Act).

<sup>188</sup> Comments of the Nat’l Emergency Number Ass’n, Facilitating the Deployment of Text-to-911 and Other Next Generation 911 Applications, Framework for Next Generation 911 Deployment, FCC Docket No. 11-153 (filed Dec. 2011).

<sup>189</sup> Comments of Analect at 2, Patented Transactions, 72 Fed. Reg. 54,615 (proposed Sept. 26, 2007) (on file with author).

<sup>190</sup> *See supra* Part II.C.1.

<sup>191</sup> *See, e.g.,* Comcast Corp. v. FCC, 600 F.3d 642, 645–47 (D.C. Cir. 2010) (describing the origins and historical development of the FCC’s ancillary authority).

<sup>192</sup> *United States v. Sw. Cable Co.*, 392 U.S. 157, 178 (1968).

*Southwestern Cable*, which upheld FCC regulations directed at cable systems. Although the FCC had no direct authority over cable television (at that time), the Commission concluded that the new technology was threatening the viability of over-the-air broadcast stations, and so issued the regulations under its “undisputed responsibility to preserve the broadcasting industry.”<sup>193</sup> The Court held that the lack of explicit jurisdiction over cable operators did not bar the agency action: “[W]e may not, in the absence of compelling evidence that such was Congress’ intention, prohibit administrative action imperative for the achievement of an agency’s ultimate purposes.”<sup>194</sup>

While ancillary jurisdiction has been largely relegated to the silo of communications regulation, it is not logically limited to that domain.<sup>195</sup> Rather, as a more general theory of regulatory jurisdiction, ancillary authority serves two related primary purposes. Ancillary authority was devised in the communications law context to assure the FCC’s ability to function coherently in an industry that “spawns new technologies and thus new regulatory issues far more quickly than Congress can legislate to address them.”<sup>196</sup> Thus, such authority avoids the very “intolerable regulatory burden” of constant legislative and judicial intervention that Congress “sought to escape by delegating administrative functions” to an agency.<sup>197</sup>

In patent contexts, such authority similarly bridges gaps in delegations of agency authority by allowing nonpatent agencies to address problems that result from unanticipated conflicts between patents and other fields of regulation. Patent conflicts would seem to present issues similar to those that presented in communications regulation. Innovations, both in technology and in what may be patentable, move faster than Congress and the courts.<sup>198</sup> Thus, applying a theory

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<sup>193</sup> JONATHAN E. NUECHTERLEIN & PHILIP J. WEISER, *DIGITAL CROSSROADS: TELECOMMUNICATIONS LAW AND POLICY IN THE INTERNET AGE* 233 (2d ed. 2013).

<sup>194</sup> *Sw. Cable Co.*, 392 U.S. at 177–78 (quotation marks and alterations omitted).

<sup>195</sup> *Cf. id.* (citing examples of similar authority in transportation and energy regulation); *KPMG, LLC v. SEC*, 289 F.3d 109, 112 (D.C. Cir. 2002) (describing the ancillary authority of the Securities and Exchange Commission).

<sup>196</sup> NUECHTERLEIN & WEISER, *supra* note 193, at 233.

<sup>197</sup> *United States v. Midwest Video Corp.*, 406 U.S. 649, 665 n.23 (1972).

<sup>198</sup> Skeptics might point to examples of explicit authority to regulate patents, such as Section 308 of the Clean Air Act, as evidence for claims that Congress is fully capable of identifying patent-implicating regulatory mandates and that Congress will delegate such authority when it sees fit to do so. But that Congress anticipated two regulatory programs (at the EPA and the Atomic Energy Commission) that implicate patents need not suggest that Congress is a reliable predictor of such patent conflicts. The varied examples described earlier, including especially the cases giving rise to a post-hoc congressional reaction, might equally (if not more strongly) suggest the contrary. Indeed, the difficulty in predicting which regulatory programs implicate patents may counsel in favor of the expanded vision of ancillary authority here. *See infra* note 200.



of ancillary authority to support patent-related regulation helps to ensure an agency's ability to carry out regulatory programs, notwithstanding developments in patent policy or in the corpus of granted patents,<sup>199</sup> and may better reflect the totality of Congress' legislative goals.<sup>200</sup>

One prominent application of such an expanded view of ancillary authority can operate to convert a patent's property rule into a liability regime. The FCC might, consistent with the petition filed by TCS, require the licensing of those patents that are necessary to the implementation of its updated 911 standards.<sup>201</sup>

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<sup>199</sup> Cf. *United Video v. FCC*, 890 F.2d 1173, 1182–1192 (D.C. Cir. 1989) (the FCC's ancillary authority extends to support copyright-related regulation).

<sup>200</sup> See *id.* at 1184 (“Congress did not imagine copyright law and communications law to be two islands, separated by an impassable sea. Rather, Congress was aware of the interplay between copyright and communications law, and knew that the FCC would have a role to play . . . .”); Jason Marisam, *Duplicative Delegations*, 63 ADMIN. L. REV. 181, 192–93 (2011); Kevin Werbach, *Off the Hook*, 95 CORNELL L. REV. 535, 596–98 (2010); Jacob E. Gersen, *Overlapping and Underlapping Jurisdiction in Administrative Law*, 2006 SUP. CT. REV. 201, 212 (“Giving authority to multiple agencies and allowing them to compete against each other can bring policy closer to the preferences of Congress than would delegation to a single agent.”) (citation omitted); see also Dan L. Burk, *Patent Reform in the United States: Lessons Learned*, 2012-2013 REGULATION 20, 21 (“The manifest impracticality of continuous legislative attention leaves courts and administrative agencies as the likely institutional stewards of statutory tailoring.”).

<sup>201</sup> Here, an analogy to standard-setting organizations can be instructive. Standards-setting organizations develop technology standards that help assure interoperability across platforms and manufacturers. WiFi and USB are examples of such standards. These standards often implicate patents, and thereby give patent holders significant bargaining power that can lead to anticompetitive behavior or can hold up the implementation of the standard. Leading competition regulators thus have urged standard-setting organizations to require their members to commit to not seek injunctions and instead license these patents on fair and reasonable terms. See e.g., U.S. DEP'T OF JUSTICE & U.S. PATENT & TRADEMARK OFFICE, POLICY STATEMENT ON REMEDIES FOR STANDARDS-ESSENTIAL PATENTS SUBJECT TO VOLUNTARY F/RAND COMMITMENTS (2013) [hereinafter DOJ & PTO JOINT POLICY STATEMENT]; Renata Hesse, Deputy Assistant Att'y Gen., Antitrust Div., U.S. Dep't of Justice, Prepared Remarks for the ITU-T Patent Roundtable, Six “Small” Proposals for SSOs Before Lunch (Oct. 10, 2012); see also Kai-Uwe Kühn, Fiona Scott Morton & Howard Shelanski, *Standard Setting Organizations Can Help Solve the Standard Essential Patents Licensing Problem*, 3 CPI ANTITRUST CHRONICLE (SPECIAL ISSUE) 2, 3–4 (2013) (the chief economists at U.S. and European competition regulators expressing similar views). Some standard-setting organizations have followed suit. See, e.g., INST. OF ELECTRICAL & ELECTRONICS ENG'RS STANDARDS ASS'N (IEEE-SA), *IEEE-SA Standards Board Bylaws*, cl. 6.2 (Patents, Policy) (amended Feb. 2015) available at <http://standards.ieee.org/develop/policies/bylaws/approved-changes.pdf> (requiring fair and reasonable licensing and prohibiting injunctions against willing licensees).

Mandatory regulations that implicate patents, such as the FCC's 911 rules, can have similar effects. A critical difference, of course, is that patentees voluntarily bind themselves to the terms of the private standard-setting process. But the shift from exclusionary to liability regimes in regulatory contexts can be conceived of as an implied term in a patent's social contract. See generally Shubha Ghosh, *Patents and the Regulatory State: Rethinking the Patent Bargain Metaphor*

Likewise, the Commission could revisit the conclusion that mandatory licensing of patents essential to sending emergency alerts via cellular phone was outside the scope of its jurisdiction.<sup>202</sup>

The reach of a patent-focused theory of ancillary authority extends beyond mandatory patent licensing to other types of regulatory programs.<sup>203</sup> The Hatch-Waxman Act, for example, explicitly directs the FDA to publish the “number and the expiration date of any patent” pertaining to a New Drug Application in the *Approved Drug Products with Therapeutic Equivalence Evaluations* publication (more commonly known as the Orange Book).<sup>204</sup> The Orange Book has important implications for competition in the drug industry, as any prospective generic competitor must certify to the FDA that any patents listed in the Orange Book are already expired or that those patents are either invalid or will not be infringed by the new competitor.<sup>205</sup> Furthermore, if the patent holder decides to challenge the claim that a patent is invalid or not infringed, the FDA is precluded from approving the generic’s application for a period of 30 months.<sup>206</sup> This regulatory design perversely “encourages NDA holders to incorrectly list patents in the Orange Book to obtain 30-month stays,” with significant competitive effects.<sup>207</sup> In *Mylan Pharmaceuticals, Inc. v. Thompson*,<sup>208</sup> for example,

a brand whose original patent on a drug was set to expire listed a new patent ostensibly extending its rights over the drug, but in fact covering neither the compound nor any method of using it. The FDA, as was (and

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*After Eldred*, 19 BERKELEY TECH. L.J. 1315 (2004) (criticizing a rigid social contract theory of patents, arguing that the “social contract should be reformulated to take into consideration modern theories of law and regulation as well as the importance of reciprocity and trust in the innovation process”); *see also* Precision Instrument Mfg. v. Auto. Maint. Mach., 324 U.S. 806, 816 (1945) (“[A] patent is by its very nature is affected with a public interest.”); Ben Johnson, *Public Standards and Patent Damages*, 14 J. MARSHALL. REV. INTELL. PROP. L. 199, 227 (2015) (“[C]alculating damages for public standard patents requires an explicit, thorough consideration of the public interest . . . .”); *infra* Part III.B.2.

<sup>202</sup> Commercial Mobile Alert System, *First Report and Order*, 23 FCC Rcd. 6144, 6160 (2008).

<sup>203</sup> In addition to the FDA example described here, such a theory of ancillary authority can support the proposed IRS regulation described in *supra* notes 140–35 and accompanying text.

<sup>204</sup> 21 U.S.C. § 355(b)(1) (2012).

<sup>205</sup> *Id.* §§ 355(b)(2)(A)(ii), 355(b)(2)(A)(iv), respectively. Alternately, the generic competitor may certify that it will wait until the patents are expired, or that “such patent information has not been filed.” *Id.* §§ 355(b)(2)(A)(iii), 355(b)(2)(A)(i), respectively.

<sup>206</sup> *Id.* § 355(e)(3)(C); *see also* Hemphill, *supra* note 25, at 1566 (explaining that the stay is often longer than thirty months).

<sup>207</sup> Brian J. Malkin & Andrew S. Wasson, *Should FDA Undertake More than a “Ministerial” Role with Respect to Patent Information?* 1 FOOD & DRUG POL’Y F. 1, 1 (2011).

<sup>208</sup> 268 F.3d 1323 (Fed. Cir. 2001).

is) its wont, accepted the listing at its word and accordingly declined to approve a generic product.<sup>209</sup>

Despite the inverted incentive structure generated by the Hatch-Waxman Act's listing requirement, the FDA has repeatedly argued the statute delegates only "ministerial" authority, and that it is only authorized under the Act to transcribe submissions into the Orange Book.<sup>210</sup> That is, the FDA has determined that there is no "statutory basis for a substantive agency review of patents"<sup>211</sup> and has pursued a course of inaction, "declin[ing] to create an additional administrative process for challenging patent listings."<sup>212</sup>

This cramped interpretation of its authority has significant consequences for pharmaceutical competition. By leaving the question of whether a patent is appropriately listed to the courts,<sup>213</sup> generic entry "comes much later, and at considerable additional costs" of litigation.<sup>214</sup> Even more significantly, the prospect of litigation may have a general "chilling effect" on generic entry altogether.<sup>215</sup> As noted above, delayed generic entry can result in billions of dollars of annual consumer loss. These effects have generated calls for Congress to amend the statute to clarify the "FDA's obligation to administer the Act in a responsible way."<sup>216</sup> In the decade since, Congress has not done so.<sup>217</sup>

But under the view of agency jurisdiction described above, the FDA can implement a procedure for the substantive review of Orange Book listings using usual procedures under administrative law. That is, the FDA's existing authority to enter patent listings in the Orange Book should be read to include the authority to ensure that those listings are accurate. Indeed, others have suggested that the FDA should interpret the Hatch-Waxman Act as a grant of precisely this sort of

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<sup>209</sup> *Caraco Pharm. Labs. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1678 (2012) (describing *Mylan*).

<sup>210</sup> Applications for FDA Approval to Market a New Drug, 68 Fed. Reg. 36,676, 36,683 (June 18, 2003) (to be codified at 21 C.F.R. pt. 314).

<sup>211</sup> *Id.* Congress has since amended the statute to allow generic competitors to file a counterclaim that seeks correction of the Orange Book listing. 21 U.S.C. § 355(c)(3)(D)(ii); *Caraco Pharm. Labs.*, 132 S. Ct. at 1678. Nevertheless, leaving this question to judicial determination not only delays and raises the cost of generic entry, it also has a general "chilling effect" on generic entry altogether. See *infra* notes 215–216 and accompanying text.

<sup>212</sup> Applications for FDA Approval, *supra* note 210, at 36,683.

<sup>213</sup> See *Caraco Pharm. Labs.*, 132 S. Ct. at 1678 (describing judicial mechanism for correcting Orange Book listings).

<sup>214</sup> *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1353 (Fed. Cir. 2003) (Plager, J., concurring).

<sup>215</sup> *Id.*

<sup>216</sup> *Id.* at 1354.

<sup>217</sup> To be sure, Congress has amended the statute in other ways. See *supra* note 211. But it has not taken steps to require the FDA to police Orange Book listings, despite calls for such an amendment.

authority: “The FDA claims the power to police the listing process to the extent of ensuring that patents that should be listed are listed; it is a relatively straightforward step to ensure that those patents that obviously should not be listed are not.”<sup>218</sup>

To be sure, the scope of ancillary authority is not boundless. Rather, an agency’s ancillary jurisdiction depends upon the relationship between the proposed administrative action and agency’s specific preexisting regulatory mandates. In particular, the regulation must both fall within the agency’s “general grant of jurisdiction”<sup>219</sup> and, as noted above, be “reasonably ancillary to the effective performance” of its clearly delegated responsibilities.<sup>220</sup> In the communications context, these requirements have imposed significant substantive limits on the FCC’s authority to regulate. Likewise, exercises of ancillary authority directed at patents would face similar constraints. Thus, while the FCC might issue

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<sup>218</sup> *Apotex*, 347 F.3d at 1353; see also Jacob S. Sherkow, *Administrating Patent Regulation*, 90 WASH. L. REV. (forthcoming 2015) (manuscript at 11) (noting that “the FDA’s authority with respect to policing Orange Book listings is far from ‘purely ministerial,’” and highlighting the FDA’s inconsistency on the scope of its authority) [hereinafter Sherkow, *Administrating*].

The FDA has also resisted these alternative interpretations on competency grounds, noting that it “lack[s] expertise in patent matters.” See Applications for FDA Approval, *supra* note 210, at 36,683. But as Judge Plager has noted, this problem is easily overcome if the more fundamental question of the FDA’s regulatory authority is addressed. See *Apotex*, 347 F.3d at 1353 (Plager, J., concurring) (not unreasonable for the FDA to hire “a handful of competent patent analysts” to work alongside its existing “multitude of scientific specialists” to police Orange Book listings).

<sup>219</sup> *Am. Library Ass’n v. FCC*, 406 F.3d 689, 692 (D.C. Cir. 2005). In the context of communications regulation, this requires that the regulation involve “interstate and foreign communication by wire or radio.” *Id.* (quoting 47 U.S.C. § 152(a) (1996)). Some commentators have argued that the FCC’s ancillary jurisdiction derives from its authority to “perform any and all acts . . . necessary in the execution of its functions” under Section 4(i) of the Communications Act, sometimes termed the FCC’s “necessary and proper” clause. See, e.g., *Mobile Comm’ns Corp. of Am. v. FCC*, 77 F.3d 1399, 1404 (D.C. Cir. 1996). While such a limitation is not necessarily evident from the Supreme Court’s decision in *Southwestern Cable*, see *supra* notes 192–194 and accompanying text, it does not operate to significantly limit the theory of patent-related jurisdiction articulated above: such broadly worded enabling statutes are relatively common across agencies. See, e.g., Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 371(a) (2012) (granting the general “authority to promulgate regulations for the efficient enforcement of this chapter”); see also *Tafas v. Doll*, 559 F.3d 1345, 1365 (Fed. Cir. 2009) (Bryson, J., concurring) (collecting examples of such statutes); Sarah Tran, *Patent Powers*, 25 HARV. J.L. & TECH. 609, 614 n.29 (2012) (same). Similar provisions in other agency statutes might, to the extent necessary, support a theory of patent-oriented ancillary authority. But see Thomas W. Merrill & Kathryn Tongue Watts, *Agency Rules with the Force of Law: The Original Convention*, 116 HARV. L. REV. 467, 472–73, 517–19 (2002) (such broadly worded grants of authority, including in the Communications Act, do not give agencies, including the FCC, the authority to issue rules that carry the force of law).

<sup>220</sup> *Am. Library*, 406 F.3d at 693 (quoting *United States v. Sw. Cable Co.*, 392 U.S. 157, 167 (1994)).

rules pertaining to patents implicated in the transmission of a broadcast signal,<sup>221</sup> it would seem to lack the authority to, for example, require licensing for patents implicated by the recording of video programs after transmission.<sup>222</sup> But within these important constraints, ancillary authority may provide agencies with a useful font of jurisdiction to address patent conflicts and help assure the integrity of Congress's various policy designs.

## 2. Executive Coordination

The direct assertion of authority, however, is not the only mechanism available to agencies seeking to address patent conflicts. Indeed, as suggested earlier, direct agency capacity to intervene into patent policy may be constrained by an agency's inherent limits (notwithstanding the regulatory jurisdiction offered by an agency's ancillary authority). In *Myriad*, for example, the NIH's decision to withdraw its DNA-related patent applications, while influential, was alone not enough to shift the standards of patentability. Indeed, the NIH has practically no direct substantive authority to effect change in the PTO's standards of patentability.<sup>223</sup> Likewise, while the IRS's proposed regulations presented a clever solution to the problems posed by tax strategy patents, a preferable approach might have simply been to prevent such patents from ever issuing at all.<sup>224</sup>

In cases where exercises of agency authority alone may be insufficient or second-best,<sup>225</sup> new options might be found in analogues to the indirect action

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<sup>221</sup> See, e.g., Reasonable and Nondiscriminatory Licensing of Patents Essential to Implementation of Mandatory Digital Television Standards, *Petition for Rulemaking and Request for Declaratory Ruling*, Docket No. 09-23 (2009) ("ask[ing] the FCC to modify its rules and policies governing licensing of patents that are essential to implementation of the Commission's digital television standards.").

<sup>222</sup> See *Am. Library*, 406 F.3d at 692 ("[T]he Broadcast Flag rules do not regulate interstate radio communications . . . because the Flag is not needed to make a DTV transmission, does not change whether DTV signals can be received, and has no effect until *after* the DTV transmission is complete.") (citation omitted); cf. *United States v. Addyston Pipe & Steel Co.*, 85 F. 271, 282–83 (6th Cir. 1898) (Taft, J.) (limits of permissible ancillarity in antitrust).

<sup>223</sup> See Rebecca S. Eisenberg & Michael A. Heller, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 *SCIENCE* 698, 699–700 (1998).

<sup>224</sup> Cf. *Bilski v. Kappos*, 561 U.S. 593, 659 (Breyer, J., concurring in the judgment) (noting the "granting of patents that ranged from the somewhat ridiculous to the truly absurd" (citations and internal quotation marks omitted)).

<sup>225</sup> To be sure, some examples belie such neat categorization. Consider the IRS example described *supra* Part II.B.2. In one sense, tax strategy patents present a discrete policy problem which the IRS's proposed regulations might have fully addressed. See *supra* notes 140–141 and accompanying text, and note 203. In another sense, however, they relate to a more general question regarding the types of invention the patent system should aim to support. The choice between agency responses partially depends on this characterization. The IRS might have

examples described above—but with a focus instead on actors within Executive Branch, rather than on the courts or Congress. This section and the next offer two variations on that theme.

The first approach depends on a focal point for policy coordination within the Executive Branch. That is, a single institutional actor takes responsibility for mediating the policy competition between patent institutions and other agencies. To the extent that such patent policy coordination takes place at all in the Executive Branch, this structure is the typical model—and coordination responsibilities have usually (though not exclusively) fallen to the Department of Justice’s Office of the Solicitor General (OSG). Indeed, the Solicitor General has catalyzed patent policy coordination across the Executive Branch on several occasions, and it has achieved significant successes in persuading the Supreme Court to adopt its preferred outcomes.<sup>226</sup>

Consider two of the examples discussed earlier. In *Myriad*, patent policymaking institutions and the NIH held competing visions of how to best promote innovation in biotechnology spaces. The Solicitor General took on the task of balancing the competing views of several agencies, including the PTO, NIH, HHS, and the White House’s Office of Science and Technology Policy.<sup>227</sup> Despite the lack of consensus among these interested parties, the process yielded a single “view of the United States” that the Solicitor General presented to the Federal Circuit and the Supreme Court.<sup>228</sup>

The Solicitor General played a similar coordination function—on multiple occasions—in the context of the policy conflict between the PTO and FTC regarding settlements of Hatch-Waxman Act litigation. In *Schering-Plough*, the Solicitor General weighed the considerations presented in an FTC-filed petition

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rejected claims that it lacked regulatory authority and, instead, proceeded directly to address the problems created by tax strategy patents for the efficient administration of tax policy. But to the extent that the tax strategy patent is characteristic of a broader set of patents claiming methods of complying with the law, the problem may be better addressed through other mechanisms, as described below.

<sup>226</sup> See Duffy, *supra* note 8, at 519; Colleen V. Chien, *Patent Amicus Briefs: What the Courts’ Friends Can Teach Us About the Patent System*, 1 U.C. IRVINE L. REV. 397, 429–430 (2011) *see also* Arti K. Rai, *Competing with the “Patent Court”: A Newly Robust Ecosystem*, 13 CHI.-KENT J. INTELL. PROP. 386, 389 (2014) [hereinafter Rai, *Robust Ecosystem*]; Rai, *Patent Validity*, *supra* note 8, at 1244–48.

<sup>227</sup> See *supra* Part II. To be sure, the presence of the White House’s Office of Science and Technology Policy, among others, raises some question as to which entity controlled the policy decision. But there is little doubt that *Myriad*’s litigation context served as an important catalyst for policy coordination. See Rebecca Ingber, *Interpretation Catalysts & Executive Branch Legal Decisionmaking*, 38 YALE J. INT’L L. 359, 368 (2013).

<sup>228</sup> Hear Oral Argument at 30:18–31:38, *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303 (Fed. Cir. 2012) (No. 2010-1406), *available at* [http://oralarguments.cafc.uscourts.gov/Audiomp3/2010-1406\\_7202012.mp3](http://oralarguments.cafc.uscourts.gov/Audiomp3/2010-1406_7202012.mp3).

for certiorari as well as the policy views offered by the PTO, and recommended that the Court not grant the petition.<sup>229</sup> And in *Actavis*, the Solicitor General reconsidered those arguments, and decided instead to join the FTC's petition to seek review.<sup>230</sup> The Supreme Court followed the Solicitor General's advice each time.

The Hatch-Waxman Act petitions present something of a puzzle. Why did OSG modify its position in *Actavis*? While several possibilities might explain the shift, including the emergence of a clear circuit split and the compilation of additional evidence in support of the FTC's view,<sup>231</sup> one obvious candidate is the change in administration—from President Bush to President Obama—during the period between the petitions. This explanation (to the extent it is one) might give cause for concern: Should patent policy outcomes be influenced by political changes? John Duffy, for example, has cautioned against allowing such political pressure to exert significant influence over patent policy.<sup>232</sup> But the litigation positions of the United States are, as a general matter, routinely subject to such political influence,<sup>233</sup> and there seems little reason to insulate patent policy in particular from such pressures.<sup>234</sup> Indeed, immunizing patent might be said to have the untoward effect of reducing the extent to which patent policy is politically accountable.

Although the influence exerted by differing administrations may not present concerns that are specific to patent policy coordination, there are still reasons to question the efficacy of relying on Solicitor General as a policy coordinator. Although the instantiation of such a policy coordination role within OSG may be an artifact of the judiciary's significant role in patent policymaking, it seems suboptimal to have this function carried out by a body primarily charged with litigation-related responsibilities. For one, the "intense timetable of litigation" may

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<sup>229</sup> See *supra* Part I.A.

<sup>230</sup> See *supra* Part I.B.

<sup>231</sup> Petition for a Writ of Certiorari at 12–16, *FTC v. Watson Pharms., Inc.*, 133 S. Ct. 787 (2012) (mem.) (No. 12-416), 2012 WL 4750283.

<sup>232</sup> Duffy, *supra* note 8, at 549–550 (“In evaluating the weight to be given to the Solicitor General’s position, the Court should be especially attentive to the *durability* of the position through different administrations and should, in crafting judicial doctrine, try to avoid relying excessively on positions adopted by a particular Solicitor General’s Office.”)

<sup>233</sup> See, e.g., Transcript of Oral Argument at 32, *U.S. Airways, Inc. v. McCutchen*, 133 S. Ct. 1537 (2013) (No. 11-1285), available at

[http://www.supremecourt.gov/oral\\_arguments/argument\\_transcripts/11-1285.pdf](http://www.supremecourt.gov/oral_arguments/argument_transcripts/11-1285.pdf) (statements of Chief Justice Roberts) (“It’s perfectly fine if you want to change your position, but . . . [t]ell us it’s because there is a new Secretary.”).

<sup>234</sup> To be sure, it may be prudent, in general, to note the durability of a particular government position, but it is not clear that there is any particular reason to do so in patent law but not in other areas of regulatory law.

place artificial limits on interagency deliberation and negotiation.<sup>235</sup> And to the extent OSG actually makes patent policy decisions, rather than relays the policy choices of the current administration,<sup>236</sup> this would seem to be a significant departure from OSG's usual function and core competency.

But even depending on the Solicitor General to simply relay administration policies might yield some of the same problems that arise when agencies turn to the court or to Congress to resolve such policy clashes. Because the Justice Department ultimately controls the presentation to the judiciary, an agency's voice and expertise may be filtered through OSG's filings.<sup>237</sup> Likewise, because the Solicitor General necessarily operates through the judiciary, an ultimate decision will depend on judicial resolution.

There are alternatives. Other Executive Branch bodies, such as the Office of Management and Budget (OMB) or its Office of Information and Regulatory Affairs (OIRA), which are routinely tasked with interagency policy coordination,<sup>238</sup> might substitute for the Solicitor General. But relying on these entities does not avoid all of the problems that arise out of the litigation context in which OSG operates.<sup>239</sup> And OIRA and OMB may, like OSG, end up filtering an agency's expertise through its more general process.<sup>240</sup> On this point, the White House's Office of Science and Technology Policy (OSTP), or even a new entity entirely,<sup>241</sup> may fare better. Indeed, OSTP has taken tentative steps towards such a role in the distinct (but related) conflict between the Digital Millennium Copyright Act (DMCA) and communications regulations.<sup>242</sup> But so far, the involvement of any of these bodies in patent questions has been largely on an ad hoc basis.

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<sup>235</sup> Ingber, *supra* note 227, at 382–83.

<sup>236</sup> *But see supra* note 227.

<sup>237</sup> See Margaret H. Lemos, *The Solicitor General as Mediator Between Court and Agency*, 2009 MICH. ST. L. REV. 185, 222–223. To be sure, others have argued in favor of greater intervention by the Department of Justice, on grounds that it might better represent the interests of other agencies and avoid harm to regulated industries. See Sherkow, *Administrating*, *supra* note 218, at 45 (arguing in favor of increased intervention by the Department of Justice on behalf of other agency interests).

<sup>238</sup> See, e.g., Freeman & Rossi, *supra* note 75, at 1173–81 (“describ[ing] some of the well-established coordination instruments that are uniquely available to the President, including centralized White House review”); DeShazo & Freeman, *supra* note 112, at 2298 (“The most important player in coordinating regulatory action across multiple agencies may be [OIRA].”).

<sup>239</sup> See Marisam, *Duplicative Delegations*, *supra* note 200, at 207, 220 (noting “slow moving” nature of Executive Branch coordination).

<sup>240</sup> See Freeman & Rossi, *supra* note 75, at 1200 (“White House offices and councils [other than OIRA] with relevant policy expertise may be better equipped to” engage in policy coordination).

<sup>241</sup> Cf. Stuart Minor Benjamin & Arti K. Rai, *Fixing Innovation Policy: A Structural Perspective*, 77 GEO. WASH. L. REV. 1, 61–62 (2008) (proposing creation of Office of Innovation Policy).

<sup>242</sup> See *infra* note 313 and accompanying text (describing an example where the OSTP took on a similar function in a copyright-related context); see also *supra* note 227.



Formalizing a centralized and coordinated approach to patent policymaking might better allow a diverse set of agencies to offer their relative expertise in the resolving competitions both within innovation policy as well as between patent policy and other regulatory aims.

### 3. Interagency Interaction

An alternative to the centralized and hierarchical model described above is one that focuses on interagency interactions. That is, rather than rely on a particular Executive Branch body for policy coordination, agencies might rely on bilateral engagement with the PTO. In particular, a review procedure, newly instituted as part of recent patent reforms, provides an important new tool for coordination on patent policy questions. The use of this administrative structure can have several discrete benefits. It leverages the salient expertise of nonpatent agencies<sup>243</sup> by presenting it to the PTO via effective advocates.<sup>244</sup> And both the PTO and nonpatent agencies may have strong institutional incentives to create and use such an administrative interface.<sup>245</sup> The net result may be a policy regime that, like direct exercises of agency authority,<sup>246</sup> better reflect the totality of Congress's regulatory programs.<sup>247</sup> Stated simply, an administrative interface for interagency dialogue at the patent office can provide an improved mechanism for indirect agency action.

The America Invents Act devised new such procedures. Specifically, the statute provides for third-party challenges to patent applications after their initial adjudication by the patent office.<sup>248</sup> These proceedings are open to nonpatent

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<sup>243</sup> See, e.g., DeShazo & Freeman, *supra* note 112, at 2290; see also Jason Marisam, *Interagency Administration*, 45 ARIZ. ST. L. REV. 183, 191 (2013) (“[A] contributing agency’s analysis and policy recommendations are generally based on superior expertise . . . .”); Freeman & Rossi, *supra* note 75, at 1142 (2012) (noting that “disperse[d] [regulatory] authority” allows policymakers to “harness the unique expertise and competencies of different agencies”).

<sup>244</sup> Benjamin & Rai, *supra* note 241, at 87, and DeShazo & Freeman, *supra* note 112, at 2295, respectively argue that sister agencies, whose “comments . . . receive particular attention,” “can be the most frequent and effective intervenors in an administrative process.”

<sup>245</sup> See Marisam, *Interagency Administration*, *supra* note 243, at 191–97 (describing why an agency would “contribut[e] resources and expertise to another agency’s regulatory program”); Clarisa Long, *The PTO and the Market for Influence in Patent Law*, 157 U. PA. L. REV. 1965, 1972–81 (2009) (describing PTO incentives to increase its influence over the development of patent law).

<sup>246</sup> See *supra* note 200 and accompanying text.

<sup>247</sup> DeShazo & Freeman, *supra* note 112, at 2230 (“[E]ffective legislative control can take the form of interagency lobbying.”); see also Mathew D. McCubbins, et al., *Administrative Procedures as Instruments of Political Control*, 3 J.L. ECON. & ORG. 243 (1987).

<sup>248</sup> Specifically, the Act creates two separate administrative proceedings by which third-parties can challenge granted patents. Post-grant review is available to during the nine-month period immediately following the grant of patent. 35 U.S.C. § 321 (2012). Alternatively, *inter partes*

agencies,<sup>249</sup> and they thereby create an important avenue by which the PTO can receive input on its patentability standards from other regulators. Other agencies may directly challenge PTO decisions in post-grant review proceedings where its challenge “raises a novel or unsettled legal question that is important to other patents or patent applications.”<sup>250</sup> That is, while agencies do not typically have a “roving commission to question the validity of any patent lurking in the background” of their regulatory programs,<sup>251</sup> post-grant review creates such an opportunity via administrative procedure.

This mechanism is analogous to calls for a multiagency approach to the development of the PTO’s internal examination guidelines,<sup>252</sup> but focuses instead on the PTO’s (ex post) adjudicatory power, rather than the PTO’s (ex ante) rulemaking capacity.<sup>253</sup> Channeling nonpatent agency input through the PTO’s new adjudicatory mechanism allows agencies to react to PTO decisions, and avoids relying on the PTO to predict which agencies or regulatory program might

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review is available after the period during which post-grant review is either available or pending, and the grounds for challenging a patent or claim in *inter partes* review are limited to only those that “raised under section 102 or 103 and only on the basis of prior art consisting of patents or printed publications.” 35 U.S.C. § 311(b) (2012). *See also infra* note 250 and accompanying text.

<sup>249</sup> The statute makes these procedures open to “a person who is not the owner of a patent.” 35 U.S.C. §§ 311, 321. While the statute does not explicitly define “person” for the purposes of post-grant and *inter partes* review, the AIA gives the PTO the authority to define its own procedural requirements, including the authority to define such third-parties. It is therefore within the PTO’s discretion to issue a procedural rule noting that agency heads, acting in their official capacity, are among the “persons” eligible to seek review of a patent. 35 U.S.C. §§ 316, 326 (2012) (granting the PTO procedural rulemaking authority for *inter partes* post-grant review, respectively); *see also* *Tafas v. Doll*, 559 F.3d 1345, 1351–54 (Fed. Cir. 2009) (describing judicial deference for PTO procedural rules).

<sup>250</sup> 35 U.S.C. § 324(b) (2012); *see also* 154 CONG. REC. S9982-02, S9988-02 (daily ed. Sept. 27, 2008) (statement of Sen. Jon Kyl) (the provision “creates an avenue by which the question [whether a particular subject matter or thing is really patentable] can be conclusively resolved . . . before a large number of improper patents are granted and allowed to unjustifiably disrupt an industry . . .”). This standard applies only to post-grant proceedings, and not *inter partes* proceedings, thereby limiting an agency’s window for challenge to nine months after a patent issues.

<sup>251</sup> *United States v. Glaxo Grp.*, 410 U.S. 52, 59 (1973). It bears noting, however, that an agency may be able to meet challenges to direct agency exercises of regulatory authority with counterclaims that implicated patents are invalid. *Id.* Glaxo opposed “compulsory licensing” as an antitrust remedy, “asserting that the Government would deny defendants an essential ingredient of their rights under the patent system,” but court ruled that “[i]n this context . . . it would have been appropriate, if it appeared that the Government’s claims for further relief were substantial, for the court to have also entertained the Government’s challenge to the validity of those patents.” *Id.*

<sup>252</sup> *See Rai, Patent Validity, supra* note 8, at 1241–43.

<sup>253</sup> *But see id.* at 1280 (“An approach based on ex ante PTO guidelines backed by the full weight of the executive branch has already shown some promise.”).

be implicated by a given patent.<sup>254</sup> That is, nonpatent agencies must note patent decisions of interest themselves, or they must be alerted to them by the regulated industry.

Consider, again, the example of tax strategy patents. Tax and accounting professionals often criticized these patents on the grounds that they were sometimes expressly based on IRS guidance. Furthermore, the accountants' confidentiality obligations prevented them from challenging the validity of these patents—a constraint that would seem to apply equally across both federal litigation and administrative procedure. Thus, although the IRS was not involved in the patent office's examination of a tax strategy patent application,<sup>255</sup> nor does it seem to have been consulted when the PTO first began to issue such patents, the IRS might have considered challenging those patents in either a post-grant or *inter partes* review proceeding—if the right administrative channels had been available at the time.<sup>256</sup> U.S. Patent No. 7,149,712, for example, covers a tax reduction strategy that “was approved by the IRS in 1989 in Letter Ruling 9009047 and addressed favorably by the IRS in 1997 in Technical Advice Memorandum 9825001.”<sup>257</sup> This patent would seem ripe for IRS opposition.

Such a hypothetical challenge might have had at least two important effects. First, where a patent was indeed expressly based on IRS documents, the agency could bring that prior art to the attention of the PTO, thereby invalidating claims that were either not novel or obvious. Second, and more importantly, the IRS might have emphasized that tax strategy patents are, in general, based on disclosed features of federal law, and thereby urged the PTO to adopt by adjudication the more general conclusion that was eventually codified in Congress: The existence of the tax code renders “any strategy for reducing, avoiding, or deferring tax liability . . . insufficient to differentiate a claimed invention from the prior art.”<sup>258</sup> Stated simply, an early and strong challenge to tax strategy patents by the IRS might have diverted the entire practice altogether. Indeed, the IRS might have helped the PTO adopt a more general policy, via adjudication, that methods of complying with legal requirements generally—tax laws and privacy rules,<sup>259</sup> among others—are insufficiently differentiated from the

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<sup>254</sup> Cf. Keith Bradley, *The Design of Agency Interactions*, 111 COLUM. L. REV. 745, 777–78 (2011) (describing benefits of structured interagency interfaces).

<sup>255</sup> See e.g., 157 CONG. REC. S1199 (daily ed. Mar. 3, 2011).

<sup>256</sup> To be sure, *inter partes* reexamination might have been available to the IRS. I have, however, found no indication that IRS considered filing such a challenge.

<sup>257</sup> Cathey, et al., *supra* note 135, at 40–41.

<sup>258</sup> Leahy-Smith America Invents Act, Pub. L. No. 122-29, § 14(a), 125 Stat. 284, 327 (2011).

<sup>259</sup> For an example of how this practice has begun to migrate out of tax and into other legal methods, see U.S. Patent Application No. 20140150068 (filed May 29, 2014), a patent application

requirements themselves, thereby preventing private actors from claiming ownership to features of federal laws or broadly claiming methods of complying with the law.

To be sure, the scope of challenges that the PTO can entertain within the confines of post-grant and *inter partes* review is quite limited. Indeed, the statute confers no new discretion to the patent office to reject a patent application on general public interest grounds. But where there may be an honest question as to whether an application actually meets the standards of patentability, such as for methods of legal compliance, a nonpatent agency can provide critical and persuasive expertise that avoids a policy clash.

## B. WHEN AND HOW SHOULD AGENCIES ACT?

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assigned to Facebook, Inc., for a method of complying with the Children’s Online Privacy Protection Act, 15 U.S.C. §§ 6501, *et seq.* (2012). The application claims:

A computer-implemented method comprising:

receiving, from a purported parent user, a request to regulate actions of a child user in a social networking system, the child user having an age that is less than a threshold age;

accessing information associated with an account in the social networking system of the purported parent user and accessing information associated with an account in the social networking system of the child user;

determining whether a parent-child relationship exists between the purported parent user and the child user based at least in part on (1) the information associated with the account of the purported parent user and (2) the information associated with the account of the child user;

responsive to determining that the parent-child relationship exists between the purported parent user and the child user, prompting the purported parent user to provide one or more administrative settings regulating actions of the child user in the social networking system;

receiving, from the purported parent user, one or more administrative settings regulating actions of the child user in the social networking system; and

managing actions by the child user in social networking system based at least in part on the one or more administrative settings received from the purported parent user.

Under the proposal suggested above, the FTC, which administers the Children’s Online Privacy Protection Act as part of its consumer protection responsibilities, may decide to challenge this patent in a post-grant review proceeding (if the patent is issued).

Independent of the question of what forms of response—direct agency action and interagency interaction, among others—are available to address patent conflicts is the question whether an agency should act at all. That is, how can an agency determine if—and how—to respond to a patent conflict? Several considerations might guide an agency’s decision of whether to act, and what mode to choose. The agency might examine the conflicting policy vis-à-vis its own expertise; it might examine whether nonpatent agency action is consistent with principles of property theory; it might consider the likelihood of success before the PTO or the courts; or it might simply turn to the standard administrative law tool of cost-benefit analysis. Although none of these factors, standing alone, can determine the best approach—indeed, they may even conflict with each other on occasion—they nevertheless outline some features relevant to the questions of when and how to react to patent conflicts.

### 1. Agency Expertise

The most important consideration may be the salience of the nonpatent agency’s expertise. Consider, for example, those agency clashes that seem confined entirely to the domain of innovation. *Myriad*, and the general debate regarding standards for DNA-related patents, for example, may be best characterized as a clash between competing visions on how to promote research in biotechnology spaces. Likewise, the episode regarding tax-strategy patents might be thought to present a more general question regarding the types of invention the patent system should aim to support.<sup>260</sup>

In such innovation-specific contexts, agency intervention seems especially warranted. Although patent provides a uniform incentive for innovation across industries and contexts—that is, patent law is “technology-neutral in theory”—innovation policy is more efficient when it is context sensitive.<sup>261</sup> Such claims in favor of variability may seem counterintuitive—after all, the historical trajectory of patent policy has been one of consolidation: federal patent laws preempt state laws, the federal judiciary has exclusive jurisdiction over patent cases, and jurisdiction over patent appeals has been consolidated at the Federal Circuit—the

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<sup>260</sup> To be sure, this is not a complete characterization of *Myriad* nor of the tax strategy patents episode. See, respectively, Park, *supra* note 119, at 520 (describing several non-innovation-related interests in *Myriad*, including “bodily integrity, human dignity, and scientific freedom”), and *supra* note 225 (two competing characterizations of the tax strategy patent episode).

<sup>261</sup> See Burk & Lemley, *supra* note 15, at 1577.

pursuit of uniformity in patent law has given rise to several significant problems.<sup>262</sup>

For example, a primary criticism leveled at the patent policymaking apparatus has been its apparent proclivity to favor formalistic rules that sacrifice the policy aims of the patent laws at the altar of predictability. To be sure, a centerpiece of the Federal Circuit's mandate has been to promote certainty in the patent laws. But the effect of providing such certainty through a preference for rules over standards—despite the repeated caution of the Supreme Court<sup>263</sup>—has been to “distance the patent law” from a broader vision of “innovation policy.”<sup>264</sup>

By contrast, the intervention of nonpatent agencies helps to craft a more context-sensitive, and thus less formalistic, regime that is consistent with a more comprehensive innovation policy (that includes and extends beyond patent).<sup>265</sup> It capitalizes on the innovation-related expertise that has been located elsewhere in the administrative state—such as the particular expertise of the NIH or HHS in the context of promoting health and biological technologies.<sup>266</sup>

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<sup>262</sup> See, e.g., Rai, *Robust Ecosystem*, *supra* note 226, at 388 (“Although formalism, uniformity, and predictability can promote innovation, they can also retard it.”); see also Hon. J. Diane P. Wood, Keynote Address at the Chicago-Kent Supreme Court IP Review, *Is It Time to Abolish the Federal Circuit's Exclusive Jurisdiction in Patent Cases?* (Sept. 26, 2013), in 13 CHI.-KENT J. INTELL. PROP. 1 (2013); Craig Allen Nard & John F. Duffy, *Rethinking Patent's Uniformity Principle*, 101 NW. U. L. REV. 1619 (2007).

<sup>263</sup> Holbrook, *supra* note 69, at 77 (reviewing the Supreme Court's rejection of the Federal Circuit's bright-line rules in cases such as *Festo*, *KSR*, *eBay v. MercExchange*, *Quanta*, *Bilski*, and *MedImmune*).

To the extent that the Federal Circuit's tendency toward formalism can be explained through information cost theory, see, e.g., Lee, *supra* note 60, at 25–27, the policy input of other agencies helps to mediate and to mitigate the costs associated with more complex standards-based decisionmaking. The cost of subject matter expertise is significantly less burdensome for those agencies that happen to be expert in the field in which the technology applies. The FCC, for example, is expert in wireless networks and communication, and might therefore be better equipped than either the Federal Circuit or the PTO to adjudge the effect of a patent over location-tracking technology—or, more precisely, the relative effect of a mandatory damages rule—on future innovation in that industry. That is, the non-patent agency's expertise in the field in which the patent applies may be more salient than “patent law expertise” for the purposes of crafting a rule that is sensitive to the economic context of the industry and the underlying public policy. See Dyk, *supra* note 60, at 352–53 (acknowledging problems associated with the insular nature of patent litigation, and seeking the policy input of those involved in antitrust or who represent consumer interests).

<sup>264</sup> John R. Thomas, *Formalism at the Federal Circuit*, 52 AM. U. L. REV. 771, 774 (2003).

<sup>265</sup> E.g., Dreyfuss, *Case Study*, *supra* note 16; see also Lisa Larrimore Ouellette, *Patentable Subject Matter and Non-Patent Innovation Incentives*, 5 U.C. IRVINE L. REV. (forthcoming 2015), manuscript at 26–29.

<sup>266</sup> See 2010 HHS GENE PATENT REPORT, *supra* note 130, at 6.

The benefits of nonpatent agency expertise persist even where the conflict ranges beyond the domain of innovation and implicates distinct public policy goals.<sup>267</sup> In analogous cases, preference has been given to the regulatory design most likely to incorporate relevant market and technical expertise.<sup>268</sup> In areas of conflict between antitrust and industry-specific competition regulation, for example, the Court has emphasized that “antitrust analysis must sensitively recognize and reflect the distinctive economic and legal setting of the regulated industry to which it applies” and that claims of harm under the antitrust laws may give way to a comprehensive “regulatory structure” that is built on such expertise.<sup>269</sup> Moreover, these principles hold true “even in areas of law where national uniformity is important,” such as patent.<sup>270</sup>

To be sure, countervailing interests may counsel against direct agency intervention in policy conflicts that extend beyond innovation. Agencies may act self-interestedly to protect the scope of its own regulatory domain, and thereby undervalue the competing innovation policy goal.<sup>271</sup> Prioritization among competing policies in such cases may better rest with a more politically accountable entity, such as an Executive Branch arbiter or Congress, or with an impartial body, such as the courts. Indeed, the *Actavis* example presents a case where such prioritization responsibilities fell, in the first instance, to the Solicitor General—and where, perhaps in response to political changes (among other features), such priorities shifted.<sup>272</sup> But even in these cases, there is good reason to think that deploying agency expertise in response to changes to regulatory

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<sup>267</sup> See, e.g., Sarah Tran, *Prioritizing Innovation*, 30 WISC. INT’L L.J. 499, 543–44 (2012) (noting that the patent office considers hydroelectric facilities to be “renewable energy” for the purposes of a PTO pilot program despite the fact that such facilities “have been the frequent subject of attacks by environmentalists” and therefore suggesting that FERC “would be better equipped to weigh these competing” concerns).

<sup>268</sup> See *Pom Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2238 (2014) (preferring structures more likely to draw upon “perspective or expertise in assessing market dynamics”); see also *Verizon Commc’ns, Inc. v. Law Offices of Curtis V. Trinko*, 540 U.S. 398, 412–14 (2004) (describing how industry-specific regulation may be a superior substitute for general antitrust enforcement in some instances); Molly Shaffer Van Houweling, *Communication’s Copyright Policy*, 4 J. TELECOMM. & HIGH TECH. L. 97, 116–118 (2005) (favoring FCC regulation of copyright based on its knowledge of “industry conditions and practices” and its other “substantive expertise”).

<sup>269</sup> *Trinko*, 540 U.S. at 411–412 (quoting *Concord v. Boston Edison Co.*, 915 F.2d 17, 22 (1st Cir. 1990) (Breyer, C.J.)); see also *Credit Suisse Secs. (USA) v. Billing*, 551 U.S. 264, 267–68 (2007) (“[W]e must interpret the securities laws as implicitly precluding the application of the antitrust laws to the conduct alleged in this case.”).

<sup>270</sup> *Pom Wonderful*, 134 S. Ct. at 2240.

<sup>271</sup> But see *Universal Encryption Standard for Satellite Cable Programming, Report*, 5 FCC Rcd. 2710, 2717–18 (1990) (prioritizing patent’s goal of inducing innovation).

<sup>272</sup> See *supra* Part III.A.2.

conditions—including patent-related changes—will yield a policy outcome that is consistent with legislative will.<sup>273</sup>

## 2. Hold Up and Transaction Costs

Beyond an agency’s own expertise, principles derived from eminent domain and property theory can help guide agency responses to patent conflicts. Just as the Constitution authorizes the taking of property for public uses in exchange for just compensation,<sup>274</sup> 28 U.S.C. § 1498 enables the federal government to procure patented technology for an appropriate fee without fearing that an injunction will hold up the government use. Likewise, the view that an agency’s authority inherently extends to patents that are implicated by a delegated policy may suggest that Congress has authorized several public policies that an agency may effectuate by converting a patent’s property rule into a liability rule.

The decision whether to exercise such authority may thus depend on whether the patent can be analogized to real property properly subject to eminent domain.<sup>275</sup> For example, shifting a patent’s exclusionary regime to a liability rule can, analogously to classic eminent domain cases, help assure that patent holders do not hold up the implementation of a public policy, or help assemble several patents critical to an agency mandate that would otherwise be difficult to independently license.<sup>276</sup>

That is, while patent law itself would seem to lack “formal mechanisms to deter excessive fragmentation” of intellectual property rights, targeted

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<sup>273</sup> See *supra* notes 200, 247 and accompanying text.

<sup>274</sup> U.S. CONST., amend. V.

<sup>275</sup> Indeed, the case for takings-like actions may be even stronger in patent than for real property. Along dimensions of certainty and notice, real property fares better than intellectual property, and so moving toward a governance-like regime for real property imposes significantly higher information costs. But the bounds of a patent are already ambiguous and often require litigation to sort out, and so the shift to a liability rule in patent might be thought to impose a relatively smaller cost than in real property. *But see* Henry E. Smith, *Intellectual Property as Property: Delineating Entitlements in Information*, 116 YALE L.J. 1742, 1819 (2007). (“[T]he information-cost advantage of basic exclusion points toward greater strength of the presumption in favor of exclusion and property rules than is often argued.”).

<sup>276</sup> See *id.* at 1781 (“Liability rules represent a partial withdrawal of this delegation and make sense when we do not trust the owner to make the right choice or when we worry about holdouts and other high-transaction-cost scenarios in the presence of potential valuable use by multiple parties.”); *cf.* *eBay, Inc. v. MercExchange, LLC*, 547 U.S. 388, 396–97 (2006) (Kennedy, J., concurring) (noting public interest concerns that may weigh against issuing injunctions in patent cases); Sarah R. Wasserman Rajec, *Regulatory & Judicial Implementations of Patent Law Flexibilities*, 43 INT’L REV. OF INTELL. PROP. & COMP. L. 245, 246–247 (2012) (disfavoring exclusionary relief in cases that present significant externalities, such as “urgent, public health concerns”).



intervention by nonpatent agencies provides an alternative.<sup>277</sup> Given the stated public interest in modernizing the nation’s public safety communications infrastructure, the threat of holdout by 911-related patent owners might justify administrative intervention.<sup>278</sup> Likewise, the problem of “patent clutter”<sup>279</sup> that motivated the NIH’s actions in the 1990s, and eventually culminated in the Supreme Court’s recent decision in *Myriad*, presents a case of high-transaction cost assembly.<sup>280</sup> Altogether, the conditions that justify the exercise of eminent domain authority—“holdouts and other high-transaction cost scenarios”—can guide an agency’s application of its inherent patent-related authority.<sup>281</sup>

Inversely, where patents implicated by regulatory programs seem unlikely to present such issues, agency intervention may be less warranted. Consider a stylized example from the FCC.<sup>282</sup> The FCC has adopted a technical standard for the transmission of digital television (DTV). The standard itself was developed by an industry association that mandates its members and non-member participants to disclose and license essential patents.<sup>283</sup> Patent licensing has been robust, and the DTV market has grown significantly since the adoption of the standard.<sup>284</sup> However, some manufacturers facing infringement claims have argued that the prevailing licensing terms are significantly more expensive than international

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<sup>277</sup> Michael A. Heller, *The Boundaries of Private Property*, 108 YALE L.J. 1163, 1175 (1999) [hereinafter Heller, *Boundaries*]; see also Michael A. Heller, *The Tragedy of the Anticommons: Property in the Transition from Marx to Markets*, 111 HARV. L. REV. 621, 641 (1998).

<sup>278</sup> See *supra* note 201 and accompanying text.

<sup>279</sup> Varmus, *supra* note 104, at 68 (internal quotations omitted); see also Eisenberg & Heller, *supra* note 223; Heller, *Boundaries*, *supra* note 277, at 1174–75.

<sup>280</sup> See *supra* Part II.B.1.

<sup>281</sup> Smith, *supra* note 275, at 1781; cf. *Ala. Power Co. v. FCC*, 311 F.3d 1357, 1369–71 (11th Cir. 2002) (describing a federal agency’s compensatory regime for the taking of a “nonrivalrous” property right).

<sup>282</sup> The description that follows is based on comments presented to the FCC in an open proceeding, and is stylized in the sense that it takes the assertions in certain comments as true in order to present a scenario—true or not—that compares to other cases described above. To be clear, I make no claim that the stylized presentation here is in fact an accurate representation of the licensing market for patents necessary to the DTV standard.

Another example may be found in the FCC’s Report in Universal Encryption Standard for Satellite Cable Programming, 5 FCC Rcd. 2710 (1990), which declined to regulate the licensing of patents necessary to a *de facto* encryption standard, finding that no regulatory intervention was warranted by the public interest. *Id.* at 2716–18.

<sup>283</sup> See Petition for Rulemaking and Request for Declaratory Ruling Filed by the Coalition United to Terminate Financial Abuses for the Television Transition, LLC, *Comments of the Advanced Television Systems Committee, Inc.*, Docket No. MB 09-23 (2009).

<sup>284</sup> See Petition for Rulemaking and Request for Declaratory Ruling Filed by the Coalition United to Terminate Financial Abuses for the Television Transition, LLC, *Comments of Zenith Electronics LLC.*, Docket No. MB 09-23 (2009).

counterparts,<sup>285</sup> and are therefore seeking a rule that caps licensing fees by reference to these comparators.<sup>286</sup>

Although the FCC's ancillary authority to regulate would seem to extend to the relief sought,<sup>287</sup> the case in favor of the actual exercise of such authority is much less obvious. The DTV example would seem to present neither a case where a single patent owner is likely to hold up the implementation of the standard (indeed, the standard-setting organization has required licensing), nor a case where the transaction costs of obtaining necessary licenses are unwieldy. Thus, the requested regulatory action might be thought to undermine market price for the patent license, and administrative intervention would seem to be unjustified as simply for the benefit of a particular competitor, rather than in the broader interest of communications policy.<sup>288</sup>

### 3. Cooperation from Patent Institutions

The extent to which the primary institutions of patent are willing to cooperate can also affect a nonpatent agency's intervention. For example, the success of agency-initiated review of patents hinges on the willingness of the PTO to consider the input of nonpatent agencies. Despite evidence suggesting that sister agencies can be the most effective advocates,<sup>289</sup> some might argue that, on the basis of prior experience, the patent office seems particularly reluctant to accept and incorporate the views of other agencies. In the context of the *Myriad* litigation, for example, the PTO "remained firmly behind its policy," even as several other Executive Branch actors adopted a stance against patentability.<sup>290</sup> To the extent that this outcome is the product of influence by the patent bar, nonpatent agencies can neutralize the effects of such capture.<sup>291</sup>

But to the extent that the PTO's obstinacy is attributable to an inherent tendency to overestimate the importance of patent, or to a resistance to accept the policy input of nonpatent agencies, such institutional characteristics would

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<sup>285</sup> See *id.*

<sup>286</sup> Reasonable and Nondiscriminatory Licensing of Patents Essential to Implementation of Mandatory Digital Televisions Standards, *Petition for Rulemaking and Request for Declaratory Ruling*, Docket No. MB 08-117 (2009).

<sup>287</sup> See *supra* Part III.A.1.

<sup>288</sup> NUCHESTERLEIN & WEISER, *supra* note 193, at 222 ("[E]conomic regulation should be designed to promote *competition* in the interest of consumers . . . ." (emphasis in original) (citation omitted)).

<sup>289</sup> *Supra* note 244.

<sup>290</sup> See Park, *supra* note 119, at 526.

<sup>291</sup> See Freeman & Rossi, *supra* note 75, at 1186 (effects on capture when authority is "dispersed"); DeShazo & Freeman, *supra* note 112, at 2291-92 (2006) (effects on capture when one agency acts to influence another).

undercut the effectiveness of a PTO-centric review proceeding. The governing question is the degree to which the PTO seems able to assess, accept, and incorporate the policy views of nonpatent agencies.

These objections would seem to hold much less sway than in the past. The PTO has taken significant steps toward building greater internal capacity for policy-related thinking, and, as a result, scholars who have previously “stopped short” of advocating for increased policymaking authority for the PTO have since argued in favor such authority.<sup>292</sup>

Indeed, the PTO has recently proved to be responsive to the input of nonpatent agencies. The PTO and the DOJ, for example, recently issued a joint policy statement regarding some of the harms that may result from the anticompetitive assertion of standards-essential patents. Specifically, the Antitrust Division and the PTO agreed that injunctive relief may “harm competition and consumers” by undermining the ability of standards-developing organizations to police opportunistic conduct.<sup>293</sup> Thus, the two agencies jointly concluded that, in certain situations, “the remedy of an injunction or exclusion order may be inconsistent with the public interest.”<sup>294</sup> This conclusion led the U.S. Trade Representative to overturn an order by the International Trade Commission preventing the importation of products that incorporated elements that, though patented, were subject to licensing commitments.<sup>295</sup> Stated simply, agency-to-

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<sup>292</sup> Rai, *Patent Validity*, *supra* note 8, at 1278–80.

<sup>293</sup> DOJ & PTO JOINT POLICY STATEMENT, *supra* note 201, at 6. Notably, the foundations for the joint policy statement seem to have been laid at “the first event that had ever been jointly hosted by the PTO, DOJ, and FTC.” See, e.g., Symposium, *Summary of Commentary at the Intersection of Competition Policy and Patent Policy Symposium*, at 1, 3–4 (May 26, 2010), available at [http://www.uspto.gov/ip/global/patents/Summary\\_of\\_Commentary\\_on\\_Competition\\_and\\_Patent\\_Policy5262010.pdf](http://www.uspto.gov/ip/global/patents/Summary_of_Commentary_on_Competition_and_Patent_Policy5262010.pdf).

<sup>294</sup> DOJ & PTO JOINT POLICY STATEMENT, *supra* note 201, at 6.

<sup>295</sup> The ITC is endowed with the authority, under Section 337 of the Tariff Act of 1930, to block the importation of articles that infringe U.S. patents. See 19 U.S.C. §§ 1337(a)(1)(B)(ii), 1337(d) (2012). In an import dispute between Apple and Samsung—one front in a wide-ranging patent battle—Samsung alleged that some popular models of Apple’s iPhone and iPad infringed several Samsung patents, including a standards-essential patent that Samsung had agreed to license on F/RAND terms. The ITC agreed. *Certain Electronic Devices*, *Commission Opinion*, ITC Inv. No. 337-TA-794 (June 2013) (public version).

Critically, the ITC found Apple’s defense, based on Samsung’s previous commitment to license, unpersuasive. The ITC found “no binding legal authority for [the] proposition that the Commission may not investigate a violation of Section 337 based on infringement of a patent subject to a FRAND” license, and the Commission further declined to draw a distinction between patents that “have [and] have not been declared to be essential.” *Id.* at 45–46. Rather, the ITC’s ruled that its statutory mandate simply required it to exclude infringing articles, and that this mandate applied indiscriminately and without regard to any licensing commitments attached to the patent. *Id.* at 46. *But see id.* at D1–D8 (Pinkert, Comm’r, dissenting).

agency engagement between the PTO and the DOJ helped to avoid a potentially anticompetitive patent assertion. This cooperative effort may suggest that the PTO may be increasingly receptive to the working across the Executive Branch to identify and mitigate issues that arise in areas of overlap between the patent regime and other regulatory initiatives.

Likewise, nonpatent agency success may also depend on the cooperation of the judiciary. In *In re Ciprofloxacin*, for example, the Federal Circuit's flat rejection of the FTC's arguments further curtailed its authority to sanction patent-related anticompetitive conduct. Thus, nonpatent agencies may prefer forms of intervention that are more likely to garner the support of the Federal Circuit or of the Supreme Court. For example, the PTO's new post-grant review procedures can be read to give the patent office the formal authority to create standards of patentability that are subject to some form of judicial deference.<sup>296</sup> (The PTO has typically not received such deference.) Thus, where the PTO and the nonpatent

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However, the President, acting through the U.S. Trade Representative, exercised his authority to review the ITC's decision and reversed it. Letter from Michael B.G. Froman, Amb., U.S. Trade Rep., to Irving A. Williamson, Chairman, U.S. ITC (Aug. 3, 2013). In expressly disapproving the decision—while approvingly citing the joint policy statement of the DOJ and PTO—the USTR noted that owners of patents that are essential to “consensus standards” will often make a “voluntary commitment to offer to license [those patents] on terms that are fair, reasonable, and non-discriminatory.” *Id.* at 2. Thus, the USTR commands the ITC to consider “whether a particular remedy is in the public interest” in future cases and cautions that that it “will look for these elements in any future decisions involving FRAND-encumbered [standards-essential patents].” *Id.* at 3.

Notably, while the USTR asks the ITC consider “whether a particular remedy is in the public interest,” *id.*, the ITC lacks the authority to grant non-injunctive (i.e., damages) relief. Thus, under the USTR's new guidance, the ITC may be altogether disabled from issuing any remedy at all in cases involving FRAND-encumbered patents. Instead, as the Trade Representative stated, it is preferable from the Executive Branch's perspective to have the complainant pursue “a remedy . . . through the courts”—where damages relief may instead be available. *Id.* at 4. The effect, however, is striking: In the *Actavis* context, the positions of the Federal Circuit and the PTO constrained the ability of competition regulators to pursue anticompetitive conduct. See *supra* Part I.A. In this example, however, the joint position of the Justice Department and the PTO had the effect of ensuring that the ITC did not wield its authority to support potentially anticompetitive patent assertions, and further represents an example of Executive Branch policymaking that has the effect of constraining Executive authority, preferring instead to defer to the judiciary.

<sup>296</sup> See Melissa F. Wasserman, *The Changing Guard of Patent Law: Chevron Deference for the PTO*, 54 WM. & MARY L. REV. 1959, 1965 (2013) (concluding “that the AIA rejects over two hundred years of court dominance in patent policy by anointing the PTO as the chief expositor of substantive patent law standards”); see also John M. Golden, *The USPTO's Soft Power: Who Needs Chevron Deference?*, 66 SMU L. REV. 541, 550 (2013) (*Chevron* does not apply, but *Skidmore* does); Rai, *Patent Validity*, *supra* note 8, at 1280 (PTO decisions made in post-grant proceedings clear *Mead's* standard for deference).

agency are in accord, the Federal Circuit ought to defer more strongly to the joint policy conclusion.<sup>297</sup> And even where the PTO and a nonpatent agency disagree, the conflict itself may serve to undermine any deference to the PTO's position,<sup>298</sup> and to signal a case's particular importance. Indeed, such interagency conflict has, in previous cases, signaled that Supreme Court review is warranted.<sup>299</sup>

Taken together, the question of cooperation from patent institutions present as a two-stage game. If, in the first stage, the PTO seems inclined to concur, then the case for agency of action is relatively strong, especially if the courts can be persuaded to grant deference to a combined policy outcomes. But if the PTO is likely to disagree, then the case for agency action depends largely on the extent to which the agency's conflicting position would undercut any deference accorded to the PTO policy, or the extent to which the agency is willing to engage in an indirect course of action through the Supreme Court, Congress, or another entity within the Executive Branch.

#### 4. Cost-Benefit Analysis

Lastly, administrative law's standard tool of cost-benefit analysis might help determine whether and how to address patent conflicts. Cost-benefit analysis, however, can be especially problematic in innovation contexts. The endeavor is, to extend a familiar metaphor, like comparing apple seeds with orange seeds: The analysis depends on a prediction of whether the value of future innovations exceeds the future value of the competing policy. To be sure, recent amendments to Executive Orders governing the rulemaking process helpfully require agencies to account for effects on innovation in the standard regulatory and rulemaking process,<sup>300</sup> and some further progress has been made on modeling innovation effects for the purpose of cost-benefit analysis.

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<sup>297</sup> See Freeman & Rossi, *supra* note 75, at 1205 (“[W]e expect strong agency coordination to produce decisions that will tend to attract greater judicial deference.”). This may be especially so if only *Skidmore*, rather than *Chevron*, would typically apply to the PTO's determination as a formal matter. See Golden, *supra* note 296, at 550.

<sup>298</sup> See *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1357–58 (Fed. Cir. 2012) (Bryson, J., dissenting) (“[W]hatever force the PTO's views on the issue of patent eligibility may have had in the past has, at the very least, been substantially undermined by the position the government [through the DOJ] has taken in this case.”).

<sup>299</sup> *Supra* note 126 and accompanying text.

<sup>300</sup> See Exec. Order No. 13563, 76 Fed. Reg. 3821, 3821 (Jan. 18, 2011) (“Our regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation.”); *id.* at 3822 (“Each agency shall also seek to identify, as appropriate, means to achieve regulatory goals that are designed to promote

In the context of the Manufacturers' Aircraft Association (MAA), for example,<sup>301</sup> commentators have typically argued that the government intervention was a success, not only because the military procured adequate aircraft for the war effort, but also because aeronautic innovation continued for decades beyond the war. From the perspective of patent policy's innovation-inducing goal, however, this is to focus on the wrong result. The question for cost-benefit analysis purposes is not whether innovation continued, but rather, whether it continued at a slower pace than it would have absent the intervention. Thus, an appropriate accounting for the innovation-related effects of the MAA would quantify the differential between actual subsequent innovation and the hypothetical innovation that might have been induced if the patent's exclusionary right were not softened by congressional threat of condemnation and the subsequent amendment to 28 U.S.C. § 1498. And determining whether the Navy and Congress's actions were in the public interest would require comparing this outcome to a similar analysis of actual and hypothetical military readiness just prior to and during World War I.

Perhaps this difficult cost-benefit calculus would have justified the creation of the MAA. But even if not, other factors, including those outlined above, could support the military's intervention. For example, it might have been appropriate for the armed services to conclude that national security interests trumped the innovation policies embodied by the patent grants.<sup>302</sup> Furthermore, the many patents implicated by airplanes, including the Wright Brothers' pivotal patent, might have created unworkably high transaction costs, or allowed the Wrights to hold up the manufacture of necessary warplanes.<sup>303</sup> Whatever the determinant, the net result was a regime that aimed to balance the innovation incentives that gave rise to flight with immediate needs to fly.

#### CONCLUSION: CONFLICT BEYOND PATENT

The patent regime is the product of the influence of a wide range of administrative actors across the Executive Branch. Where patent clashes with other regulatory regimes, agencies as varied as the FTC, NIH, FCC, IRS, and EPA, among others, can all play a critical role in balancing patent's general policy to induce innovation against distinct public aims, including public safety, national defense, and environmental protection.

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innovation."); *see also* Exec. Order No. 13579, 76 Fed. Reg. 41,587, 41,587 (July 11, 2011) (noting that Executive Order No. 13563 applies to both independent and Executive Branch agencies).

<sup>301</sup> *See supra* Part II.B.3.

<sup>302</sup> *Cf. Sherkow, Criminal Conduct, supra* note 91, at 24 ("[T]he ability of a cell phone user to call for help in a life-or-death emergency should morally trump an intellectual property right.").

<sup>303</sup> *See supra* Part III.B.2.

This dynamic extends beyond patent. Copyright, for example, similarly grants individual rights of exclusion that can, in some instances, frustrate other regulatory goals or public policies. In some instances, for example, copyright assertions have restricted public access to laws themselves.<sup>304</sup> In response, regulated entities have sought access to governing rules through judicial means.<sup>305</sup> Statutes that favor or compel disclosure have also sometimes been at odds with the right of a copyright owner to control and limit the distribution of a copyrighted work. SEC policies requiring the disclosure of financial information have, for example, run up against copyright claims seeking to restrict or monetize the dissemination of that information.<sup>306</sup> And in a twist on the theme of patent conflict, the PTO's requirement that a patent applicant disclose previous discoveries that bear on an invention's patentability has run into claims that applicants violate copyright law by submitting copies of relevant journal articles.<sup>307</sup> As with the examples described above, copyright assertions over these prior art submissions

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<sup>304</sup> Peter Strauss has described the clash between copyrights held by standard-setting organizations and those privately-set standards that have been incorporated into law in *Private Standards Organizations and Public Law*, 22 WM. & MARY BILL RTS. J. 497, 498 (2013), noting that the result of this conflict is that “the only practical course for someone . . . who . . . wishes to learn the [law] will usually be to purchase the standard from the [private standard-setting organization] whose intellectual property it is, at whatever price that organization chooses to set.” *Id.* at 507.

Christopher Sprigman has analogously asserted that because “numerous courts have mandated use of The Bluebook,” it “has been adopted as an edict of government and its contents are in the public domain” and not subject to copyright protection. Letter from Christopher Jon Sprigman, Professor of Law, N.Y.U. Sch. of Law, on behalf of Carl Malamud of Public Resource.Org, to Mr. Peter M. Brody, Ropes & Gray LLP (Oct. 6, 2014) (on file with author). Mr. Brody represents the publisher of The Bluebook, the Harvard Law Review Association.

<sup>305</sup> See, e.g., *Veeck v. S. Bldg. Code Cong. Int'l*, 293 F.3d 791, 793 (5th Cir. 2002) (en banc) (“[A]s law, the model codes enter the public domain and are not subject to the copyright holder’s exclusive prerogatives.”).

<sup>306</sup> See *Swatch Grp. Mgmt. Servs. v. Bloomberg LP*, 756 F.3d 73, 82–83 (2d Cir. 2014) (considering the effect, if any, of SEC Regulation FD, 17 C.F.R. § 243.100, on copyright protection for the recording of an investor telephone conference); *Int’l Swaps & Derivatives Ass’n, Inc. v. Socratek, LLC*, 712 F. Supp. 2d 96, 100 (S.D.N.Y. 2010) (finding only “scant case law that more generally analyzes conflicts between the Copyright Act and a federal statute” and, within the case’s specific domain, finding that the “copyright implications of documents filed with the SEC and available on EDGAR appear to be a matter of first impression”).

<sup>307</sup> See, e.g., Complaint at 2–4, *John Wiley & Sons, Ltd. v. McDonnell Boehnen Hulbert & Berghoff, LLP*, 2013 WL 5230636, at \*1 (N.D. Ill. Sept. 16, 2013), (No. 1:12CV01446); Complaint at 1–4, *Am. Inst. of Physics v. Schwegman, Lundberg & Woessner, P.A.*, 2013 WL 4666330, at \*1 (D. Minn. Aug. 30, 2013) (No. 12CV00528).

impose unanticipated costs on the patent application process and interfere with the patent examination system.<sup>308</sup>

Other nonpatent examples bear on competition, rather than disclosure, policies. The Second Circuit ruled that pharmaceutical companies cannot use the copyright laws to subvert the competitive aims of the Hatch-Waxman Act, which require generic drug manufacturers to use warning labels practically identical to those developed by the original pharmaceutical innovator.<sup>309</sup> Furthermore, the Supreme Court's decision in *American Broadcasting Cos. v. Aereo* gave rise to a conflict between copyright rules regarding television programming and the FCC's authority to regulate competition among cable companies and other similar video providers.<sup>310</sup> Likewise, the Library of Congress's authority over the Digital Millennium Copyright Act (DMCA) provides another example of conflict between intellectual property and competition regulation. The Library of Congress has the authority to exempt certain technologies from the DMCA.<sup>311</sup> In 2012, the Library declined to extend its exemption for the act of "unlocking" a cell phone for use on

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<sup>308</sup> See USPTO's Memorandum in Opposition to Plaintiffs' Motion to Dismiss or for Summary Judgment on USPTO's Counterclaim at 2, *Am. Inst. of Physics*, 2013 WL 4666330, at \*1 (No. 12CV00528) (noting "potential ramifications for [PTO] patent examination and review procedures").

<sup>309</sup> See *SmithKline Beecham Consumer Healthcare, LP v. Watson Pharms., Inc.*, 211 F.3d 21, 23 (2d Cir. 2000) (Generic drug companies are not "liable for copyright infringement because the Hatch-Waxman Amendments require generic drug producers to use the same labeling as was approved by the FDA for . . . the producer of the pioneer drug").

<sup>310</sup> 134 S. Ct. 2498 (2014). In *Aereo*, the Supreme Court held that Aereo's internet-based television streaming service infringed the copyrighted content of network television providers, such as ABC, noting that Aereo effectively functioned as a cable TV provider. See *id.* at 2502–03. Aereo, in response, sought refuge in the Copyright Act's compulsory licensing provisions for "cable systems," see 17 U.S.C. § 111(c) (2012), but the Copyright Office responded with a letter finding that Aereo's services "fall outside the scope" of the statute. Letter from Jacqueline C. Charlesworth, Gen. Counsel & Assoc. Register of Copyrights, to Matthew Calabro, Aereo, Inc., (July 16, 2014) (on file with author) (regarding Section 111 Statement of Account Filings). The Copyright Office, however, noted that it was amenable to "further review of the issue" "depending upon further regulatory . . . developments." *Id.* The FCC responded with a proceeding of its own that tentatively treats services like Aereo, Inc. as analogous to other programming providers; however, the FCC's Notice of Proposed Rulemaking notes the possibility for continuing conflict between the regulatory bodies. See *Promoting Innovation and Competition in the Provision of Multichannel Video Programming Distribution Services*, 80 Fed. Reg. 2078-01, 2078 (proposed Jan. 15, 2015) (to be codified at 47 C.F.R. pt. 46).

The history of the regulatory clash between video programming and copyright is deep. See, e.g., *United Video v. FCC*, 890 F.2d 1173, 1176–78 (D.C. Cir. 1989); Tim Wu, *Copyright's Communications Policy*, 103 MICH. L. REV. 278, 311–324 (2004) (describing extended conflict and negotiations between FCC and copyright in the context of broadcasting and cable television).

<sup>311</sup> See 17 U.S.C. § 1201(a)(1)(B) (1999).



a competing company's network.<sup>312</sup> The decision caused an uproar, as over 100,000 people petitioned the White House to undo the decision. The Obama Administration's response agreed that "consumers should be able to unlock their cell phones without risking criminal or other penalties," and accordingly turned to the FCC, in its capacity as wireless industry competition regulator, to "address[] this urgent issue."<sup>313</sup> The FCC helpfully intervened, but only to the extent that it could extract a voluntary agreement from the rightsholders,<sup>314</sup> and Congress eventually passed legislation that, as in the examples of conflict described above, only partially remediated the problem.<sup>315</sup>

Thus, examples of conflict among innovation-inducing, creativity-inducing, and other regulatory regimes abound. Patent, copyright, trademark, and forms of *sui generis* regulatory protection, all implicate important policy regimes that extend across the administrative state.<sup>316</sup> These conflicts with varied fields of regulatory law thus present an important subset of interagency interactions,

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<sup>312</sup> See 37 C.F.R. § 201.40(b)(iii)(3) (2014); see also Exemption to Prohibition on Circumvention of Copyright Protection Systems for Access Control Technologies, 77 Fed. Reg. 65,260, 65,264–66 (Oct. 26, 2012) (to be codified at 37 C.F.R. pt. 201) (explaining rationale for decision behind 37 C.F.R. § 201.40).

<sup>313</sup> White House Response to Petition *Make Unlocking Cell Phones Legal: It's Time to Legalize Cell Phone Unlocking*, (Mar. 4, 2013) available at <https://petitions.whitehouse.gov/response/its-time-legalize-cell-phone-unlocking>; see also Van Houweling, *supra* note 268, at 99 ("Some regulation of [technological protection measures] may . . . be in important part of balanced copyright policy and the FCC has expertise that it might usefully contribute to this regulatory task."); Letter from Lawrence E. Strickling, Ass. Sec'y for Commc'ns & Info., U.S. Dep't of Commerce, to Maria Pallante, Register of Copyrights, Library of Cong. (Sept. 21, 2012) available at [http://www.ntia.doc.gov/files/ntia/publications/ntia\\_2012\\_dmca\\_letter\\_final.pdf](http://www.ntia.doc.gov/files/ntia/publications/ntia_2012_dmca_letter_final.pdf) ("NTIA is persuaded that an exemption continues to be necessary to permit consumers affected by access controls to unlock their phones."). The letter was submitted pursuant to a statutorily-mandated interagency consultation process. 17 U.S.C. § 1201(a)(1)(C) (The Register of Copyrights "shall consult with the Assistant Secretary for Communications and Information of the Department of Commerce . . .").

<sup>314</sup> See Thomas E. Wheeler, Chairman, Fed. Commc'ns Comm'n, Statement on the Industry Agreement on Device Unlocking (Dec. 12, 2013), available at <http://www.fcc.gov/article/doc-324664a2>; see also Letter from Steve Largent, Pres. & CEO, The Wireless Assoc. (CTIA), to the Chairman & Comm'rs of the Fed. Commc'ns Comm'n (Dec. 12, 2013) available at <http://www.ntia.doc.gov/fcc-filing/2013/ntia-petition-rulemaking-unlocking-mobile-devices> (regarding "Carrier Unlocking Voluntary Commitment"). To be sure, the Obama Administration tried to push the FCC into further regulatory action. See, e.g., NAT'L TELECOMM. & INFO. ADMIN., Petition for Rulemaking Before the Fed. Commc'ns Comm'n (Sept. 17, 2013) available at <http://www.ntia.doc.gov/fcc-filing/2013/ntia-petition-rulemaking-unlocking-mobile-devices>.

<sup>315</sup> See Unlocking Consumer Choice and Wireless Competition Act, Pub. L. No. 113-144, 128 Stat. 1751, 1751–52 (2014) (overturning the Library of Congress's decision for one triennial review cycle, but returning the matter to the Library's discretion thereafter).

<sup>316</sup> See, e.g., 16 C.F.R. § 1.51 (1967) (FTC authority to seek cancellation of a trademark); see also *Thomas v. Union Carbide Agric. Prods.*, 473 U.S. 568, 585, 589 (1985) (discussing public rights embodied in the Federal Insecticide, Fungicide, and Rodenticide Act).

defined by the clash between individual grants of exclusionary rights (and the policies that define those rights) and the many public policies beyond those typically contemplated by competing regulatory agencies.

The mode of an agency's response to such conflict can be of critical importance. While the individual rights of exclusion endowed by the intellectual property system form a critical basis for creativity and innovation, these goals need not necessarily trump the policies that other agencies are charged with deploying. Congruence between these competing policy aims may be better achieved through direct intervention by outside agencies and through stronger interagency coordination within the Executive Branch. But across these forms of conflict and modes of responses, agencies should seek balance between the important innovation and creativity-inducing goals embodied in the intellectual property laws and the other important public policies contained in competing regimes.

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