

# ADMINISTRATING PATENT LITIGATION

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*Abstract:* Recent patent litigation reform efforts have focused on every branch of government—Congress, the President, and the federal courts—save the fourth: administrative agencies. Agencies, however, possess a variety of functions in patent litigation: they serve as “gatekeepers” to litigation in federal court; they provide scientific and technical expertise to patent disputes; they review patent litigation to fulfill their own mandates; and they serve, in several instances, as entirely alternative fora to federal litigation. Understanding administrative agencies’ functions in managing or directing, i.e., “administrating,” patent litigation sheds both descriptive and normative insight on several aspects of patent reform. These include several problems inherent in patent litigation generally, and ways of fixing them that focus less on the identities or characteristics of litigants and more on agencies’ (and courts’) institutional incentives. This Article synoptically describes the functions of administrative agencies in patent litigation, elucidates several problems with agencies’ operation of those functions, and provides several cheap, easy, and politically viable solutions to better administrating patent litigation.

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## INTRODUCTION

Recent efforts to reform patent litigation have involved every branch of the federal government. Congress, after repeated calls to action,<sup>1</sup> passed the 2011 Leahy-Smith America Invents Act, the largest and most expansive overhaul to the patent statute in almost sixty years.<sup>2</sup> The White House, an office not well known for influencing patent policy,<sup>3</sup> announced a multipart executive initiative aimed at curbing some of the abuses of the patent system.<sup>4</sup> And the federal judiciary—especially the Supreme Court—has been busy crafting new doctrines and modifying old ones in an attempt to shape patent litigation.<sup>5</sup>

But despite this wide marshalling of federal resources, one branch remains curiously absent from the chorus of patent litigation reform: administrative agencies. The U.S. Patent and Trademark Office (PTO), while admirably vocal in its efforts to improve patent issuance, has

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1. *E.g.*, Susan Decker, *Patent Fights Create Too Much Litigation, Google Lawyer Says*, SAN JOSE MERCURY NEWS, July 27, 2011, at 2D (describing tech companies “calling on Congress and the Federal Trade Commission to rein in lawsuits”); Michael Fitzgerald, Op-Ed., *A Patent Is Worth Having, Right? Well, Maybe Not*, N.Y. TIMES, July 15, 2007, at A3 (“Congress could step in . . . reining in litigation and damage awards. But this marks the third consecutive year that Congress has considered patent reform, and there is enough opposition from large companies to suggest that it will again have to wait until next year.”); Jessica Guynn, *Google Bids for Nortel Patents*, L.A. TIMES, Apr. 5, 2011, at B2 (“[Google] has also advocated for patent litigation reform, although Congress has yet to act.”); Jim Landers, *Trouble Impending in Patent Process*, DALL. MORNING NEWS, May 1, 2007, at 1D (describing technologies companies’ efforts in persuading Congress to reform patent litigation damages).

2. Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011).

3. *But see* Colleen Chien, Senior Advisor for Intellectual Prop. & Innovation, Office of Sci. & Tech. Policy, Keynote Address at the Stanford Law School Patent Trolls and Patent Reform Conference (Mar. 26, 2014), available at [https://www.youtube.com/watch?v=iIPdc6U\\_l6g](https://www.youtube.com/watch?v=iIPdc6U_l6g) (describing the patent reform initiatives of Presidents Kennedy, Johnson, Truman, Franklin D. Roosevelt, and Madison).

4. *Protecting American Inventors and Innovators*, THE WHITE HOUSE, <http://perma.cc/CC6L-G6J4> (last visited May 8, 2014) [hereinafter PROTECTING INVENTORS].

5. *E.g.*, *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, \_\_\_ U.S. \_\_\_, 134 S. Ct. 1749 (2014) (realigning the standard for awarding attorneys’ fees in “exceptional cases”); *Nautilus, Inc. v. Biosig Instruments, Inc.*, \_\_\_ U.S. \_\_\_, 134 S. Ct. 2120 (2014) (reassessing the standard for ambiguous claim interpretation); *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, \_\_\_ U.S. \_\_\_, 134 S. Ct. 2347 (2014) (reviewing the doctrine of patentable subject matter).

largely disclaimed a role in reforming patent litigation.<sup>6</sup> Non-PTO administrative agencies, meanwhile, have remained mostly silent on the issue.<sup>7</sup> And the recent legislative, executive, and judicial efforts in the area have largely ignored the variety of roles administrative agencies—especially agencies other than the PTO—play in patent litigation.<sup>8</sup>

This silence is not because administrative agencies have little invested in patent law. To the contrary, agencies have recently been playing increasingly important roles in patent policy debates.<sup>9</sup> And there has also been an increase in several specialized species of patent litigation that directly involve non-PTO agency adjudication.<sup>10</sup> How agencies

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6. See, e.g., David Kappos, Dir. of the USPTO, Keynote Address at the Center for American Progress (Nov. 20, 2012), available at <http://perma.cc/4ER9-PBJY> (“The fact is, the explosion of innovation—and follow-on litigation—that we see across consumer electronics hardware and software is a direct reflection of how our patent system wires us for innovation. It’s both natural and reasonable that in a fast-growing, competitive market, innovators would seek to protect their breakthroughs using our patent system.”). Recently, however, the PTO has placed links to several patent litigation resources on its website. See *Resources*, U.S. PAT. & TRADEMARK OFF., <http://www.uspto.gov/patents/litigation/Resources.jsp> (last visited Jan. 24, 2015).

7. Within the past decade, no non-PTO agencies—other than the Federal Trade Commission (FTC)—have issued any notices published in the Federal Register concerning patent litigation reform. See, e.g., Agency Information Collection Activities; Proposed Collection; Extension of Public Comment Period, 78 Fed. Reg. 71613 (Nov. 29, 2013) (requesting comments concerning patent assertion entities in the wireless communications sector); Agency Information Collection Activities; Proposed Collection; Comment Request, 78 Fed. Reg. 61352 (Oct. 3, 2013) (same); Statement of Regulatory Priorities, 74 Fed. Reg. 64363 (Dec. 7, 2009) (setting forth policy on reverse payment settlements).

8. Regarding the PTO, Congress did not vest it with any substantive rule-making authority in the America Invents Act, despite repeated, vocal calls to do so. Melissa F. Wasserman, *The Changing Guard of Patent Law: Chevron Deference for the PTO*, 54 WM. & MARY L. REV. 1959, 1998 (2013) (“Moreover, the AIA declined to grant the PTO the robust substantive rule-making powers that had been proposed in earlier versions of the legislation.”). The White House’s current initiatives regarding the PTO have encouraged various forms of data-sharing and crowd-sourcing, but do little in the way of patent litigation. See PROTECTING INVENTORS, *supra* note 4. And the Supreme Court has refused to revisit the U.S. Court of Appeals for the Federal Circuit’s decision in *Animal Legal Def. Fund v. Quigg*, 932 F.2d 920 (Fed. Cir. 1991), which stripped the PTO of all substantive rule-making authority. See generally Sarah Tran, *Administrative Law, Patents, and Distorted Rules*, 80 GEO. WASH. L. REV. 831 (2012) (discussing the history of the case and its progeny).

As for other administrative agencies, these patent litigation reform efforts have been mostly silent. No agencies, besides the PTO, are directly mentioned in the AIA or the President’s Protecting American Inventors and Innovators initiative. See Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011); PROTECTING INVENTORS, *supra* note 4. There have been virtually no judicial decisions regarding the extent of other agencies’ substantive authority in patent disputes. See, e.g., *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, \_\_\_ U.S. \_\_\_, 132 S. Ct. 1670, 1677 n.2 (2012) (declining to express a view on whether the Food and Drug Administration (FDA) possesses only a “ministerial” role in managing the Orange Book). Disclosure: The author represented Novo Nordisk in this dispute.

9. See generally Arti K. Rai, *Patent Validity Across the Executive Branch: Ex Ante Foundations for Policy Development*, 61 DUKE L.J. 1237 (2012) (discussing how various administrative agencies—other than the PTO—have contributed and can contribute to patent policy-making).

10. See Colleen V. Chien & Mark A. Lemley, *Patent Holdup, the ITC, and the Public Interest*, 98

function—and should function—in patent litigation is consequently becoming an increasingly important area of patent litigation reform.<sup>11</sup>

To that end, this Article provides an account of administrative agencies in patent litigation missing from patent reform proposals and current scholarship. It provides a synoptic view of the functions that administrative agencies currently play in patent litigation; it describes some of the problems with this involvement; and it provides several cheap, easy, and politically available tools to solve them. Specifically, this Article provides a framework for when and how agencies should—and should not—become involved in patent litigation, either as parties, as experts, or as traditional rule-making authorities. This prescription ultimately seeks to better “administrate” patent litigation.<sup>12</sup>

Indeed, administrative agencies currently have a variety of roles in administrating patent litigation. From “litigation gatekeepers” with the authority to “oversee and manage private litigation efforts,”<sup>13</sup> to scientific and technical experts,<sup>14</sup> to bodies of post-adjudicatory

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CORNELL L. REV. 1, 2–3 (2012) (calculating the rise of patent disputes adjudicated by the International Trade Commission (ITC)); Janet Freilich, *Patent Infringement in the Context of Follow-On Biologics*, 16 STAN. TECH. L. REV. 9, 11 (2012) (examining the “potential for patent conflict every time a follow-on biologic enters the market” given the divided authority for managing follow-on biologics between the FDA and the PTO); Henry Grabowski, *Are the Economics of Pharmaceutical Research and Development Changing?: Productivity, Patents and Political Pressures*, 22 (Supp. 2) PHARMACOECONOMICS 15, 19–21 (2004) (describing the increase in Hatch-Waxman Act litigation involving the FDA); Bureau of Competition, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Overview of Agreements Filed in FY 2012* (2013), <http://perma.cc/H7EY-2QYP> (describing the increase in the FTC’s review of pharmaceutical drug patent litigation settlements).

11. See Jonathan S. Masur, *Regulating Patents*, 2010 SUP. CT. REV. 275, 279 (2011) (“The time has come to consider reorienting patent law’s institutional arrangements to bring them more into line with the rest of the administrative state. And the most straightforward means of achieving this would be for Congress to endow the PTO with substantive rule-making authority.”).

12. Cf. 1 OXFORD ENGLISH DICTIONARY 163 (2d ed. 1989) (defining “administrate” to mean “[t]o manage or direct (affairs)”).

13. David Freeman Engstrom, *Agencies as Litigation Gatekeepers*, 123 YALE L.J. 616, 619 (2013); see, e.g., *Caraco*, 132 S. Ct. at 1676 (discussing the FDA’s management of the Orange Book); Jason Kanter & Robin Feldman, *Understanding and Incentivizing Biosimilars*, 64 HASTINGS L.J. 57, 69–74 (2012) (discussing similar authority invested in the FDA regarding biosimilar patent litigation); Eric J. Rogers, *Ten Years of Inter Partes Patent Reexamination Appeals: An Empirical View*, 29 SANTA CLARA COMPUTER & HIGH TECH. L.J. 305, 318–21 (2013) (calculating the effect of PTO reexamination requests on stays of district court litigation); Note, *Recasting the U.S. International Trade Commission’s Role in the Patent System*, 126 HARV. L. REV. 2337, 2354–55 (2013) (discussing the operation of mandatory district court stays on parallel ITC patent litigation).

14. See, e.g., Jeremy W. Bock, *Neutral Litigants in Patent Cases*, 15 N.C. J.L. & TECH. 233, 289–90 (2014) (describing the FTC’s expertise in patent disputes); Sapna Kumar, *Expert Court, Expert Agency*, 44 U.C. DAVIS L. REV. 1547, 1589–92 (2011) (describing the ITC’s expertise in patent disputes); Rai, *supra* note 9, at 1241 (recounting the National Institute of Health’s (NIH’s) involvement in the *Myriad Genetics* litigation concerning gene patents).

review,<sup>15</sup> to alternative venues,<sup>16</sup> administrative agencies appear to have wide-ranging functions in a broad number of patent disputes. Furthermore, these administrative proceedings take place over a broad stretch of a patent dispute's life cycle, from the initial complaint, through trial and settlement, and even beyond. This descriptive account of agency functions in patent litigation challenges the widely held notion that federal courts alone have the authoritative say over who may sue for patent infringement, where, and how.<sup>17</sup>

Unsurprisingly, agency administration of patent litigation is not without its own set of problems. As with other private interactions with agencies, agency administration of patent litigation suffers from “regulatory gamesmanship,”<sup>18</sup> industry and political capture,<sup>19</sup> adjudicatory uncertainty,<sup>20</sup> and inconsistent judgments.<sup>21</sup> These

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15. See, e.g., *Fed. Trade Comm'n v. Actavis, Inc.*, \_\_\_ U.S. \_\_\_, 133 S. Ct. 2223, 2227–28 (2013) (discussing the FTC's review of “reverse payment” or “pay-to-delay” patent settlements); Tony V. Pezzano & Jeffrey M. Telep, *Latest Developments on Injunctive Relief for Infringement of FRAND-Encumbered SEPS—Part III*, 26 INTEL. PROP. & TECH. L.J. 21, 21–22 (2014) (discussing the law concerning the U.S. Trade Representative's review of ITC Section 337 patented import investigations).

16. See, e.g., Michael A. Carrier & Daryl Wander, *Citizen Petitions: An Empirical Study*, 34 CARDOZO L. REV. 249, 272–74 (2012) (characterizing the rise in citizen petitions before the FDA, including those concerning issues related to patent infringement); Chien & Lemley, *supra* note 10, at 2–3 (discussing the rise in the ITC as an alternative venue for patent disputes); Diane H. Crawley, *America Invents Act: Promoting Progress or Spurring Secrecy?*, 36 U. HAW. L. REV. 1, 11–12 (2014) (describing the newly formed post-grant review and inter partes review proceedings before the PTO as an additional “arsenal of weapons available to third parties in attacking a patent”).

17. See, e.g., Paul R. Gugliuzza, *Patent Law Federalism*, 2014 WIS. L. REV. 11, 55 (2014) (“Under a long-standing regime of exclusive jurisdiction, only the federal courts can hear patent cases and develop expertise.”).

18. See Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 TEX. L. REV. 685, 687 (2009) (“We define ‘regulatory gaming’ as private behavior that harnesses procompetitive or neutral regulations and uses them for exclusionary purposes. . . . The pharmaceutical industry has witnessed this behavior for years, as branded drug companies have used exclusionary tactics to stay one step ahead of generic entry.”).

19. See Gugliuzza, *supra* note 17, at 43 n.187 (discussing the U.S. Trade Representative's overturning of the ITC's injunction against certain Apple, Inc. products); Janice M. Mueller, *Patent Misuse Through the Capture of Industry Standards*, 17 BERKELEY TECH. L.J. 623, 666–67 (2002) (discussing the FTC's controversial consent decree in *In re Dell Computer Corp.*, 121 F.T.C. 616 (1996)); Kristen Osenga, *Entrance Ramps, Tolls, and Express Lanes—Proposals for Decreasing Traffic Congestion in the Patent Office*, 33 FLA. ST. U. L. REV. 119, 137 (2005) (“[T]he Food and Drug Administration (FDA) approval process [is influenced by] . . . a powerful congressional lobby that has obtained provisions to extend a pharmaceutical patent's term beyond the twenty-year period because of the additional dead period due to the FDA regulatory approval process.”); Zach Carter, *The Spoilsmen: How Congress Corrupted Patent Reform*, HUFFINGTON POST (Oct. 4, 2011, 5:12 AM), <http://perma.cc/P42T-TGP4> (discussing banks' political influence on patent reform efforts).

20. See Aaron Edlin et al., *Activating Actavis*, 28 ANTITRUST 16, 16 (2013) (describing uncertainties that remain in the FTC's approval of “reverse payment” or “pay-to-delay” patent settlements); Stu Woolman, Elliot Fishman, & Michael Fisher, *Evidence of Patent Thickets in Complex Biopharmaceutical Technologies*, 53 IDEA 1, 14 n.62 (2013) (“Despite the strength of the

problems, to be sure, are neither new nor unique to patent litigation. But patent litigation—given the putatively regulatory nature of the patent right itself<sup>22</sup>—gives these problems a texture all their own. Poor agency administration of patent litigation affects patent holders as well as accused infringers,<sup>23</sup> delays litigation,<sup>24</sup> slows investment,<sup>25</sup> and makes settlement problematic.<sup>26</sup> Parties facing patent lawsuits where agencies

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US patent regime, the variability of FDA approval for a drug, difference in judicial recognition as to whether a patent obtains in a given set of circumstances, and the success that the producers of generic drugs have had despite the presence of an applicable patent, dampens enthusiasm for new research and development projects that would bring much needed pharmaceuticals to market.” (citing Harry Surden, *Efficient Uncertainty in Patent Interpretation*, 68 WASH. & LEE L. REV. 1737, 1743 (2011))).

21. See Gugliuzza, *supra* note 17, at 43–44 (discussing the negative effect of agency litigation on adjudicative uniformity); Sapna Kumar, *The Other Patent Agency: Congressional Regulation of the ITC*, 61 FLA. L. REV. 529, 538–40 (2009) (discussing conflicting judgments at the ITC).

22. See Mark A. Lemley, *The Regulatory Turn in IP*, 36 HARV. J.L. & PUB. POL’Y 109, 110 (2013) (“Is intellectual property (IP) a ‘Mother, may I?’ regime? The answer is complex. . . . It is at once a basis around which we can contract and allow the spread of new ideas and a government regulatory intervention in the marketplace that is designed to restrict what people can do with their own ideas and their own property.” (emphasis in original)).

23. See Damon C. Andrews, *Why Patentees Litigate*, 12 COLUM. SCI. & TECH. L. REV. 219, 234–37 (2011) (describing the effect of inter partes review at the PTO on plaintiffs and defendants); Bock, *supra* note 14, at 250–51 (“The presence of the ITC staff attorney as a neutral third party litigant creates a litigation dynamic in Section 337 actions that is different from district court litigation.”); Herbert Hovenkamp, *Anticompetitive Patent Settlements and the Supreme Court’s Actavis Decision*, 15 MINN. J.L. SCI. & TECH. 3, 20–22 (2014) (discussing the effects on both plaintiffs and defendants on invalidity arguments in light of the FTC’s scrutiny of reverse payment settlements); Mark Lyon & Sarah Piepmeier, *ITC Section 337 Investigations: Patent Infringement Claims*, GIBSON DUNN 4 (2011), <http://perma.cc/WF4Q-T277> (“The typical plaintiff-defendant dynamic is quite different when a neutral third party is also participating in the litigation. The Staff’s participation can be to a party’s benefit or detriment, depending on the circumstances, and underestimating the Staff’s importance and role is a typical and sometimes costly mistake for new ITC litigants.”).

24. See, e.g., *Affinity Labs of Tex. v. Apple Inc.*, No. 09-04436 CW, 2010 WL 1753206, at \*2 (N.D. Cal. Apr. 29, 2010) (“As of December 31, 2009, the average length of an *inter partes* reexamination is 36.2 months. The average length of delay is likely to increase considering the steady rise in the number of reexaminations filed in the past several years.” (emphasis in original)); S. Peter Ludwig et al., *Hatch-Waxman in the Federal Courts: From 1994–2004*, 31 DRUG DEV. INDUS. PHARMACY 215, 221 (2005) (describing the length of Hatch-Waxman litigation). *But see* Kumar, *supra* note 21, at 536–37 (discussing the relative speed of ITC patented import proceedings compared to district court litigation).

25. See Jorge L. Contreras, *Fixing FRAND: A Pseudo-Pool Approach to Standards-Based Patent Licensing*, 79 ANTITRUST L.J. 47, 92 (2013) (describing investment uncertainty in the face of FTC involvement in certain patent disputes); Yaniv Heled, *Patents vs. Statutory Exclusivities in Biological Pharmaceuticals—Do We Really Need Both?*, 18 MICH. TELECOMM. & TECH. L. REV. 419, 436–43 (2012) (describing investment uncertainty regarding the FDA and biosimilar patents); Woolman, Fishman, & Fisher, *supra* note 20, at 14 n.62 (listing the discouragement of certain research and development under Hatch-Waxman Act litigation).

26. See Edlin et al., *supra* note 20, at 16; Hovenkamp, *supra* note 23, at 16–20.

are involved frequently get more than they bargained for.<sup>27</sup>

Despite these complexities, administrative agencies possess—and can make better use of—a number of discretionary tools, currently at their disposal, to better administrate patent litigation. The first, perhaps ironically, is to become more involved in patent litigation *ex ante*. Some of the problems raised by agency administration of patent disputes, namely regulatory gamesmanship, settlement uncertainty, and inconsistent judgments, could be ameliorated through greater and more forceful oversight of private patent disputes before they arise.<sup>28</sup> Administrative agencies currently possess a variety of mechanisms to do precisely this: to delay regulatory review during the pendency of a patent suit,<sup>29</sup> to control the timing of parallel district court litigation,<sup>30</sup> and to use “march in rights” to control the direction of unfavorable litigation.<sup>31</sup> Tailoring these powers in certain, limited circumstances would limit many of the problems associated with the current regime.<sup>32</sup>

The second tool at agencies’ disposal is their own expertise. A number of agencies involved in patent litigation possess special scientific or technical expertise, often at the cutting-edge of scientific and legal development.<sup>33</sup> Sometimes, however, such expertise can get co-opted or captured by industry forces or political opportunism.<sup>34</sup> By publicly and repeatedly deploying such expertise—either as litigants, counsel to other government agencies, or by issuing reports on developing areas of science and technology—agencies could demonstrate their independence and stave off later attempts at industry and political capture.<sup>35</sup>

Lastly, where patent litigation proceeds in parallel between federal courts and administrative agencies—such as section 337 patented import proceedings before the International Trade Commission (ITC) and “post-

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27. See Contreras, *supra* note 25, at 50–52 (describing the increase in patent litigation over “fair, reasonable and non-discriminatory” patent licensing commitments); Kanter & Feldman, *supra* note 13, at 77–78 (discussing the patent litigation difficulties facing biosimilar manufacturers); Lyon & Piepmeier, *supra* note 23, at 4 (“[U]nderestimating the [ITC’s] Staff’s importance and role is a typical and sometimes costly mistake for new ITC litigants.”).

28. Cf. Engstrom, *supra* note 13, at 657–63 (discussing agencies as optimal “litigation gatekeepers”); Rai, *supra* note 9, at 1242–43 (discussing some of the benefits of patent policy-making *ex ante*).

29. See *infra* notes 50–71 and accompanying text.

30. See *infra* notes 79–92 and accompanying text.

31. See *infra* notes 266–273 and accompanying text.

32. See *infra* Part A.

33. See *infra* Part B.

34. See *infra* Parts B–C.

35. See *infra* Part B.

issuance proceedings” before the PTO—agencies (and courts) should use their discretionary power to narrow potential claimants, strengthen estoppel between the two fora, and streamline litigation stays. This would principally avoid inconsistent judgments, but may even provide a check against regulatory gamesmanship while contributing to settlement certainty.<sup>36</sup>

By taking this approach to reforming patent litigation, this Article seeks to contribute to—and synthesize—a variety of disparate strands of scholarship. One strand concerns the legal nature of the patent right, giving rise to the current, heated debate as to whether patents are better characterized as regulatory instruments or as traditional parcels of property.<sup>37</sup> By focusing on concrete examples of regulatory involvement in patent litigation, this Article strengthens the view of patents-as-regulation without philosophizing over expansive definitions of “property.”<sup>38</sup> Scholars have also recently begun to explore the limits of the public-law nature of patent litigation, highlighting the public’s interest in invalidity defenses,<sup>39</sup> remedies,<sup>40</sup> and standing.<sup>41</sup> This Article contributes to this strand of scholarship as well, by acknowledging and examining the role that regulatory actors—i.e., public bodies—play in determining private patent rights. Lastly, much has been written on “patent reform,” a topic as broad-ranging as any in intellectual property today.<sup>42</sup> This Article also hopes to contribute to this scholarship by advancing reform proposals for a small but increasingly important and

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36. See *infra* Part III.

37. Compare Mark A. Lemley, *Taking the Regulatory Nature of IP Seriously*, 92 TEX. L. REV. SEE ALSO 107, 107–08 (2014) (“Modern IP is certainly more like regulation than it is like property, at least as people traditionally think of property, though there are certain kinds of property that have regulatory characteristics because they are used to define markets or restrict entry.”), and Lemley, *supra* note 22, at 110 (advancing the patents-as-regulation argument), with Richard A. Epstein, *The Disintegration of Intellectual Property? A Classical Liberal Response to a Premature Obituary*, 62 STAN. L. REV. 455, 480–513 (2010) (defending the patents-as-property argument), and Adam Mossoff, *Exclusion and Exclusive Use in Patent Law*, 22 HARV. J.L. & TECH. 321 (2009) (same).

38. See Adam Mossoff, *The Trespass Fallacy*, 65 FLA. L. REV. 1687, 1692–95 (2013) (explaining some of the difficulties in analogizing real and intellectual property); Deepa Varadarajan, *Improvement Doctrines*, 21 GEO. MASON L. REV. 657, 660 (2014) (describing the historical expansion of conceptions of property).

39. Megan M. La Belle, *Patent Law as Public Law*, 20 GEO. MASON L. REV. 41, 41–42 (2012).

40. Ted Sichelman, *Purging Patent Law of “Private Law” Remedies*, 92 TEX. L. REV. 517, 518–20 (2014).

41. Michael J. Burstein, *Rethinking Standing in Patent Challenges*, 83 GEO. WASH. L. REV. (forthcoming 2014) (manuscript at 16–17), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2359873](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2359873).

42. See Mossoff, *supra* note 38, 1688–89, 1692 (criticizing calls for “patent reform”); Liza Vertinsky, *Comparing Alternative Institutional Paths to Patent Reform*, 61 ALA. L. REV. 501, 511 (2010) (discussing several patent reform proposals); Wasserman, *supra* note 8, at 1963–64 (reviewing PTO reform scholarship).



growing area of patent litigation.

This Article’s proposal to administrate patent litigation proceeds as follows. Part I catalogues and discerns the functions of administrative agencies in patent litigation. Part II then describes some of the difficulties that arise from these functions, and agencies’ exercise—or failure to exercise—their attendant powers. Lastly, Part III provides several solutions to these problems—currently available, politically tenable, and cheaply deployed solutions—to produce a better environment for patent litigation under a variety of administrative regimes.

## I. THE FUNCTIONS OF ADMINISTRATIVE AGENCIES IN PATENT LITIGATION

From the initial filing of a complaint to post-judgment review, administrative agencies occupy a variety of functions in patent litigation. In the earlier stages of litigation—indeed, in many instances, before litigation even arises—administrative agencies serve as “litigation gatekeepers,” authorities with “the power to oversee and manage private litigation efforts” by limiting the types of patents or classes of claims in dispute.<sup>43</sup> Agencies also participate in patent litigation itself by serving as “experts”—either as scientific experts or expert legal authorities—in a variety of capacities. And even after judgments are rendered in patent disputes, some agencies exercise their power to review the propriety of a judgment or settlement. Additionally, agencies may, throughout the sequence of a typical patent case, serve as alternative or parallel venues to traditional district court patent litigation. This Part explores each of these functions in sequence.

### A. *Litigation Gatekeeping*

A long-overlooked function of administrative agencies, generally, is their role as “litigation gatekeepers.”<sup>44</sup> In the words of David Freeman Engstrom, “agency litigation gatekeeping” is:

the power to oversee and manage private litigation efforts . . . [to] use their expertise and synoptic perspective to weigh costs and benefits and determine whether private rights of action should lie at all . . . [or] the power to evaluate private lawsuits on a case-by-case basis, blocking bad cases, aiding

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43. See Engstrom, *supra* note 13, at 619.

44. See *id.* at 621 (describing the gap in scholarship concerning this aspect of agency behavior); Arthur F. Greenbaum, *Government Participation in Private Litigation*, 21 ARIZ. ST. L.J. 853, 882–983 (1989) (first identifying this function).

good ones, and otherwise husbanding private enforcement capacity in ways that conserve scarce public enforcement resources for other uses.<sup>45</sup>

This function of administrative agencies has been commonly ascribed to agencies that oversee litigation with a strong public interest, such as the Equal Employment Opportunity Commission's (EEOC's) review of employment discrimination actions or the Environmental Protection Agency's (EPA's) stewardship of citizen petitions.<sup>46</sup> Agency litigation gatekeeping for purely private litigation—as patent litigation is classically viewed<sup>47</sup>—has been seemingly unexplored. But an examination of agency administration of patent litigation demonstrates that, in several critical respects, administrative agencies do “oversee and manage private litigation efforts . . . and determine whether private rights of action should lie at all.”<sup>48</sup> Invested with the power to police the border between regulation and market exclusivity,<sup>49</sup> some agencies directly limit which patents and claims can be sued on, when and by whom, and whether concurrent district court proceedings should be stayed pending the agencies' own review of the patents in dispute.

The most salient example of this gatekeeping authority lies with the Food and Drug Administration (FDA). Because the FDA is responsible for authorizing newly developed drugs and medical devices, and because patents play an essential role in the development process,<sup>50</sup> the FDA's regulatory powers are inextricably intertwined in patent disputes.<sup>51</sup> Notably, the FDA is entrusted with managing the “Orange Book,” a list of which patents cover which FDA-approved drugs.<sup>52</sup> The Orange Book plays a critical role in patent disputes between brand and generic pharmaceutical manufacturers. As part of a New Drug Application, a brand manufacturer must submit to the FDA, for inclusion in the Orange Book, a list of which patents cover its proposed drug.<sup>53</sup> A generic

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45. Engstrom, *supra* note 13, at 619–20.

46. *See, e.g., id.* at 646 tbl.2; Greenbaum, *supra* note 44, at 978–79.

47. *See sources cited supra* notes 39–41.

48. Engstrom, *supra* note 13, at 619.

49. *See Heled, supra* note 25, at 428–30 (describing the interaction between FDA exclusivity and patent monopolies).

50. *See id.* at 426–28 (briefly reviewing the literature on this topic).

51. *See id.* at 428–30.

52. *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, \_\_ U.S. \_\_, 132 S. Ct. 1670, 1676 (2012) (“To facilitate the approval of generic drugs as soon as patents allow, the Hatch-Waxman Amendments and FDA regulations direct brand manufacturers to file information about their patents. . . . [The FDA] publishes the . . . corresponding patent numbers and expiration dates, in a fat, brightly hued volume called the Orange Book (less colorfully but more officially denominated Approved Drug Products with Therapeutic Equivalence Evaluations).”).

53. 21 U.S.C. § 355(b)(1) (2012) (“The applicant shall file with the application the patent number

applicant, in turn, must certify to the FDA that its proposed generic product does not infringe any of the listed patents.<sup>54</sup> Although the generic applicant need not have “made, used, sold, or offered to sell” the brand manufacturer’s drug—all potentially acts of patent infringement<sup>55</sup>—the generic application is, by statute, itself an artificial act of patent infringement.<sup>56</sup> Accordingly, the FDA conditions its approval for any generic drugs covered by patents listed in the Orange Book on the final resolution of the resulting patent dispute between the brand and generic manufacturers.<sup>57</sup>

As a practical matter, the FDA has long abdicated any substantive authority over policing Orange Book listings, going so far as to denigrate its own power as “purely ministerial.”<sup>58</sup> And scholars studying this corner of patent law have mostly agreed: new drug applicants submit patent information to the FDA; the FDA dutifully lists it in the Orange Book without a glance.<sup>59</sup> But this descriptive view of the FDA’s

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and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.”).

54. *Id.* § 355(j)(2)(A)(vii)(IV) (requiring “a certification . . . that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted”).

55. 35 U.S.C. § 271(a) (2012) (“[W]hoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.”).

56. *Caraco Pharm.*, 132 S. Ct. at 1672 (“[A] so-called paragraph IV certification . . . is treated as an act of infringement, giving the brand an immediate right to sue and resulting in a delay in the generic drug’s approval.”).

57. 21 U.S.C. § 355(j)(5)(B)(iii) (allowing the approval of generic drugs covered by Orange Book patents only if no action is brought for patent infringement within the forty-five-day statutory period).

58. *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 237 (4th Cir. 2002) (“The FDA defends this purely ministerial conception of its role in the Orange Book listing process by explaining that it lacks both the resources and the expertise to police the correctness of Orange Book listings.”); *see also Caraco Pharm.*, 132 S. Ct. at 1677 (mentioning the FDA’s perception of its role in Orange Book listings, but declining to express a view on the matter).

59. *See, e.g., Thomas F. Cotter, Antitrust Implications of Patent Settlements Involving Reverse Payments: Defending a Rebuttable Presumption of Illegality in Light of Some Recent Scholarship*, 71 ANTITRUST L.J. 1069, 1076 n.19 (2004) (“[N]ote only that the FDA does not attempt to verify the Orange Book filings made by drug manufacturers, but rather plays a purely ministerial role.”); Marina Lao, *Reforming the Noerr-Pennington Antitrust Immunity Doctrine*, 55 RUTGERS L. REV. 965, 993–94 (2003) (“The FDA’s role in listing the patents in the Orange Book is purely ministerial; it does not review the propriety of the patent listings.”); Jessie Cheng, Note, *An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry*, 108 COLUM. L. REV. 1471, 1507 (2008) (“The FDA claims to play a purely ‘ministerial role’ and has shied away from actively intervening to resolve issues related to competition—e.g., the scope of intellectual property rights and their conferral of monopoly power, or the manipulation of the regulatory regime for anticompetitive ends.”).

authority—both potential and actually exercised—is incomplete. Despite its insistence that it “lacks both the resources and the expertise to police the correctness of Orange Book listings,”<sup>60</sup> the FDA has issued a number of substantive regulations doing just that. Prior to August 2003, for example, the FDA—for over fifteen years—authored and published “patent use codes,” short interpretations of method-of-use claims for Orange Book-listed patents.<sup>61</sup> Although applicants submit their own patent use codes today, the FDA nonetheless engages in its own analysis as to whether brand applicants’ use codes overlap with generic manufacturers’ proposed method of use, wholly rejecting generic applications that do so.<sup>62</sup> Lastly, the FDA’s current rule in 21 C.F.R. § 314.53 further prohibits “[p]rocess patents, patents claiming packaging, patents claiming metabolites, and patents claiming intermediates” from being listed in the Orange Book.<sup>63</sup>

Contrary to common wisdom, these procedures strongly suggest that the FDA’s authority with respect to policing Orange Book listings is far from “purely ministerial.” It does, in fact, engage in limited attempts at interpreting applicants’ patent information—having done so explicitly for over a decade. And the agency limits which types of patents and claims can and cannot be listed in the Orange Book, ultimately conditioning its authority—regulatory approval of drug applications—on patent construction. These Orange Book listings shape the very form of patent litigation that takes place between brand and generic applicants: they determine which patents can and cannot be sued upon, which counterclaims can be permissibly brought, and what rights and responsibilities each applicant possesses.<sup>64</sup> Although it is true that the FDA exercises this power mechanically, and refuses to correct errors on its own initiative,<sup>65</sup> these regulations are nonetheless a form of administrative gatekeeping: they carry with them “the power to oversee and manage private litigation efforts.”<sup>66</sup>

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60. *aaiPharma Inc.*, 296 F.3d at 237.

61. Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed, 68 Fed. Reg. 36676, 36683 (June 18, 2003) (“Traditionally, we have created the use code description for the Orange Book from the information submitted by the NDA applicant or holder.”).

62. *Caraco Pharm.*, 132 S. Ct. at 1677 (“Of particular relevance here, the FDA will not approve such an [Abbreviated New Drug Application] if the generic’s proposed carve-out label overlaps at all with the brand’s use code.”).

63. 21 C.F.R. § 314.53(b)(1) (2014).

64. *Caraco Pharm.*, 132 S. Ct. at 1675.

65. See *aaiPharma Inc.*, 296 F.3d at 237 (discussing the FDA’s refusal to correct Orange Book-listed patent information).

66. Engstrom, *supra* note 13, at 619.

The FDA also acts as a litigation gatekeeper in its role in interim patent term extensions, albeit indirectly. Under 35 U.S.C. § 156, a patent covering a “product [that] has been subject to a regulatory review period before its commercial marketing or use,” i.e., an FDA regulated drug or device, may be extended for a portion of the period during which the product was subject to FDA review.<sup>67</sup> The purpose of this section is “to ameliorate the loss incurred when patent terms tick away while the patented product is awaiting [the FDA’s] regulatory approval for marketing.”<sup>68</sup> But to avoid giving patent holders additional protection for drugs or devices for which they did not seek FDA approval, the extension under § 156 is limited to the specific “product” and “use” shepherded through regulatory approval.<sup>69</sup> What constitutes the specific “product” and “use” for § 156’s purposes depends on how the FDA crafts its approval letter,<sup>70</sup> making its approval letters—especially in a contested area of technology—a form of indirect litigation gatekeeping. In the recent dispute between Edwards Lifesciences AG and CoreValve, Inc., for example, much of the litigation turned on the precise wording of the FDA’s approval letter for CoreValve’s allegedly infringing device—whether the approval covered only certain sizes of CoreValve’s device, whether the approval was limited to “extreme risk patients,” and whether the approval was conditioned on a “best outcomes” approach.<sup>71</sup>

Other agencies also act as patent litigation gatekeepers, not by rulemaking or overseeing private litigation itself, but by controlling the timing and scope of district court patent litigation. Patented import investigations before the ITC, for example, routinely affect parallel district court litigation. Under 28 U.S.C. § 1659(a), parties in parallel proceedings before the ITC and federal district court may demand to stay the district court proceedings until the ITC’s final determination;<sup>72</sup> “Congress has not authorized the ITC to stay *its* proceedings in favor of

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67. 35 U.S.C. § 156(a)(4) (2012).

68. *Unimed, Inc. v. Quigg*, 888 F.2d 826, 829 (Fed. Cir. 1989).

69. 35 U.S.C. § 156(b)(1)(A); *Merck & Co. v. Kessler*, 80 F.3d 1543, 1547 (Fed. Cir. 1996) (“[T]he restoration period of the patent does not extend to all products protected by the patent but only to the product on which the extension was based.”).

70. *See Merck & Co.*, 80 F.3d at 1547 (linking the “product” for § 156’s purposes to the FDA’s approval letter).

71. *Edwards Lifesciences AG v. CoreValve, Inc.*, C.A. No. 08-91 (GMS), 2014 WL 1493187, at \*8–11 (D. Del. Apr. 15, 2014); Letter from Bram D. Zuckerman, M.D., Dir., Div. of Cardiovascular, Devices Office of Device Evaluation, Center for Devices and Radiological Health, to Mansi Gala, Principal Specialist, Regulatory Affairs, Medtronic CoreValve LLC (Jan. 17, 2014), available at <http://perma.cc/F6GL-U25L> (approval order re P130021, Medtronic CoreValve System (MCS)).

72. 28 U.S.C. § 1659(a) (2012).

parallel district court proceedings.”<sup>73</sup> The mandatory district court stay may, therefore, encourage (or dissuade) the parties to settle,<sup>74</sup> or the accused infringer to design around the asserted patents,<sup>75</sup> in the intervening time period. This makes the timing of the ITC’s proceedings, for which Administrative Law Judges (ALJs) “normally have unreviewable discretion,”<sup>76</sup> a potentially powerful lever to open—or close—traditional district court litigation.<sup>77</sup>

In a similar vein, the PTO itself plays a role in patent litigation—not merely patent prosecution—through its several “post-issuance proceedings.” Today, the PTO may review the validity of a previously issued patent in five distinct proceedings: reexamination, inter partes review, post-grant review, covered business method review (also known as “transitional [p]ost-grant [r]eview of . . . business methods”), and supplemental examination.<sup>78</sup> In reexamination proceedings, for example, “any person” may request that the PTO re-exam a patent if there exists a “substantial new question of patentability,”<sup>79</sup> a determination that “rests solely in the PTO’s discretion.”<sup>80</sup> Because the PTO engages in reexaminations de novo,<sup>81</sup> and because reexamination proceedings tend to be more adversarial in nature than original prosecutions,<sup>82</sup> re-exam has become a potent weapon-of-choice for accused infringers seeking to invalidate the asserted patents.<sup>83</sup> By some measures, accused infringers facing district court litigation have requested patent reexaminations in seventy-five percent of their cases.<sup>84</sup> They also frequently request that

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73. *Recasting*, *supra* note 13, at 2353 (emphasis added).

74. *See id.* at 2348 (discussing how the length of the ITC stay may give rise to “attractive settlement” offers, “undercut[ting] an alleged infringer’s incentive to stay in the fight to the finish” (quoting Joseph Scott Miller, *Building a Better Bounty: Litigation-Stage Rewards for Defeating Patents*, 19 BERKELEY TECH. L.J. 667, 668 (2004))).

75. *See* Chien & Lemley, *supra* note 10, at 34–36 (discussing this in the context of stays of the exclusion order).

76. *Recasting*, *supra* note 13, at 2344 n.51.

77. *See id.* at 2348 (discussing how the length of the ITC stay may give rise to “attractive settlement” offers, “undercut[ting] an alleged infringer’s incentive to stay in the fight to the finish” (quoting Miller, *supra* note 74, at 668))).

78. *See generally* Andrei Iancu & Ben Haber, *Post-Issuance Proceedings in the America Invents Act*, 93 J. PAT. & TRADEMARK OFF. SOC’Y 476, 486 (2011).

79. 35 U.S.C. §§ 302, 303 (2012).

80. *Pieczenik v. Domantis*, 120 F. App’x 317, 319–20 (Fed. Cir. 2005).

81. *See* 35 U.S.C. § 305 (“[R]eexamination will be conducted according to the procedures established for initial examination . . .”).

82. *See* Stefan Blum, Note, *Ex Parte Reexamination: A Wolf in Sheep’s Clothing*, 73 OHIO ST. L.J. 395, 423–28 (2012) (discussing the adversarial nature of ex parte reexamination proceedings, contrary to common wisdom that such proceedings are non-adversarial).

83. *See generally* Ben M. Davidson, *Reexamining Reexaminations*, 34 L.A. LAWYER 26 (2011).

84. Rogers, *supra* note 13, at 320 (citing Jack B. Blumenfeld & Leslie A. Polizoti, *Stays Pending*

district courts stay the underlying litigation pending the PTO's reexamination proceedings, a procedure that works roughly fifty percent of the time.<sup>85</sup> All in all, these numbers suggest that roughly thirty percent of patent litigation is at some point stayed pending the PTO's reexamination procedure.<sup>86</sup>

And yet, because the issue of whether, how, and to what extent a reexamination is to proceed “rests solely in the PTO's discretion,”<sup>87</sup> the PTO plays an outsize role in determining the length and scope of the stay, issues that may ultimately affect the ultimate resolution of the underlying patent dispute. First, if the PTO grants a reexamination request and cancels a patent's claims, that decision is binding on the district court, essentially removing the “case or controversy” required for the court to have heard the infringement dispute in the first place.<sup>88</sup> Second, as with district court stays in section 337<sup>89</sup> proceedings before the ITC, stays may encourage (or dissuade) the parties to settle or for the accused infringer to design-around the asserted patent.<sup>90</sup> And lastly, while reexaminations that fail to cancel any claims are not binding on parallel litigation in the district courts, they may subtly and positively alter how courts—and juries—view the asserted claims' validity.<sup>91</sup> The power that comes with the PTO's assessment of patent reexamination, therefore, grants the agency a de facto role in litigation gatekeeping, using the agency's “expertise and synoptic perspective to weigh costs and benefits and determine whether private rights of action should lie at all.”<sup>92</sup>

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*Reexamination*, 908 PLI/PAT 91, 97–98 (2007)).

85. *Id.*

86. The statistics presented by Blumenfeld & Polizoti, *supra* note 84, suggest that the PTO receives a request for reexamination in seventy-five percent of all patent litigation; that litigants request litigation stays in eighty percent of those requests; and that half of those requests—as averaged, nationally—are ultimately granted. Taking these numbers as true, multiplying them together ( $0.75 * 0.80 * 0.50$ ) yields 0.30, or thirty percent. A fuller assessment would need to be required to ascertain the true percentage.

87. *Piecznenik v. Domantis*, 120 F. App'x 317, 319–20 (Fed. Cir. 2005).

88. *Rogers*, *supra* note 13, at 325 (“However, if the USPTO cancels a patent claim, then any concurrent judicial proceeding must dismiss any claim based solely on patent rights conferred by the now canceled claim.”).

89. For a discussion of Section 337 proceedings, see generally Kumar, *supra* note 21.

90. See sources cited *supra* notes 74–75.

91. See Joshua D. Sarnoff, Bilcare, KSR, *Presumptions of Validity, Preliminary Relief, and Obviousness in Patent Law*, 25 CARDOZO ARTS & ENT. L.J. 995, 1023–25 (2008) (reviewing the literature of how patents subject to reexamination proceedings may experience fewer district court invalidations).

92. Engstrom, *supra* note 13, at 619.

### B. *Scientific and Technical Expertise*

In several ways, administrative agencies also serve as scientific and technical “experts” in patent litigation; entities that can—and do—persuade federal courts by reason of their “knowledge, skill, experience, training, or education.”<sup>93</sup> This expertise comes in a variety of forms: as public advocates in high-profile patent litigation; as advisors to government litigants, such as the Office of the Solicitor General; and as more generalized policymakers, issuing white papers and inter-agency agreements upon which courts may rely.

The Federal Trade Commission (FTC), for example, has been heavily involved as amici in several high-profile patent disputes. In *Apple Inc. v. Motorola, Inc.*<sup>94</sup>—part of the global “smartphone patent wars” featured on the front pages of national newspapers<sup>95</sup>—the FTC filed an amicus brief in support of neither party on the competitive effects of preliminary injunctions in patent disputes.<sup>96</sup> Of particular concern to the FTC was the effect of Motorola’s request for injunctive relief, despite the fact that Motorola had voluntarily joined a “standard-setting organization[.]” (SSO) with the promise that it would license its “standard-essential patent[s]” on “fair, reasonable, and non-discriminatory” (FRAND) terms.<sup>97</sup> The FTC’s concern with patent hold-up—using the threat of injunctive relief as “a club to be wielded by a patentee to enhance his negotiating stance”<sup>98</sup>—ultimately guided the U.S. Court of Appeals for the Federal Circuit to the conclusion that Motorola was not entitled to an injunction.<sup>99</sup> In doing so, the FTC relied on its “substantial experience applying its competition policy expertise to the patent system to advance the goals of enhancing consumer welfare and promoting innovation.”<sup>100</sup>

Aside from its involvement in standard-essential patents litigation, the FTC has also participated as expert amici in a variety of other patent litigation contexts. In *Teva Pharmaceuticals USA, Inc. v. Pfizer Inc.*,<sup>101</sup>

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93. Cf. FED. R. EVID. 702.

94. 757 F.3d 1286 (Fed. Cir. 2014).

95. E.g., Andrea Chang & Jessica Guynn, *Jury Sides with the iPhone-Maker in Its Lawsuit Accusing Samsung of Patent Infringement*, L.A. TIMES, Aug. 25, 2012, at AA1; Charles Duhiigg & Steve Lohr, *The Patent, Used as a Sword*, N.Y. TIMES, Oct. 8, 2012, at A1; Amir Efrati & Spencer E. Ante, *Google’s \$12.5 Billion Gamble*, WALL ST. J., Aug. 16, 2011, at A1.

96. Brief of Amicus Curiae Federal Trade Commission Supporting Neither Party, *Apple Inc. v. Motorola, Inc.*, 757 F.3d 1286 (Fed. Cir. 2014) (Nos. 2012–1548, 2012–1549), 2012 WL 6655899.

97. *Id.* at 3–4.

98. *Foster v. Am. Mach. & Foundry Co.*, 492 F.2d 1317, 1324 (2d Cir. 1974); see also Brief of Amicus Curiae Federal Trade Commission, *supra* note 96, at 14.

99. *Apple Inc.*, 757 F.3d at 1331–32.

100. Brief of Amicus Curiae Federal Trade Commission, *supra* note 96, at 1.

101. 405 F.3d 990 (Fed. Cir. 2005).



the FTC employed its “significant expertise in the pharmaceutical industry and the Hatch-Waxman Act” in interpreting a statutory provision concerning the timing of a generic applicant’s request to bring a declaratory judgment suit against a brand competitor if the brand refused to sue the generic applicant.<sup>102</sup> Although the Federal Circuit refused to hear the case en banc,<sup>103</sup> Congress—shortly after the FTC’s brief on the issue—amended the statutory provision in dispute in accordance with the FTC’s argument.<sup>104</sup> In *Ritz Camera & Image, LLC v. SanDisk Corp.*,<sup>105</sup> the FTC similarly lent its expertise in antitrust law to persuasively help the Federal Circuit trace the contours of *Walker Process* claims—allegations that a patentee’s enforcement of its patent rights constitute an “unlawful monopoly” if the patent was procured by fraud.<sup>106</sup> And in *TiVo Inc. v. EchoStar Corp.*,<sup>107</sup> the FTC, in light of its “substantial experience addressing restraints on competition involving patents,” filed an amicus brief arguing for leniency in contempt where the accused infringer had made a good faith attempt to “design around” the asserted patent.<sup>108</sup> Although the FTC was not able to move a majority of the Federal Circuit to its position in *TiVo*, its amicus brief did bolster a spirited and lengthy dissent-in-part from five of the judges.<sup>109</sup>

It is important to note that the FTC’s assertiveness in private patent disputes is relatively rare among administrative agencies.<sup>110</sup> Some of that

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102. Brief of Amicus Curiae Federal Trade Commission Supporting Appellant’s Combined Petition For Rehearing and Rehearing En Banc at 1, *Teva Pharm. USA, Inc. v. Pfizer Inc.*, 405 F.3d 990 (Fed. Cir. 2005) (No. 04-1186), 2005 WL 4121866.

103. *Teva Pharm. USA, Inc.*, 405 F.3d at 990–91.

104. See 21 U.S.C. § 355(j)(5)(C) (2006); see also Ankur N. Patel, Comment, *Delayed Access to Generic Medicine: A Comment on the Hatch-Waxman Act and the “Approval Bottleneck,”* 78 *FORDHAM L. REV.* 1075, 1091–93 (2009) (discussing the history behind the change).

105. 700 F.3d 503 (Fed. Cir. 2012).

106. Brief for the United States and the Federal Trade Commission as Amici Curiae in Support of Appellee, *Ritz Camera & Image, LLC v. SanDisk Corp.*, 700 F.3d 503 (Fed. Cir. 2012) (No. 12-1183), 2012 WL 2375063; see also *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965).

107. 646 F.3d 869 (Fed. Cir. 2011).

108. Brief of Amicus Curiae Federal Trade Commission on Rehearing En Banc Supporting Neither Party at 1, *TiVo Inc. v. EchoStar Corp.*, 646 F.3d 869 (Fed. Cir. 2011) (No. 2009-1374), 2010 WL 3389919.

109. *TiVo Inc.*, 646 F.3d at 891 (Dyk, J., dissenting in part) (citing Brief of Amicus Curiae Federal Trade Commission, *supra* note 108, at 4–10).

110. Some isolated exceptions do exist. See, e.g., *Covad Commc’n Co. v. Bell Atl. Corp.*, 407 F.3d 1220 (D.C. Cir. 2005) (concerning the Federal Communications Commission’s amicus in a telecommunications patent dispute); *SK & F, Co. v. Premo Pharm. Labs., Inc.*, 625 F.2d 1055, 1067 (3d Cir. 1980) (discussing the FDA’s amicus concerning patents and generic competition, prior to the passage of the Hatch-Waxman Act); *In re Brueckner*, 623 F.2d 184, 186–87 (C.C.P.A. 1980) (discussing the Department of Energy’s amicus brief concerning the unpatentability of atomic

stems from the FTC's independent statutory authority to "prosecute any inquiry necessary to its duties."<sup>111</sup> Some of that is due to a renewed culture of assertive litigation within the agency.<sup>112</sup> And some is likely because legal issues concerning the competitive effects of intellectual property most naturally overlap with issues concerning "unfair methods of competition."<sup>113</sup> Other agencies, meanwhile, are generally cabined by 28 U.S.C. § 516, which reserves agencies' litigation authority to the Department of Justice (DOJ).<sup>114</sup>

But administrative agencies do, nonetheless, serve as scientific and technical experts in patent litigation in other ways. The National Institutes of Health's (NIH's) involvement in *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*<sup>115</sup>—the "gene patenting" case—serves as an excellent example. In *Myriad*, Myriad Genetics held several patents encompassing the sequences of two human genes strongly correlated with early-onset breast and ovarian cancer, *BRCA1* and *BRCA2*.<sup>116</sup> At issue before the Court was whether Myriad's patents—and other patents claiming the sequences of human genes—were ineligible for patent protection as "products of nature," or whether some exception applied.<sup>117</sup> Deciding that issue was—and still is—fraught with scientific and legal complexity.<sup>118</sup> But the Court's decision was also one with considerable government interest, one that implicated over thirty years of patent practice before the PTO, over twenty years of NIH involvement in "gene patent" policy, and over a decade of enforcing several exclusive government licenses to similar technology.<sup>119</sup> In that

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weapons).

111. 15 U.S.C. § 43 (2012); *see also* *Humphrey's Ex'r v. United States*, 295 U.S. 602, 625 (1935) ("[T]he tribunal should be of high character and 'independent of any department of the government. . . a board or commission of dignity, permanence, and ability, independent of executive authority, except in its selection, and independent in character.'" (alteration in original)).

112. *See generally* Edward F. Cox, *Reinvigorating the FTC: The Nader Report and the Rise of Consumer Advocacy*, 72 ANTITRUST L.J. 899 (2005) (discussing this culture shift following the release of the Nader Report in 1969).

113. 15 U.S.C. § 45(a)(1).

114. 28 U.S.C. § 516 (2012) ("Except as otherwise authorized by law, the conduct of litigation in which the United States, an agency, or officer thereof is a party, or is interested, and securing evidence therefor, is reserved to officers of the Department of Justice, under the direction of the Attorney General.").

115. \_\_\_ U.S. \_\_\_, 133 S. Ct. 2107 (2013).

116. *Id.* at 2112.

117. *Id.* at 2111 ("This case involves claims from three of them and requires us to resolve whether a naturally occurring segment of deoxyribonucleic acid (DNA) is patent eligible under 35 U.S.C. § 101 by virtue of its isolation from the rest of the human genome.").

118. *See* Jacob S. Sherkow, *The Natural Complexity of Patent Eligibility*, 99 IOWA L. REV. 1137, 1155–66 (2014) (discussing patent eligibility's disharmony with natural complexity theory).

119. *See* *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303,

vein, the NIH played an aggressive role in courting the DOJ's Office of the Solicitor General, "successfully convinc[ing] the Solicitor General to reject the U.S. Patent and Trademark Office's long-held, but only lightly theorized, position of allowing claims on all 'isolated' DNA molecules."<sup>120</sup> It was the NIH's position, channeled through the Solicitor General, that ultimately won at the Supreme Court in *Myriad*. Today, claims on isolated human genes are ineligible for patent protection, while claims to synthetic transcripts of only the coding portions of those genes remain patent eligible.<sup>121</sup>

In other instances, administrative agencies deploy their expertise through issuing white papers or reports on issues concerning patent litigation. In recent years, the FTC has issued a number of influential reports on patent litigation: *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (2002),<sup>122</sup> *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (2003),<sup>123</sup> and *The Evolving IP Marketplace: Aligning Patent Notice and Remedies with Competition* (2011).<sup>124</sup> Each has been cited by the Supreme Court, and other federal courts, as an expert guide to especially thorny cases at the intersection of private patent litigation and competition law.<sup>125</sup>

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1343–44 (Fed. Cir. 2012) (Moore, J., concurring) (discussing the PTO's history in granting patents to "isolated DNA"), *aff'd in part, rev'd in part sub nom.* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., \_\_ U.S. \_\_, 133 S. Ct. 2107 (2013); Rai, *supra* note 9, at 1249–56 (discussing the NIH's history in gene patent policy); Brief for the United States as Amicus Curiae in Support of Neither Party at 6 n.2, Ass'n for Molecular Pathology v. Myriad Genetics, Inc., \_\_ U.S. \_\_, 133 S. Ct. 2107 (2013) (No. 12-398), 2013 WL 390999 (mentioning that "[i]n 1995, the government granted an exclusive license under [four of the asserted] patents to respondent Myriad").

120. Arti K. Rai, *Biomedical Patents at the Supreme Court: A Path Forward*, 66 STAN. L. REV. ONLINE 111, 115 (2013), available at <http://www.stanfordlawreview.org/online/biomedical-patents-supreme-court-path-forward>.

121. *Myriad*, 133 S. Ct. at 2111 ("For the reasons that follow, we hold that a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but that cDNA is patent eligible because it is not naturally occurring.").

122. FED. TRADE COMM'N, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY* (2002), available at <http://perma.cc/JNA3-3M48> [hereinafter FTC, *GENERIC DRUG ENTRY*].

123. FED. TRADE COMM'N, *TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY* (2003), available at <http://perma.cc/4CYK-WAQF> [hereinafter FTC, *TO PROMOTE INNOVATION*].

124. FED. TRADE COMM'N, *THE EVOLVING IP MARKETPLACE: ALIGNING PATENT NOTICE AND REMEDIES WITH COMPETITION* (2011), available at <http://perma.cc/QH8N-96LB> [hereinafter FTC, *EVOLVING IP*].

125. *E.g.*, *Nautilus, Inc. v. Biosig Instruments, Inc.*, \_\_ U.S. \_\_, 134 S. Ct. 2120, 2129 (2014) (quoting FTC, *EVOLVING IP*, *supra* note 124, to demonstrate "that [the] patent system fosters 'an incentive to be as vague and ambiguous as you can with your claims' and 'defer clarity at all costs'"); *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, \_\_ U.S. \_\_, 132 S. Ct. 1670, 1678 (2012) (citing FTC, *GENERIC DRUG ENTRY*, *supra* note 122, as evidence that "some brands were exploiting [the Hatch-Waxman Act] to prevent or delay the marketing of generic drugs"); *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 134 (2006) (Breyer, J., dissenting from dismissal

Similarly, the ITC routinely publishes snapshot reports of the patent litigation it oversees, commenting on “non-practicing entities” (NPEs)—also known as “patent trolls”—and “whether certain NPEs should be permitted to obtain relief against infringing imports at the USITC.”<sup>126</sup> These, and similar reports, have served as important tools for patent litigants seeking to restrict the ITC’s jurisdiction by narrowing its “domestic industry” requirement.<sup>127</sup> And regarding the (heavily patented) intersection between telecommunications and internet protocols,<sup>128</sup> the Federal Communications Commission (FCC) has issued an instrumental report on “E911” and “VOIP” technologies,<sup>129</sup> crucial to several ongoing patent disputes.<sup>130</sup> This “soft expertise,” while not necessarily deployed in the courtroom, has increasingly shaped a wide variety of private patent disputes.

### C. *Post-Adjudicatory Review*

With respect to patent litigation, several administrative agencies also function as bodies of post-adjudicatory review: agencies that review the merits and substance of traditional patent litigation for the purposes of fulfilling their own mandates. And, like other agency functions in patent litigation, those mandates vary: to fulfill an agency’s core function, as a simple statutory constraint, or even to serve as a political check on yet

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of writ of certiorari) (citing FTC, TO PROMOTE INNOVATION, *supra* note 123, as supporting an industry-specific approach to distinguishing abstract concepts from patent eligible inventions).

126. U.S. INT’L TRADE COMM’N, FACTS AND TRENDS REGARDING USITC SECTION 337 INVESTIGATIONS 2 (Apr. 15, 2013), available at <http://perma.cc/4YUC-AXEN> [hereinafter ITC, FACTS AND TRENDS].

127. *E.g.*, Brief of Dell Inc. and Ford Motor Co. as Amici Curiae in Support of Petition for a Writ of Certiorari at 5–6, *Nokia Inc. v. Int’l Trade Comm’n*, \_\_ U.S. \_\_, 134 S. Ct. 469 (2013) (No. 12-1352), 2013 WL 2726788 (citing ITC, FACTS AND TRENDS, *supra* note 126, at 4).

128. *See, e.g.*, *Verizon Servs. Corp. v. Vonage Holdings Corp.*, 503 F.3d 1295 (Fed. Cir. 2007) (VoIP patent litigation); *800 Adept, Inc. v. AT&T Mobility, LLC*, No. 5:07CV23, 2008 WL 4831093 (E.D. Tex. July 23, 2008) (E911 patent litigation); *TracBeam L.L.C. v. AT&T Inc.*, No. 6:11-CV-96, 2013 WL 6175372 (E.D. Tex. Nov. 25, 2013) (E911 patent litigation).

129. E911 concerns that technology that allows “wireless 911 callers [to] receive the same level of emergency service as that available to wireline callers,” even though wireless callers have no fixed location. *See generally* James M. Zagami et al., *Providing Universal Location Services Using a Wireless E911 Location Network*, IEEE COMM. MAG., Apr. 1998, at 66. VOIP technology concerns the real-time transmission of voice communication over the internet, i.e., “voice over IP.” *See* Joe Hallock, A Brief History of VoIP (Nov. 26, 2004) (unpublished thesis for Masters of Communication in Digital Media, University of Washington), available at <http://perma.cc/EGW4-4FW6>.

130. *See* FED. COMM’NS COMM’N, LEGAL AND REGULATORY FRAMEWORK FOR NEXT GENERATION 911 SERVICES 39 (Feb. 22, 2013), available at <http://perma.cc/E8AL-8SLM> (“[I]ncreased emphasis on standards-based and outcome-oriented requirements, rather than specific technologies, ‘can better prevent some of the intellectual property litigation issues that have arisen in the E911 context from extending to NG911.’”).

another agency's authority.

Recently, the FTC has arguably played the most prominent role as a body of post-adjudicatory review of patent litigation. In particular, the FTC has been heavily involved in “reverse payment” or “pay-to-delay” settlements in the pharmaceutical context.<sup>131</sup> Under the Hatch-Waxman Act, the FDA may not approve an Abbreviated New Drug Application (ANDA), i.e., an application for a generic version of a brand drug, as long as the brand drug is covered by any valid, unexpired patents.<sup>132</sup> To gain entry to the brand drugs' market, generics typically challenge the brand drugs' patents through traditional patent litigation.<sup>133</sup> Where a brand's patents are weak, or where a generic's challenge appears that it will ultimately be successful, a brand pharmaceutical manufacturer has strong incentives to settle any patent litigation. Otherwise, the brand manufacturer risks a judgment that its patents are invalid or unenforceable or that a generic product would not infringe the patents in the first instance.<sup>134</sup> Brand manufacturers' drive to settle has frequently led to agreements to delay the generic's entry to the market in exchange for ancillary licenses, cash payments, and other compensation paid to the generic manufacturer.<sup>135</sup> This arrangement is somewhat peculiar because, typically, it is the accused infringer who pays the patent holder—not the other way around.<sup>136</sup> But, in the words of Michael A. Carrier, such agreements occur “because of the parties' aligned incentives. By delaying generic entry, the brand firm can increase its monopoly profits. It can then use a portion of those profits to pay the generic more than it would have received by entering the market.”<sup>137</sup>

Suffice it to say, such agreements to “pay to delay” market entry raise

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131. See *Fed. Trade Comm'n v. Actavis*, \_\_\_ U.S. \_\_\_, 133 S. Ct. 2223, 2227–28 (2013) (discussing the FTC's review of “reverse payment” or “pay-to-delay” patent settlements).

132. 21 U.S.C. § 355(j)(5)(B)(iii) (2012).

133. See *id.* (setting forth the procedure for initiating such a suit); ADAM GREENE & D. DEWEY STEADMAN, RBC CAPITAL MARKETS, PHARMACEUTICALS: ANALYZING LITIGATION SUCCESS RATES, RBC CAP. MARKETS 3 (Jan. 15, 2010), available at <http://perma.cc/E57L-JX2H> (finding that, for 2009, generic competitors filed sixty-five “first-to-file” challenges to brand pharmaceutical patents).

134. See C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1580–88 (2006) (discussing the incentives of settlement).

135. See David W. Opderbeck, *Rational Antitrust Policy and Reverse Payment Settlements in Hatch-Waxman Patent Litigation*, 98 GEO. L.J. 1303, 1308 (2010) (“[M]ost of these settlements address the following four fundamental points: (1) amount of reverse payment; (2) length of generic marketing restriction; (3) retention of generic market exclusivity; and (4) ancillary licenses.”).

136. See *Actavis*, 133 S. Ct. at 2227 (“Because the settlement requires the patentee to pay the alleged infringer, rather than the other way around, this kind of settlement agreement is often called a ‘reverse payment’ settlement agreement.”).

137. Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 39–40 (2009).

traditional antitrust concerns.<sup>138</sup> And the FTC has been especially vigilant about policing them, instituting numerous antitrust investigations against brand and generic manufacturers alike.<sup>139</sup> It is those investigations that frequently function as fora for mid- to post-adjudicatory review of underlying patent litigation. In their antitrust complaints against settling pharmaceutical competitors, the FTC has routinely required parties to re-engage in analyses as to the strength of the underlying patents,<sup>140</sup> their exclusionary scope,<sup>141</sup> and the reasonableness of the parties' arguments in the initial patent litigation proceeding.<sup>142</sup> In *Federal Trade Commission v. Watson*,<sup>143</sup> for example, the "lynchpin" of the FTC's original antitrust complaint against the brand manufacturer was that the brand manufacturer "probably would have lost the underlying patent infringement action—that is, [the generic challengers] had a strong case that the [asserted] patent did not bar their entry into the generic [product's] market."<sup>144</sup> To prove its case, the FTC sought to relitigate, in district court, the strength of the asserted patent's validity, the extent of its scope, and the reasonableness of the parties' validity and infringement arguments.<sup>145</sup>

Although the Supreme Court has since attempted to cabin these sorts of inquiries in the FTC's review of reverse payment settlements,<sup>146</sup> they are not gone entirely, and pharmaceutical manufacturers facing FTC scrutiny of their patent settlements may, in fact, wish to raise patent validity arguments in their defense.<sup>147</sup> But in any event, it is likely that

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138. See, e.g., *Actavis*, 133 S. Ct. at 2227.

139. See *id.* at 2227–28; see generally James C. Burling, *Hatch-Waxman Patent Settlements: The Battle For A Benchmark*, 20 ANTITRUST 41 (2006) (discussing the early history of the FTC's interest in reverse payment settlements).

140. See *Schering-Plough Corp. v. Fed. Trade Comm'n*, 402 F.3d 1056, 1061 (11th Cir. 2005) (recounting the FTC's arguments that the underlying patents, despite the settlement between the brand and generic manufacturers, were invalid).

141. See *id.* at 1066 (discussing the importance of "the exclusionary potential of the patent").

142. *Fed. Trade Comm'n v. Watson Pharm., Inc.*, 677 F.3d 1298, 1311 n.8 (11th Cir. 2012) (discussing, but rejecting, the weight FTC's investigations placed on "the strength of the patent holder's claims of validity and infringement, as objectively viewed at the time of settlement"), *rev'd and remanded sub nom. Actavis, Inc.*, 133 S. Ct. 2223.

143. *Id.*

144. *Id.* at 1305.

145. *In re Androgeol Antitrust Litig. (No. II)*, 687 F. Supp. 2d 1371, 1376–79 (N.D. Ga. 2010).

146. See *Actavis, Inc.*, 133 S. Ct. at 2234 ("[A]ntitrust scrutiny of a reverse payment agreement would require the parties to litigate the validity of the patent in order to demonstrate what would have happened to competition in the absence of the settlement. Any such litigation will prove time consuming, complex, and expensive. The antitrust game . . . [may] not be worth that litigation candle."); Edlin et al., *supra* note 20, at 19 ("The Court makes clear that litigating the patent is not necessary for the affirmative antitrust case.")

147. See Comment, *Hatch-Waxman Act—Reverse-Payment Settlements—FTC v. Actavis, Inc.*,

the FTC will continue to assess such issues in its initial internal investigations. Much as large, pay-to-delay settlements on weak intellectual property harm consumers, brand-generic “early entry” settlements on strong, pioneering drug patents do little competitive harm, whether a reverse payment is involved or otherwise. Similarly, sheltering narrowly construed patents from forced litigation raises less anticompetitive concerns, generally, than doing the same for broadly claimed patents.<sup>148</sup> Determining which is the case nonetheless places the FTC as a body of post-adjudicatory review of the merits of an original patent suit.

To a lesser extent, the FDA also engages in a type of post-adjudicatory patent litigation analysis. The statute concerning the FDA’s approval of patent-threatening generic products conditions that approval on a federal court judgment as to the patent’s invalidity or the proposed product’s noninfringement.<sup>149</sup> But patents routinely consist of multiple, independent claims, some of which may be valid and some of which may not.<sup>150</sup> And, even a judgment of patent infringement against a proposed generic product may focus on only one particular dosage or method of use out of many proposed by the generic manufacturer.<sup>151</sup> Thus, in the case of a mixed judgment, the FDA may need to serve as a reviewing panel of the underlying patent litigation, determining which claims of a multiple-claim patent remain valid; which claims, if any, the generic manufacturer infringes; and which specific form of the proposed generic product infringes, or does not infringe, the listed patent.

This was precisely the role played by the FDA in *Pfizer, Inc. v. Apotex, Inc.*<sup>152</sup> In *Pfizer, Apotex*, a generic manufacturer, unsuccessfully challenged the patent covering Pfizer’s Norvasc product for treating hypertension and heart pain.<sup>153</sup> On appeal, the Federal Circuit reversed the district court and declared three of the patent’s eleven claims invalid

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127 HARV. L. REV. 358, 367 (2013) (“[P]harmaceutical developers’ best defense against these antitrust challenges will be establishing the validity of the patent . . .”).

148. See Hemphill, *supra* note 134, at 1606–07 (discussing the difference in competitive effects between the intellectual property at issue in narrow versus broad cases).

149. 21 U.S.C. § 355(j)(5)(B)(iii) (2012).

150. See 35 U.S.C. § 282(a) (2012) (“Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim.”).

151. See *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 903 (6th Cir. 2003) (reviewing the patent litigation between Hoescht Marion Roussel, the brand, and Andrx Pharmaceuticals, the generic, concerning Andrx’s design-around Hoescht’s Orange Book-listed formulation patent covering dissolution profiles).

152. 480 F.3d 1348 (Fed. Cir. 2007).

153. *Id.* at 1352.

for obviousness.<sup>154</sup> But while the FDA then approved Apotex's generic product, it denied a host of follow-on generic applications on the grounds that "the Federal Circuit's ruling invalidated only certain portions of the Norvasc patent, [such that] Pfizer's patent remains valid as to any remaining claims."<sup>155</sup> This had the effect, under the FDA's reading of the operative statute, of demanding that "no generic manufacturers except for Apotex [could] benefit from the Federal Circuit's [mixed] ruling."<sup>156</sup> A later lawsuit filed by the later-generic applicants against the FDA directly was unsuccessful.<sup>157</sup> Thus, despite the FDA's disclaimer of possessing expertise in patent law,<sup>158</sup> Pfizer and the agency's own interpretation of the Hatch-Waxman Act required it, in some sense, to sit as a body of post-adjudicatory review; to determine which claims of Pfizer's patent were still valid and which the follow-on generics' proposed products putatively infringed.

Not all agency review of patent litigation arises from judgments in federal court. In an interesting variation on the post-adjudicatory review function, the Office of the United States Trade Representative (USTR) has final say over any judgments arising from section 337 patented import proceedings before the ITC.<sup>159</sup> Because the ITC serves as an alternative venue for patent disputes, patented import litigation before the ITC focuses on the same core issues of invalidity and infringement as does traditional patent litigation in district courts, with its judgments reflecting similar, if not identical, analyses.<sup>160</sup> If the ITC does find a violation of section 337, i.e., it concludes that the asserted patents were valid and infringed, it must wait sixty days before effectuating any judgment against the respondent.<sup>161</sup> During that sixty-day time period, the ITC must transmit its decision to the USTR, which is entitled to disapprove of the ITC's proposed order.<sup>162</sup>

Although the statute suggests that any grounds for disapproving the ITC's findings are limited to "policy reasons,"<sup>163</sup> there is little

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154. *Id.* at 1372.

155. Mylan Labs., Inc. v. Leavitt, 484 F. Supp. 2d 109, 121 (D.D.C. 2007).

156. *Id.* at 118.

157. *See id.*

158. *See supra* notes 58–59 and accompanying text.

159. *See* 19 U.S.C. § 1337(j)(2) (2012) (investing the President with the power to nullify the ITC's findings of infringement under § 337); Presidential Documents, Memoranda of President, Assignment of Certain Functions Under Section 337 of the Tariff Act of 1930, 70 Fed. Reg. 43251 (July 21, 2005) (delegating the President's authority under § 337 to the USTR).

160. *See infra* notes 169–181 and accompanying text.

161. 19 U.S.C. § 1337(j)(2).

162. *Id.*

163. *Id.*



preventing the USTR from expanding this authority by couching a substantive review of the ITC's proposed order as a matter of economic "policy." In 1987, for example, the USTR disapproved of a proposed ITC order concerning DRAM chips, which "require[d] all importers of computers, facsimile machines, telecommunications switching equipment, and printers that contain DRAMs to determine the type and source of DRAMs contained in their machines and certify this for each import of these products."<sup>164</sup> This, the USTR believed, would have "extend[ed] far beyond [the respondent] and importers of [the respondent's] infringing products . . . [as] there [wa]s no evidence of imports of [the accused products] manufactured by [the respondent] contained in the categories of machines covered in the order."<sup>165</sup> Even though it was without statutory authority to do so, the USTR then proposed that the ITC narrow its order to three categories of products containing DRAMs that it believed captured the infringing market.<sup>166</sup> While a recent section 337 disapproval has seemingly abdicated any authority to "revisit the [ITC's] legal analysis or its findings based on its record,"<sup>167</sup> historical practice suggests that the scope of such authority is likely to change from presidential administration to presidential administration.<sup>168</sup>

#### D. *Alternative Fora*

Lastly, administrative agencies can also function as alternative fora for patent litigation. The ITC and the PTO both employ procedures that, like district court litigation, allow accused infringers or business rivals to challenge core issues of patent validity and infringement. Here, patented import proceedings before the ITC serve as the clearest example. Under section 337 of the Tariff Act of 1930 (codified at 19 U.S.C. § 1337), the ITC has the power to enjoin "[t]he importation into the United States . . . of articles that . . . infringe a valid and enforceable United

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164. Presidential Disapproval of a Section 337 Determination, 52 Fed. Reg. 46011, 46012 (Dec. 3, 1987).

165. *Id.*

166. *Id.* (proposing that the ITC limit its proposed order to certain DRAMs manufactured by the respondent; DRAMs incorporated in certain carriers, circuit boards, or memory expansion boards; and any products manufactured by the respondent that contained DRAMs).

167. Letter from Michael B.G. Froman, Ambassador, U.S. Trade Representative, to Irving A. Williamson, Chairman, Int'l Trade Comm'n, at 3 (Aug. 3, 2013), available at <http://perma.cc/B4H3-HF8E>.

168. See Tony V. Pezzano & Jeffrey M. Telep, *Latest Developments on Injunctive Relief for Infringement of FRAND-Encumbered SEPs—Part I*, 26 INTELL. PROP. & TECH. L.J. 14, 25 (2014) (recounting the historical practice of Section 337 disapprovals and suggesting that four of the previous five disapprovals all occurred during the Reagan administration).

States patent or . . . are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent.”<sup>169</sup> Procedurally, aggrieved patent holders file a complaint with the ITC, which must then determine whether the complaint is sufficient and whether the “public interest” merits investigation.<sup>170</sup> If so, the complainant and the respondent then engage in what appears, by all accounts, to look like traditional federal litigation: the respondent files a response to the complainant’s charges;<sup>171</sup> the parties engage in an early Rule 16-like scheduling conference;<sup>172</sup> discovery—including depositions, interrogatories, and requests for production and admission—commences;<sup>173</sup> the parties file motions to dismiss the complaint or for early judgment;<sup>174</sup> they narrow their claims at a pre-hearing conference;<sup>175</sup> and ultimately, an adjudicator—here, an Administrative Law Judge (ALJ)—conducts an evidentiary hearing.<sup>176</sup> Notably, many of the ITC’s own regulations for section 337 proceedings expressly incorporate the Federal Rules of Civil Procedure,<sup>177</sup> and give the agency “nationwide jurisdiction to conduct investigations, including nationwide service of process for subpoena enforcement actions.”<sup>178</sup> And, with respect to patent litigation specifically, the “parties may raise any equitable or legal defense [under the patent statute], such as patent invalidity.”<sup>179</sup> To be sure, there are differences between federal patent

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169. 19 U.S.C. § 1337(a)(1)(B) (2012).

170. *See* 19 C.F.R. § 210.10 (2014).

171. *Compare id.* § 210.13 (providing for a response to a complaint), *with* FED. R. CIV. P. 12(a)(1)(A) (providing for an answer in response to a complaint).

172. *Compare* U.S. INT’L TRADE COMM’N, PUB. NO. 4105, ANSWERS TO FREQUENTLY ASKED QUESTIONS 19 (Mar. 2009), *available at* <http://perma.cc/E7XE-PU3V> (“The dates of such hearings are usually set forth in a procedural schedule issued by the Judge early in the investigation, and if a hearing is rescheduled, the Judge will normally issue an order with the new dates.”), *with* FED. R. CIV. P. 16 (providing for setting a schedule, “establishing early and continuing control so that the case will not be protracted because of lack of management”).

173. *Compare* 19 C.F.R. §§ 210.27–210.31 (providing for discovery), *with* FED. R. CIV. P. 30–36 (providing for the same).

174. *Compare* 19 C.F.R. § 210.15 (governing motions), *with* FED. R. CIV. P. 12, 56 (governing the same).

175. *Compare* 19 C.F.R. § 210.35 (providing for a pre-hearing conference), *with* FED. R. CIV. P. 16 (providing for a pretrial conference).

176. *Compare* 19 C.F.R. § 210.42 (providing for an Administrative Law Judge to issue an “initial determination” as to infringement and validity), *with* FED. R. CIV. P. 39 (providing for a trial by a judge or by a jury, depending on the circumstances).

177. *See, e.g.*, 19 C.F.R. § 210.33 (incorporating Federal Rule of Civil Procedure 37(b) regarding sanctions); *id.* § 210.70 (incorporating Federal Rule of Civil Procedure 65 regarding the forfeiture of bonds); *id.* § 210.27 (incorporating Federal Rule of Civil Procedure 26(g) regarding attorneys’ fees).

178. Kumar, *supra* note 21, at 535.

179. *Id.* However, Kumar notes “that the ITC has held that defenses under 35 U.S.C. § 271(g) are

litigation and section 337 disputes—such as an accelerated timetable and the inclusion of a neutral-party staff attorney representing the public interest<sup>180</sup>—but litigators well-versed in district court patent litigation will find familiar comfort in these analogous proceedings before the ITC.<sup>181</sup> Indeed, “the ITC is busier with patent cases than it has ever been before.”<sup>182</sup> Since the Supreme Court limited the availability of permanent injunctions in patent disputes in 2006,<sup>183</sup> the number of section 337 ITC filings appears to have tripled from 2006–2010,<sup>184</sup> making it a viable alternative forum to district court patent litigation.<sup>185</sup>

Interestingly, several administrative procedures available at the PTO also appear to serve as an alternative patent litigation venue. In these “post-issuance proceedings,” accused infringers or business rivals may, in some circumstances, challenge the validity of previously issued patents much as they would in district court litigation.<sup>186</sup> Under the recently modified “inter partes review,” any person other than the patent holder—including defendants to ongoing patent litigation—may request that the PTO review an issued patent for invalidity if any printed materials raise a “reasonable likelihood” that the patent is, in fact, invalid.<sup>187</sup> Similarly, under “post-grant review,” any person other than the patent holder may ask the PTO to declare a patent invalid for any reason.<sup>188</sup> In addition, Congress has instituted a transitional program of post-grant review for certain financial business method patents, also known as “covered business method” (CBM) review.<sup>189</sup> Under CBM review, a defendant threatened for infringing a covered business method

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not available in § 337 proceedings.” *Id.* n.29.

180. *Id.* at 537 (describing the typical section 337 timetable—seventeen months from complaint to Initial Determination—as “faster than [sic] some so-called ‘rocket docket’ district courts”); *id.* at 534 (“A staff attorney is assigned to each investigation to represent the public interest and acts as a third-party litigant.”); *see also* Bock, *supra* note 14, at 250–52 (describing the effects of the staff attorney); *infra* Part 2 (discussing estoppel in this context).

181. *See* *Tex. Instruments Inc. v. Tessera, Inc.*, 231 F.3d 1325, 1333 (Fed. Cir. 2000) (Lourie, J., dissenting) (“Everyone familiar with patent litigation knows that ITC proceedings are considered ‘litigation.’”).

182. Chien & Lemley, *supra* note 10, at 3.

183. *See id.* at 8–19 (discussing the effect of *eBay, Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006)).

184. *See* ITC, FACTS AND TRENDS, *supra* note 126, at 1.

185. Chien & Lemley, *supra* note 10, at 2 (“In the past five years, both PAEs and product-producing companies have flocked to this once-obscure trade agency in search of injunctions or the credible threat of injunctions.”).

186. Iancu & Haber, *supra* note 78, at 476.

187. 35 U.S.C. § 311 (2012) (governing inter partes review); *id.* § 314 (setting forth the “reasonable likelihood” threshold for the commencement of inter partes review).

188. *Id.* § 321 (governing post-grant review).

189. Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 18, 125 Stat. 284, 329 (2011).

patent—by regulation, “a patent that claims a method or corresponding apparatus for performing data processing or other operations used in the practice, administration, or management of a financial product or service”<sup>190</sup>—may institute a CBM review before the PTO to challenge the patent’s validity on any grounds.<sup>191</sup>

Each of these post-issuance proceedings is procedurally “trial like.”<sup>192</sup> The challenger files a petition;<sup>193</sup> the patent owner files a response;<sup>194</sup> the parties engage in routine discovery<sup>195</sup> and filings analogous to motions practice;<sup>196</sup> a hearing before a fact-finder is held;<sup>197</sup> and the fact-finder issues a written decision.<sup>198</sup> Like litigators’ familiarity with ITC practice, these post-issuance proceedings have made the PTO—an agency much better known for examining patents than for litigating them—“viable as an alternative to district court litigation, for both patentees and potential infringement defendants with patent validity questions.”<sup>199</sup>

## II. PROBLEMS WITH AGENCY ADMINISTRATION OF PATENT LITIGATION

The diversity of agency functions in patent litigation highlights one of the classic problems in administrative law: that an increase in the amount and extent of agency involvement in shared regulatory space creates the potential to “produce redundancy, inefficiency, and gaps, [and] more than anything else, . . . create profound coordination challenges.”<sup>200</sup> Although the problems of agency administration of

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190. 37 C.F.R. § 42.301(a) (2014).

191. Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 18.

192. See Iancu & Haber, *supra* note 78, at 479.

193. 35 U.S.C. § 312 (governing petitions for inter partes review); *id.* § 322 (governing petitions for post-grant review).

194. *Id.* § 313 (governing responses to petitions for inter partes review); *id.* § 323 (governing responses to petitions for post-grant review).

195. *Id.* § 316(a)(5) (permitting the Director to issue regulations concerning discovery in inter partes review); *id.* § 326(a)(5) (permitting the Director to issue regulations concerning discovery in post-grant review).

196. *Id.* § 316(d)(2) (allowing for limited motions practice in inter partes review); *id.* § 326(d)(2) (allowing for limited motions practice in post-grant review).

197. *Id.* § 316(a)(10) (permitting oral hearings in inter partes review); *id.* § 326(a)(10) (permitting oral hearings in post-grant review).

198. *Id.* § 318 (requiring a written decision in inter partes proceedings); *id.* § 328 (requiring a written decision in post-grant proceedings).

199. See Iancu & Haber, *supra* note 78, at 476.

200. Jody Freeman & Jim Rossi, *Agency Coordination in Shared Regulatory Space*, 125 HARV. L. REV. 1131, 1135 (2012).

patent litigation differ little from traditional regulatory problems, they abound. The high-stakes nature of many patent disputes make them particularly susceptible to regulatory gamesmanship. High-profile patent litigation among frequently litigious or politically significant industries also causes agencies to suffer from both industry and political capture. The regulatory nature of agency involvement in disputes makes settlement, in some instances, uncertain. And, where regulatory decisions affect parties' core claims of infringement or validity, litigants face the prospect of inconsistent judgments. This Part explains the difficulties with agency administration of patent litigation across agencies' various functions.

### A. *Regulatory Gamesmanship*

One of the more profound problems with agency administration of patent litigation is, in the words of Stacey L. Dogan and Mark A. Lemley, “regulatory gamesmanship”: “private behavior that harnesses procompetitive or neutral regulations and uses them for exclusionary purposes.”<sup>201</sup> Generally, regulatory gamesmanship “undermines both the regulatory system itself and the long-standing, complementary relationship between regulatory and antitrust law.”<sup>202</sup> In the patent context, the exclusionary advantages generated by regulatory gaming often extend well beyond the scope of the patent at issue.<sup>203</sup> And within the crucible of litigation itself, regulatory gamesmanship generates tremendous inefficiencies, diverts courts' focus from core issues of infringement and invalidity, and causes often lengthy delays in the timely resolution of complaints.<sup>204</sup>

Commentators have written about these issues at length by focusing on a single industry: pharmaceutical manufacturers.<sup>205</sup> In particular, commentators have complained that brand manufacturers' strategy of “product hopping”—making medically insignificant alterations to previously approved, patented drugs in the hopes of forestalling generic competition—is a form of regulatory gamesmanship.<sup>206</sup> But viewed from a broader, functional perspective, regulatory gamesmanship seems to

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201. Dogan & Lemley, *supra* note 18, at 687.

202. *Id.*

203. *See id.* at 709–17 (discussing this phenomenon in the pharmaceutical context).

204. *See id.* at 712–13 (discussing this aspect of delay in *Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408 (D. Del. 2006)).

205. *E.g.*, Michael A. Carrier, *A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping*, 62 FLA. L. REV. 1009, 1016–17 (2010); Cheng, *supra* note 59, at 1486–89; Dogan & Lemley, *supra* note 18, at 709–17.

206. Dogan & Lemley, *supra* note 18, at 709–17.

occur on both the front and back ends of patent litigation: at the beginning, where agencies serve as litigation gatekeepers, and at the end, where agencies act as alternative venues to patent litigation.

Regarding litigation gatekeeping, it is true that the FDA's own regulations, in some sense, promote regulatory gamesmanship.<sup>207</sup> The phenomenon of product hopping occurs because the FDA's own interpretation of the Hatch-Waxman Act requires it to disapprove a generic's ANDA if the proposed drug does not match the precise specifications listed by the brand—the “reference listed drug” (RLD)—as opposed to a looser definition of the brand's pharmaceutical product.<sup>208</sup> In one of the more egregious cases of product hopping, Purdue Pharma, with its patents on its blockbuster drug OxyContin set to expire, changed the pharmaceutical formulation of the drug in order to prevent the entry of generic competitors.<sup>209</sup> Purdue did so by simply changing the drug's tablet shell to be more resistant to abuse.<sup>210</sup> And, once Purdue received FDA approval for its “abuse-proofed” formulation of OxyContin, it successfully filed a citizen petition—essentially, against itself—to remove as “unsafe” OxyContin's previous RLD from the FDA's rolls,<sup>211</sup> leaving generic competitors with no RLD to copy.

This banal strategy<sup>212</sup> highlights how regulatory gamesmanship fits within a concept of agency function in patent litigation. Product hopping serves to harness the FDA's neutral regulations concerning RLDs by using them to exclude generic competitors *prior* to the commencement of patent litigation—i.e., by preying on the FDA's role as a gatekeeper of patent litigation. By shuttling a defined, pharmaceutical product's RLD from one form to another, and by removing old RLDs from the FDA's rolls, a brand manufacturer can prevent generic competitors from challenging the brand's patents through traditional litigation. In that sense, what product hopping accomplishes is to divest the FDA of “the power to oversee and manage private [patent] litigation efforts.”<sup>213</sup> The

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207. *See id.* at 687 (“Indeed—and perhaps ironically—the very regulatory structure that exists to promote competition can create gaming opportunities for competitors bent on achieving anticompetitive goals.”).

208. *See* 21 C.F.R. § 314.127 (2014) (requiring the denial of an ANDA if the application does not precisely parallel the brand's reference listed drug).

209. For a recounting of the OxyContin patent litigation and antitrust saga, see *Purdue Pharma L.P. v. Boehringer Ingelheim GMBH*, 237 F.3d 1359 (Fed. Cir. 2001) and, more recently, *In re OxyContin Antitrust Litig.*, No. 04 Md. 1603(SHS), 2014 WL 2198590 (S.D.N.Y. May 27, 2014).

210. *In re OxyContin*, 2014 WL 2198590, at \*1.

211. Letter from Peter R. Mathers, Counsel to Purdue Pharma L.P., to Food & Drug Admin. (July 13, 2012), available at <http://perma.cc/XTY5-ARFV>.

212. *See* Cheng, *supra* note 59, at 1489–94 (describing AstraZeneca's, Abbott's, and Fournier's product hopping).

213. *See* Engstrom, *supra* note 13, at 619.

availability of citizen petitions similarly accomplishes this goal. Petitions that force the FDA to remove a product's RLD work in much the same fashion as product hopping: without an RLD on which to base an ANDA, generic competitors cannot, through the Hatch-Waxman framework, litigate a brand's patents. But, because the FDA must respond to all citizen petitions it receives,<sup>214</sup> citizen petitions also frequently serve to delay the FDA's consideration of a generic's ANDA and, consequently, any resulting patent litigation.<sup>215</sup> Like the ITC's and PTO's role in controlling the timing of district court litigation,<sup>216</sup> citizen petitions require the FDA to delay its considerations of generics' ANDAs, barring the gate, in some cases, to patent litigation in the first instance.<sup>217</sup>

Not all regulatory gamesmanship occurs to bar the initiation of patent litigation, however. Regulatory gamesmanship before the ITC and PTO serves to drag out patent litigation once it has already begun, clogging—as opposed to stopping—those agencies' functions as gatekeepers. In the case of the ITC, a party unsatisfied with the pace (or interim results) of district court patent litigation may file a contemporaneous section 337 complaint before the ITC.<sup>218</sup> Because of the mandatory stay imposed upon district courts in parallel proceedings,<sup>219</sup> the ITC complaint has the effect of essentially grinding the district court litigation to a seventeen-month halt.<sup>220</sup> In this way, a litigant can take advantage of the “procompetitive or neutral regulations” regarding the ITC's availability

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214. 21 U.S.C. § 355(q)(1)(F) (2012) (requiring the FDA to respond to petitions “not later than 150 days after the date on which the petition is submitted”).

215. See Ryan Abbott, *Big Data and Pharmacovigilance: Using Health Information Exchanges to Revolutionize Drug Safety*, 99 IOWA L. REV. 225, 263 (2013) (“Brand companies have significant incentives to file to delay generic competition. Their filing may delay ANDA approval even if their petition is not granted. In addition, it is inexpensive to file, and there are no consequences for filing frivolous petitions. Brand firms use these petitions as part of a comprehensive strategy, which also includes reverse-payment patent settlements and ‘product hopping,’ to delay generics’ entry into the market.”); Carrier & Wander, *supra* note 1616, at 288 (demonstrating, empirically, that citizen petitions have “played a pivotal role in delaying generic entry”).

216. See *supra* notes 72–92 and accompanying text.

217. See Matthew Avery et al., *The Antitrust Implications of Filing “Sham” Citizen Petitions with the FDA*, 65 HASTINGS L.J. 113, 135–37 (2013) (discussing the litigation delays caused by the brand's citizen petitions in the Flonase case).

218. See Colleen v. Chien, *Patently Protectionist? An Empirical Analysis of Patent Cases at the International Trade Commission*, 50 WM. & MARY L. REV. 63, 70 (2008) (“65 percent of the ITC cases studied had a district court counterpart, which indicates that the ITC is often *not* the venue of only resort as it was originally conceived to be.” (emphasis in original)).

219. 28 U.S.C. § 1659(a); see also *supra* notes 72–77 and accompanying text.

220. See Kumar, *supra* note 21, at 537 (describing the typical section 337 case before the ITC as lasting seventeen months).

and district court stays, and “use[ ] them for exclusionary purposes.”<sup>221</sup>

Post-issuance proceedings before the PTO work in a similar vein. In inter partes review, defendants in a patent infringement action may petition the PTO for review up to one year after being served with the patent holder’s complaint.<sup>222</sup> Once a request for inter partes review is filed, the district court proceedings are automatically stayed pending the outcome of review.<sup>223</sup> Given that the average patent infringement suit is typically resolved within a year,<sup>224</sup> (significantly longer for Hatch-Waxman litigation)<sup>225</sup> inter partes review’s one-year buffer essentially allows infringement defendants to test the waters of district court litigation—from answer, to both fact and expert discovery, to motions to dismiss and potentially for summary judgment—before halting the infringement suit against them. Later, inter partes review filings serve little purpose other than to control the PTO’s power as a gatekeeper to district court litigation.

The same strategy also applies to post-grant review proceedings. Although there is no time limit on filing a request for post-grant review based on the timing of a civil complaint, parties must file their requests within nine months after the patent’s issuance.<sup>226</sup> Thus, because the vast majority of patent litigation occurs on older patents,<sup>227</sup> defendants bent on waiting until litigation against them has largely progressed will have little difficulty doing so.

Lastly, the procedures for CBM review seem to acknowledge the role that post-issuance proceedings play in hampering district court litigation. There, CBM review is not available *unless* a party has been sued for patent infringement.<sup>228</sup> Here, the express purpose—by Congressional design—seems solely to allow defendants to delay contemporaneous district court litigation.<sup>229</sup> In that sense, litigants using the neutral

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221. Dogan & Lemley, *supra* note 18, at 687.

222. Leahy-Smith America Invents Act, Pub. L. No. 112–29, § 6, 125 Stat. 284, 299 (2011).

223. *Id.*

224. See Mark A. Lemley, *Where to File Your Patent Case*, 38 AIPLA Q.J. 401, 415 (2010) (noting that the typical patent case is resolved in about a year).

225. S. Peter Ludwig et al., *Hatch-Waxman in the Federal Courts: From 1994–2004*, 31 DRUG DEV. & INDUS. PHARMACY 215, 221 (2005) (assessing typical Hatch-Waxman proceedings as lasting twenty-nine months to resolution).

226. 35 U.S.C. § 321(c) (2012).

227. Dennis Crouch, *Age of Patents When Asserted*, PATENTLY-O (Oct. 31, 2012), <http://perma.cc/S2L-FGMX> (showing that the bulk of patents are first asserted well after they are a year old).

228. Leahy-Smith America Invents Act, Pub. L. No. 112–29, § 18(a), 125 Stat. 284, 329 (2011).

229. See Carter, *supra* note 19, at 2 (“The Section 18 language to swat away pesky business-method patents—for banks—was dropped into the Senate version of the bill by prolific Wall Street fundraiser and third-ranking Democratic Sen. Chuck Schumer (N.Y.) . . . . ‘This [is] the sort of gift



procedural rules governing post-issuance proceedings have harnessed the PTO's power to "determine whether private rights of action should lie at all."<sup>230</sup>

### B. *Industry Capture*

Agency administration of patent litigation, like regulation elsewhere, also suffers from the potential for industry capture, "the co-opting of regulatory agencies by [industry] groups, to the extent that the institution promotes the particular private interest of those groups rather than the overall public good."<sup>231</sup> Where agency involvement in patent litigation has the potential to ensure an IP-sensitive industry the continued vitality of its patent monopolies, or where litigation by upstart patent holders threatens to shutter established, accused infringers, industry groups will attempt to navigate agencies in patent litigation toward their own ends.<sup>232</sup> Although the normative effects of industry capture in patent litigation are difficult to generalize—it is unclear whether the outcome in any individual patent dispute will contribute or detract from the "overall public good"—industry capture short-circuits the important role that private patent litigation plays in innovation policy. It undermines the foundation of the patent grant by troubling exclusive rights to valid patents,<sup>233</sup> and it weakens the public utility of using litigation to weed out invalid patents.<sup>234</sup>

Industry capture of agency administration of patent litigation appears to occur across a broad spectrum of agency functions, from agencies' initial role as gatekeepers, through their prominence in post-adjudicatory review, and, finally, as alternative fora of litigation itself. The recently implemented Generating Antibiotic Incentives Now (GAIN) Act stands

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to major corporations that is the hallmark of bad legislation,' says Tom Giovanetti, president of the Institute for Policy Innovation . . . 'This is a case of the banks using their raw political clout.'").

230. See Engstrom, *supra* note 13, at 619.

231. K. Sabeel Rahman, Note, *Envisioning the Regulatory State: Technocracy, Democracy, and Institutional Experimentation in the 2010 Financial Reform and Oil Spill Statutes*, 48 HARV. J. LEGIS. 555, 555 (2011).

232. See George J. Stigler, *The Theory of Economic Regulation*, 2 BELL J. ECON. MGMT. SCI. 3, 5 (1971) ("[E]very industry or occupation that has enough political power to utilize the state will seek to control entry.").

233. See Dan L. Burk, *Legal and Technical Standards in Digital Rights Management Technology*, 74 FORDHAM L. REV. 537, 537 (2005) ("Copyright and similar exclusive rights regimes have long been mainstays of innovation policy, purporting to provide the incentive necessary to generate creative and innovative products for the benefit of the public.").

234. *Blonder-Tongue Lab. Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 331 n.21 (1971) ("Patent validity raises issues significant to the public as well as to the named parties. . . . It is just as important that a good patent be ultimately upheld as that a bad one be definitively stricken." (quoting *Technograph Printed Circuits v. United States*, 372 F.2d 969, 977 (Fed. Cl. 1967))).

testament to the powers of industry capture on agencies' role in litigation gatekeeping.<sup>235</sup> Prior to the GAIN Act, new drugs approved by the FDA received anywhere from four to seven-and-a-half years of market exclusivity—with or without a patent—during which the FDA was prohibited from approving any follow-on generics.<sup>236</sup> This prohibition on generic approval serves as a lock-keeper for litigation: during the period of market exclusivity, generics have no easy path into court to challenge the brand's patents; after market exclusivity expires, the floodgates of litigation open.<sup>237</sup> Faced with decreasing profitability in manufacturing antibiotics, increasing patent uncertainty, and a public health crisis regarding antibiotic overuse,<sup>238</sup> antibiotic manufacturers were able to successfully lobby Congress to include, as part of the Food and Drug Administration Safety and Innovation Act, an additional market exclusivity category for “qualified infectious disease products” (QIPDs), i.e., antibiotics.<sup>239</sup> Thanks to the GAIN Act, QIPDs now receive an *additional* five years of FDA exclusivity, tacked on to whatever exclusivity period they would have otherwise been entitled, giving QIPD manufacturers a potential for twelve years of FDA exclusivity.<sup>240</sup> During those twelve years, generic manufacturers cannot file patent challenges to the brand's QIPD under the traditional Hatch-Waxman framework, essentially barring generic adversaries from entering the courthouse doors.

In the post-adjudicatory review context, the FTC's concern with patent hold-up in standard setting organizations similarly appears to have been affected by industry capture. In a typical SSO, industry members agree to adopt certain technologies or protocols in the

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235. Generating Antibiotic Incentives Now Act of 2011, Pub. L. No. 112-114 (codified in 21 U.S.C. § 355 (2012)).

236. 21 U.S.C. § 355(c)(3)(E)(ii) (2012 & Supp. 2013).

237. Robert N. Sahr, *The Biologics Price Competition and Innovation Act: Innovation Must Come Before Price Competition*, B.C. INTELL. PROP. & TECH. F., July 19 2009, at 10 (“Since the passage of HWA, generic pharmaceutical companies have challenged the validity and enforceability of patents on nearly every profitable medicine as soon as the FDA exclusivity period expires.”).

238. See, e.g., Rebecca S. Eisenberg, *The Problem of New Uses*, 5 YALE J. HEALTH POL'Y L. & ETHICS 717, 722–23 (2005) (describing the uncertainties of patents for new uses of old drugs, citing the invalidation of the patents on an antibiotic, Augmentin); Carl Nathan & Frederick M. Goldberg, *The Profit Problem in Antibiotic R&D*, 4 NATURE REV. DRUG DISCOVERY 887 (2005) (describing the lack of profitability and public health issues concerning antibiotics); Scott Hensley & Bernard Wysocki, Jr., *As Industry Profits Elsewhere, U.S. Lacks Vaccines, Antibiotics*, WALL STREET J., Nov. 8, 2005, at A1 (describing the profitability and public health issues facing antibiotic manufacturers).

239. 21 U.S.C. § 355f (2012 & Supp. 2013) (extending the FDA exclusivity period for qualified infectious disease products).

240. Jacob S. Sherkow, *The GAIN Act Stacks 5-Years of Market Exclusivity for Antibiotics*, PATENTLY-O, Oct. 3, 2012, <http://perma.cc/D4CF-A4DL>.

development of a new technology, in order to facilitate interoperability and consumer adoption.<sup>241</sup> Recognizing that many patents, owned by a variety of members, may cover the proposed industry standard, SSO-members typically agree to license any of their intellectual property that may end up covering the standardized technology.<sup>242</sup> SSO members with particularly valuable patents may, however, hold out on their licensing commitments or wait until the standard is adopted before disclosing their interests.<sup>243</sup> This threat of holdup can raise antitrust concerns, like those typically policed in the post-adjudicatory vein by the FTC.<sup>244</sup> In the sprawling *Rambus, Inc. v. F.T.C.*,<sup>245</sup> litigation, for example, Rambus, Inc. failed to disclose its interest in several crucial pieces of intellectual property concerning a Joint Electron Device Engineering Council (JEDEC) standard for memory chips.<sup>246</sup> After the standard was set, Rambus then sued several JEDEC members for patent infringement.<sup>247</sup> These lawsuits, the FTC concluded after a lengthy investigation, constituted a violation of the antitrust laws.<sup>248</sup>

The FTC's oversight over SSO patent litigation may seem unobjectionable but for the fact that it typically serves to benefit bigger industry players with large patent portfolios. A 2003 report from the FTC concerning the intersection between intellectual property and antitrust was based mainly on information "gathered from a 2002 survey of a group of senior intellectual property managers at large companies, which was sponsored by the Intellectual Property Owners Association."<sup>249</sup> That data did not include the views of "small- and medium-sized businesses or those endeavoring to approach the issue without a specific client or with a specific agenda in mind."<sup>250</sup> Even

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241. See Janice M. Mueller, *Patenting Industry Standards*, 34 J. MARSHALL L. REV. 897, 904 (2001) ("Three primary factors are driving the rise of standards-setting: product interoperability, public health and safety, and global competitiveness.").

242. See Contreras, *supra* note 25, at 50–52 ("[M]any [SSOs] have promulgated internal policies designed to mitigate these risks. Perhaps the most prevalent of these is a requirement that [SSO] participants license their patents to all potential vendors of technologies implementing those standards on terms that are 'fair,' 'reasonable,' and 'non-discriminatory' (FRAND).").

243. *Id.* at 48–49.

244. Brief of Amicus Curiae Federal Trade Commission, *supra* note 96, at 14.

245. 522 F.3d 456, 469 (D.C. Cir. 2008), *cert. denied*, 129 S. Ct. 1318 (2009).

246. See Joel M. Wallace, *Rambus v. F.T.C. in the Context of Standard-Setting Organizations, Antitrust, and the Patent Hold-Up Problem*, 24 BERKELEY TECH. L.J. 661, 676–83 (2009) (reviewing the *Rambus* litigation).

247. *Id.* at 678.

248. *Id.* at 680.

249. F. Scott Kieff, *Coordination, Property, and Intellectual Property: An Unconventional Approach to Anticompetitive Effects and Downstream Access*, 56 EMORY L.J. 327, 413 (2006).

250. *Id.*

Rambus, at the time JEDEC set its standard for memory chips, was “a relatively small research firm . . . frustrated by many of the world’s largest DRAM manufacturers who . . . argued that the Rambus patents cover technologies that are too basic.”<sup>251</sup> In this way, the FTC’s post-adjudicatory review of patent infringement suits among SSO members seems to benefit larger, established industry players much more than IP-heavy upstarts, who may not be able to afford a protracted FTC investigation or weather whatever licensing rates the FTC may impose. This counsels that the FTC’s review of SSO violations is “consistent with a public choice agency capture story.”<sup>252</sup>

The PTO also seems to have been subject to industry capture regarding its role as an alternative forum to patent litigation. CBM review, first included as a means of post-issuance review in the 2011 Leahy-Smith America Invents Act, covers “a patent that claims a method or corresponding apparatus for performing data processing or other operations used in the practice, administration, or management of a financial product or service.”<sup>253</sup> The PTO’s language governing CBM seems broad: “it permits parties accused of infringement to challenge *any* CBM [patent] . . . on *any* validity ground.”<sup>254</sup> But in practice, it seems pointedly directed at a small subset of patents—patents on digital check-processing—on which large financial institutions were already being sued when the Act was passed.<sup>255</sup> Banks responded to this “thorn in their side” through Congressional and agency lobbying—in particular, lobbying U.S. Senator Charles E. Schumer (D-NY)—and successfully establishing CBM review as an entirely separate post-issuance proceeding before the PTO.<sup>256</sup> The words of Ben Barnes, a Democratic fundraiser who opposed the inclusion of CBM review, say it all: “I take my hat off to the Bank of New York and the senior senator from New York . . . . The banks worked very hard. I saw their footprints all over the House, and Chuck Schumer is pretty good help.”<sup>257</sup>

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251. Stephen H. Haber et al., *On the Importance to Economic Success of Property Rights in Finance and Innovation*, 26 WASH. U. J.L. & POL’Y 215, 235 (2008).

252. Kieff, *supra* note 249, at 413.

253. 37 C.F.R. § 42.301(a) (2014).

254. Megan M. La Belle & Heidi Mandanis Schooner, *Big Banks and Business Method Patents*, 16 U. PA. J. BUS. L. 431, 463 (2014).

255. *See id.* at 454–55 (discussing the infringement lawsuits concerning check-processing).

256. *Id.* at 462 (“In March 2011, the banks got what they wanted. The Senate adopted an amendment to the reform bill, including a provision sponsored by Senators Schumer and Kyl that established a new post-issuance review procedure exclusively for financial business method patents.”).

257. Carter, *supra* note 19, at 3.

### C. *Political Capture*

In other instances, it is not industry groups that co-opt agencies' roles in patent litigation, but politicians. That is, some agency-mediated patent litigation is so politically sensitive, or of such national significance, that political branches of government attempt to co-opt the agencies involved for their own ends.<sup>258</sup> Normatively, political capture may better conform to democratic ideals than leaving important patent disputes to the vicissitudes of private litigation mediated by unelected regulators.<sup>259</sup> But political capture of agency involvement in patent litigation, like industry capture of the same, nonetheless threatens the balance of innovation policy.<sup>260</sup>

Interestingly, however, political capture appears isolated to the bookended agency functions in patent litigation: litigation gatekeeping and alternative fora. Across each of these functions, political actors—faced with politically important patent litigation—have co-opted the agencies responsible for shepherding the underlying dispute, rather than directing the course of the dispute itself. Political capture, as a problem of agency involvement in patent litigation, has therefore seemingly avoided becoming involved in the nuts and bolts of patent litigation.

Perhaps the most famous example of political capture of a patent dispute concerns Cipro, the antibiotic approved to treat airborne anthrax shortly before the 2001 anthrax-terrorism scare.<sup>261</sup> After demand and public attention for the drug skyrocketed, it appeared that Cipro's manufacturer, Bayer, would be unable to produce enough of the drug to meet demand.<sup>262</sup> Some of that shortfall stemmed from earlier patent litigation, settled between Bayer and its generic rivals to keep generic copies of Cipro off the market.<sup>263</sup> Politicians—sensitive to the public's potential outrage that “patent lawyers” could be preventing them from

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258. See Ezra Ross & Martin Pritikin, *The Collection Gap: Underenforcement of Corporate and White-Collar Fines and Penalties*, 29 YALE L. & POL'Y REV. 453, 505 (2011) (“Yet another potential form of capture is political capture, in which elected officials or branches may co-opt regulatory agencies for their own purposes.”).

259. See Rachel E. Barkow, *Insulating Agencies: Avoiding Capture Through Institutional Design*, 89 TEX. L. REV. 15, 33 n.87 (2010) (discussing the seeming overlap between political pressure and democratic accountability).

260. See *supra* notes 226–228 and accompanying text.

261. See William A. Drennan, *Changing Invention Economics by Encouraging Corporate Inventors to Sell Patents*, 58 U. MIAMI L. REV. 1045, 1096–1108 (2004) (discussing the adoption of Cipro following the anthrax-terrorism scare).

262. *Id.*

263. See Uché Ewelukwa, *Patent Wars in the Valley of the Shadow of Death: The Pharmaceutical Industry, Ethics, and Global Trade*, 59 U. MIAMI L. REV. 203, 266–73 (2005) (discussing the earlier litigation).

fighting terrorism—attempted to pressure the FDA to authorize generic versions of Cipro in order to cheaply stockpile the drug, despite Bayer’s valid, Orange Book-listed patents.<sup>264</sup> This “forced authorization” essentially sought to circumvent the Hatch-Waxman Act framework of brand-generic patent litigation. Approving a generic version of an “Orange Book-protected” drug would have limited much of the resulting patent litigation typically at issue prior to a generic’s approval, leaving the parties to essentially fight over licensing rates after the fact.<sup>265</sup> At its core, therefore, the legal basis for political intervention in the Cipro dispute attempted to leverage the FDA’s role as a gatekeeper of litigation.

Patent “march-in rights” have also long been rattled as the sabers of politicians unhappy with ongoing patent disputes.<sup>266</sup> Under 35 U.S.C. § 203, any agency that funded part of a patented invention’s research and development may “march in” and compel the patent holder to grant a license on “reasonable” terms if the patent holder has not commercialized the invention or the public health or safety require it.<sup>267</sup> To a large extent this power is a “paper tiger”; “[t]he federal government has never exercised its march-in rights” and likely never will.<sup>268</sup> But some patent disputes have so occupied the public’s attention—or served as such an excellent opportunity for political gain—that legislators have nonetheless threatened to force agencies to use them. Access to AIDS drugs is a particularly pointed example. In the early 2000s, the narrative of “big pharma” patents stymying affordable access to HIV medication had reached such a fever pitch in public discourse that even taking a cautious approach to the issue was seen by many legislators as politically dangerous.<sup>269</sup> Against that backdrop—and several patent infringement lawsuits between brand and generic manufacturers<sup>270</sup>—

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264. Drennan, *supra* note 261, at 1104 n.260 (discussing Senator Schumer’s letter to the FDA concerning the Cipro patents).

265. *Id.* The other component in Senator Schumer’s letter consisted of forcing Bayer to grant compulsory licenses of its Cipro patents to its competitors, thus paving generics’ way for market entry. With both the compulsory license of generic versions of Cipro, and the FDA’s approval, little would have remained in terms of litigation other than establishing the licenses’ royalty rate.

266. See William O’Brien, Comment, *March-in Rights Under the Bayh-Dole Act: The NIH’s Paper Tiger?*, 43 SETON HALL L. REV. 1403, 1414–23 (2013) (recounting the history of march-in rights attempts by the NIH).

267. 35 U.S.C. § 203(a)(1)–(2) (2012).

268. Jacob H. Rooksby, *University Initiation of Patent Infringement Litigation*, 10 J. MARSHALL REV. INTELL. PROP. L. 623, 629 (2011); see also O’Brien, *supra* note 266, at 1413 (describing march-in rights as a “paper tiger”).

269. See J. Stephen Morrison, *The African Pandemic Hits Washington*, 24 WASH. Q. 197, 199–201 (Winter 2001) (reviewing the U.S. political response to affordable HIV medication in Africa).

270. See, e.g., *Burroughs Wellcome Co. v. Barr Lab. Inc.*, 40 F.3d 1223 (Fed. Cir. 1994)

Abbott Laboratories' massively increased the price of Norvir, a component of HIV-treatment "cocktails," which sparked public outrage.<sup>271</sup> In response, eight U.S. Senators urged the NIH, which funded some of the initial research giving rise to Abbott's patents, to exercise its march-in rights, potentially preempting or preventing patent suits between Abbott and generics.<sup>272</sup> Again, the fulcrum of legal power rested in the Senators attempting to use an agency's ability to control patent litigation, here, for the NIH to "use [its] expertise and synoptic perspective to weigh costs and benefits and determine whether private rights of action should lie at all."<sup>273</sup>

Recently, Apple and Samsung's section 337 patented-import dispute before the ITC has seemingly given rise to another form of political capture. In the parties' smartphone patent dispute, the ITC had determined that Apple violated several of Samsung's patents and voted to enjoin the importation of certain Apple products into the U.S.<sup>274</sup> During the Presidential review period, however, the USTR then disapproved of the ITC's decision—the first time in a quarter-century that it had done so.<sup>275</sup> The USTR's decision was also particularly notable because Apple had been one of the largest donors to the President's election campaigns and education initiatives.<sup>276</sup> The USTR's decision to overturn the injunction against Apple therefore seemed to serve as a form of political capture over a patent dispute; here, by directing the outcome of agency proceedings when used as an alternative forum for patent litigation. To be clear, this is to say nothing about the USTR's decision on its own merits. To the extent that the purpose of USTR and Presidential oversight over section 337 cases before the ITC is to place a political check on internationally delicate patent disputes, the Apple case may simply be an example of politics as they are supposed to be. Or, if

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(concerning patents over azidothymidine for HIV treatment).

271. See, e.g., Gardiner Harris, *Price of AIDS Drug Intensifies Debate on Legal Imports*, N.Y. TIMES, Apr. 14, 2004, at A1 ("The recent decision by Abbott Laboratories to quintuple the price of its crucial AIDS drug Norvir will be at the center of a federal hearing today in which AIDS groups and consumer advocates plan to argue that the government should begin allowing the import of cheaper drugs.").

272. See Sean M. O'Connor, *Intellectual Property Rights and Stem Cell Research: Who Owns the Medical Breakthroughs?*, 39 NEW ENG. L. REV. 665, 704 (2005) (discussing the call to march-in on Abbott's patents).

273. See Engstrom, *supra* note 13, at 619–20.

274. *In re Certain Elec. Devices*, USITC Inv. No. 337–TA–724, 2012 WL 3246515, at \*1 (Dec. 21, 2011) (USITC Comm'n Op.).

275. See Pezzano & Telep, *supra* note 168, at 25.

276. See, e.g., Shane Cole, *Apple Contributes \$100M to Obama's ConnectED High-Speed Internet for Education [u]*, APPLEINSIDER, (Feb. 4, 2014), <http://perma.cc/JJM5-FBW6> (discussing Apple's \$100 million donation).

the purpose of section 337 disputes is to protect domestic industries at the expense of foreign ones—even if foreign entities are the holders of U.S. patents—then it appears that the USTR fulfilled its mandate. Nonetheless, the USTR’s power—whether effectuated through the realpolitik of campaign donations or political populism of protecting domestic companies—is one of political capture in patent disputes.

#### D. *Settlement Uncertainty*

Agency administration of patent litigation also complicates the potential for private settlement. In a typical federal patent case, the parties have several options to resolve their dispute prior to judgment. They can stipulate to a dismissal of the action under Federal Rule of Civil Procedure 41;<sup>277</sup> by consent, the parties may amend their pleadings under Rule 15 to drop particular claims, such as counterclaims for judgments of invalidity;<sup>278</sup> or the parties may enter into an agreed-upon consent judgment.<sup>279</sup> Generally speaking, the leeway for the content of any of these settlements is expansive; the parties may agree upon judgment, so long as it is not unenforceable as a matter of public policy.<sup>280</sup> And, given the enormous costs of even moderate patent cases,<sup>281</sup> and the cognitive and scheduling burdens they place on district courts,<sup>282</sup> the advantages of settling patent disputes are numerous.<sup>283</sup>

But the leeway for settling patent disputes in the shadow of agency oversight is much narrower. In numerous instances, the agency may either hamper the parties’ attempt to settle or make unclear the true effects of settling. Concerning the FTC’s oversight of Hatch-Waxman

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277. FED. R. CIV. P. 41(a)(1)(A)(ii) (“[T]he plaintiff may dismiss an action without a court order by filing . . . a stipulation of dismissal signed by all parties who have appeared.”).

278. See FED. R. CIV. P. 15(a)(2) (“In all other cases [i.e., twenty-one days after service of a pleading], a party may amend its pleading only with the opposing party’s written consent or the court’s leave.”).

279. See *Rufo v. Inmates of Suffolk Cnty. Jail*, 502 U.S. 367, 378 (1992) (“A consent decree no doubt embodies an agreement of the parties and thus in some respects is contractual in nature. But it is an agreement that the parties desire and expect will be reflected in, and be enforceable as, a judicial decree that is subject to the rules generally applicable to other judgments and decrees.”).

280. See *Aro Corp. v. Allied Witan Co.*, 531 F.2d 1368, 1372 (6th Cir. 1976) (“Settlement agreements should therefore be upheld whenever equitable and policy considerations so permit.”).

281. See AM. INTELLECTUAL PROP. LAW ASS’N, REPORT OF THE ECONOMIC SURVEY 2013, at 34 (2013) (listing total end-costs patent lawsuits by demand).

282. See Peter Lee, *Patent Law and the Two Cultures*, 120 YALE L.J. 2, 9–17 (2010) (discussing the cognitive burdens patent litigation places on generalist judges); Lemley, *supra* note 224, at 414–15 (listing the time to judgment across the various federal districts).

283. See *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 202 (2d Cir. 2005) (noting, “[w]here a case is complex and expensive . . . the public has a strong interest in settlement”); *Aro*, 531 F.2d at 1372.



litigation, for example, the FTC has the authority to bar them outright.<sup>284</sup> Indeed, it is the settlements themselves, rather than the merits of the underlying patent litigation, in which the FTC has been recently finding antitrust violations.<sup>285</sup> In *Federal Trade Commission v. Actavis, Inc.*,<sup>286</sup> Solvay Pharmaceuticals, a brand manufacturer of a testosterone gel, had fought a three-year long, costly, and risky patent dispute against several generic companies, including Actavis' predecessor, Watson Pharmaceuticals.<sup>287</sup> Before the district court could render judgment, and before any generic competitors could enter the market, Solvay entered into several reverse payment settlement agreements with its adversaries.<sup>288</sup> It was these settlement agreements—rather than the principal litigation between Solvay and Watson—that initially caught the FTC's ire in *Federal Trade Commission v. Watson Pharmaceuticals*.<sup>289</sup> After the case and several companions wound their way to the Supreme Court, the Court reinforced the FTC's authority to prohibit settlements that have the "potential for genuine adverse effects on competition."<sup>290</sup>

The FTC's power to bar such settlements, now affirmed by the Supreme Court, complicates Hatch-Waxman patent litigation going forward. The benefits of settlement are still much the same: brand pharmaceuticals get to ensure that their patents—and monopolies—remain valid by disposing of their adversaries' patent challenges; generics receive a cash-payment and, often, an earlier date-of-entry than if they had lost the litigation; and both sides get to put an end to the expense and uncertainty of the underlying dispute.<sup>291</sup> But with the FTC now supremely vested with the power to bar such settlements based on their content, which settlements will retain their effect and evade FTC scrutiny is little more than a guess.<sup>292</sup> Some reverse payments are

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284. 15 U.S.C. § 45(b) (2012) (granting the FTC the power to prohibit "any unfair method of competition or unfair or deceptive act or practice in or affecting commerce"); *Fed. Trade Comm'n v. Actavis Inc.*, \_\_ U.S. \_\_, 133 S. Ct. 2223, 2229–30 (2013) (briefly noting the FTC's authority to bar unfair settlements).

285. *Actavis*, 133 S. Ct. at 2227–29 (discussing the FTC's review of reverse payment settlements).

286. \_\_ U.S. \_\_, 133 S. Ct. 2223 (2013).

287. *See* *Fed. Trade Comm'n v. Watson Pharm. Inc.*, 677 F.3d 1298, 1304–05 (11th Cir. 2012), *rev'd sub nom. Actavis*, 133 S. Ct. 2223.

288. *Id.* at 1305.

289. *Id.* ("After the settlement agreements ending the patent litigation were reported to the FTC as required by 21 U.S.C. § 355 . . . the FTC filed an antitrust lawsuit against Solvay, Watson, Par, and Paddock.")

290. *Actavis*, 133 S. Ct. at 2234.

291. *See supra* notes 131–137 and accompanying text.

292. *See generally* Edlin et al., *supra* note 20, at 16 (discussing the practical difficulties in crafting settlements after the *Actavis* decision).

allowed, but only for “valuable services,” and in any event, “large” payments are disfavored.<sup>293</sup> Patent weakness may be a marker for FTC scrutiny, but such circumstances are neither “inferred nor needed” to scuttle the settlement.<sup>294</sup> And consumer welfare will also play a consideration in the FTC’s review of settlements—although which way that cuts if the settlement proposes an earlier entry than the patents’ expiration dates remains as difficult an issue as before.<sup>295</sup> All in all, the FTC’s post-adjudicatory review of patent litigation will likely complicate litigation itself.

Similarly, the ITC must approve any settlements in section 337 cases litigated before it. Under 19 C.F.R. § 210.12, the parties must move the Administrative Law Judge to terminate an ITC investigation on the basis of a settlement agreement.<sup>296</sup> But the Commission Rules require that the motion must contain the settlement agreements themselves<sup>297</sup>—often, a point of sensitivity for litigants in a secretive field.<sup>298</sup> In *In re Certain Zero-Mercury-Added Alkaline Batteries*,<sup>299</sup> some parties attempted to terminate their ITC dispute by filing redacted versions of their settlement agreement before the ALJ.<sup>300</sup> The parties argued that “the release of [the] confidential information [in the settlement agreements] will severely prejudice them in future settlement negotiations.”<sup>301</sup> Nonetheless, the ALJ rebuffed the parties’ attempt at secrecy and refused to terminate the investigation unless the settling parties exchanged unredacted versions of the agreements with all of the litigants.<sup>302</sup> Determining that the standing protective order in the case provided enough protection, the ALJ agreed with the non-settling parties that keeping the settlement agreements confidential made it difficult to determine “whether the settlement agreement is in the public interest.”<sup>303</sup> This public interest determination—mandated by 19 C.F.R. § 210.50(b)(2)—may also sink any proposed settlement agreements. Under the Commission Rules, the ALJ must make a determination as to any settlement’s effect on “the

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293. *Id.* at 16–17 (discussing the FTC’s review of reverse payments, themselves).

294. *Id.* at 17.

295. *Id.*

296. 19 C.F.R. § 210.21(a)(2) (2014).

297. *Id.* § 210.21(b)(1).

298. See Alan E. Garfield, *Promises of Silence: Contract Law and Freedom of Speech*, 83 CORNELL L. REV. 261, 333 (1998) (reviewing the literature on the concerns regarding secret settlement agreements).

299. Inv. No. 337-TA-493, 2003 WL 22683954, (Oct. 30, 2003) (USITC order).

300. *Id.* at \*1.

301. *Id.*

302. *Id.* at \*2.

303. *Id.* at \*1.

public health and welfare, competitive conditions in the U.S. economy, the production of like or directly competitive articles in the United States, and U.S. consumers.”<sup>304</sup>

Together, these requirements may complicate the underlying patent litigation. For litigants, assessing whether it is in their best interests to make their settlement agreements public, and whether the agreements can be structured to ensure a positive recommendation from the ALJ’s public interest determination, may affect the parties’ positions taken during the litigation itself.<sup>305</sup> Particularly aggressive litigation tactics—such as claiming that a vast number of the respondent’s imported products infringe many U.S. patents—may ultimately doom any settlement agreements that attempt to diminish the complained-about harm to a domestic industry. At a minimum, however, the complexities of settlement before the ITC may cause some patent holders to reconsider it as an alternative forum of litigation, relative to the potential for quick, easy, and secretive settlements under Rule 41 in federal court.

Several post-issuance proceedings in front of the PTO also allow for settlement agreements under limited circumstances. For inter partes, post-grant, and CBM reviews, the parties may agree to terminate any proceedings before the PTO prior to the agency rendering its validity decision.<sup>306</sup> And, like settlements before the ITC, the settlement agreements themselves must be filed with the PTO and made public “on a showing of good cause,” although the default presumption is for them to be classified as “business confidential information.”<sup>307</sup> Settlements in post-issuance proceedings are consequently allowed, although their effect on future litigation is wholly unclear: there are no estoppel effects as there are to late amendments under Rule 15 or consent judgments.<sup>308</sup> What this means for the enforceability of any agreements—outside the usual boundaries of contract law—has yet to be tested. Thus, like proceedings before the ITC, the tenuousness of settlement may discourage litigants from using post-issuance proceedings as an

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304. 19 C.F.R. § 210.50(a)(2) (2014).

305. See Ben Depoorter, *Law in the Shadow of Bargaining: The Feedback Effect of Civil Settlements*, 95 CORNELL L. REV. 957, 979–83 (2010) (discussing the effect of the availability of secret settlements on litigant behavior).

306. See Iancu & Haber, *supra* note 78, at 479.

307. 35 U.S.C. § 317(b) (2012) (concerning inter partes review); *id.* § 327(b) (concerning post-grant review).

308. *Id.* § 317(a) (“If the inter partes review is terminated with respect to a petitioner under this section, no estoppel under section 315 (e) shall attach to the petitioner, or to the real party in interest or privy of the petitioner, on the basis of that petitioner’s institution of that inter partes review.”); *id.* § 327(a) (“If the post-grant review is terminated with respect to a petitioner under this section, no estoppel under section 325 (e) shall attach to the petitioner, or to the real party in interest or privy of the petitioner, on the basis of that petitioner’s institution of that post-grant review.”).

alternative forum to patent litigation.

*E. Inconsistent Judgments*

Finally, agency administration of patent litigation creates the potential for inconsistent judgments, especially where agencies serve as alternative fora to patent disputes. Because there are not clear preclusive effects to agency decisions in patent disputes—either across agencies or between agencies and federal courts—adversaries litigating in agency tribunals may face the prospect of competing judgments on core issues of invalidity or infringement. Inconsistent judgments here, as elsewhere, threaten “judicial economy, convenience, fairness, and comity.”<sup>309</sup> At the extreme, inconsistent judgments may even “undermine[ ] respect for law itself as well as the particular [agencies] involved.”<sup>310</sup>

Section 337 cases in the ITC are, perhaps, the most problematic. In the words of Sapna Kumar,

[w]hen a party litigates a patent infringement dispute in the ITC, it does not lose the right to litigate in federal court. Thus, [a patent holder] can pursue an ITC action in addition to a district court action and can even receive conflicting judgments. . . . [B]y allowing parallel proceedings and indeed almost encouraging them, Congress has created the real possibility of inconsistent results between ITC and district court proceedings.”<sup>311</sup>

This possibility of inconsistent results has, in several cases, turned into reality. In a dispute between General Electric Company and several Mitsubishi subsidiaries, the ITC rejected arguments that a wind turbine patent was unenforceable for failing to properly disclose all of the inventors.<sup>312</sup> Yet, in a later proceeding on the same patent before the U.S. District Court for the Eastern District of California, the judge found the same patent unenforceable on the grounds that the putative inventor failed to put forward any evidence that he contributed to the claims of the asserted patent.<sup>313</sup> This problem, though strange, does not seem altogether rare. One recent survey of parallel ITC–district court litigation

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309. *Cf. Carnegie-Mellon Univ. v. Cohill*, 484 U.S. 343, 350 (1988) (listing these normative concerns in relation to pendent jurisdiction).

310. *Cf. Jenny S. Martinez, Towards an International Judicial System*, 56 *STAN. L. REV.* 429, 472 (2003) (discussing these normative concerns in relation to international litigation).

311. Kumar, *supra* note 21, at 538–39 (quoting *Kaisha v. Bombardier Inc.*, No. 00-cv-549, 2001 WL 1388911, at \*2 (N.D. Cal. Mar. 9, 2001)).

312. *Gen. Elec. Co. v. Wilkins*, 750 F.3d 1324, 1326–29 (Fed. Cir. 2012) (discussing the ITC case).

313. *Id.* at 1329.

concluded that thirty-nine percent of cases in which judgment had been rendered both by the agency and the court contained inconsistent judgments.<sup>314</sup>

There also exists the potential for inconsistent judgments in post-issuance proceedings before the PTO. In both inter partes and post-grant reviews “that result[] in a final written decision,” the governing statutes prohibit the petitioner from “assert[ing] either in a civil action . . . or in a [section 337] proceeding before the International Trade Commission . . . that the [contested patent] claim is invalid on any ground that the petitioner raised or reasonably could have raised during [the proceeding].”<sup>315</sup> While this estoppel provision appears to prohibit the bulk of invalidity claims in later-filed suits in district court and the ITC, the statute’s language seemingly leaves large gaps regarding *concurrent* proceedings. In a typical patent infringement lawsuit, the accused infringer may concurrently file a counterclaim challenging the validity of the patent in district court and institute one of the post-issuance procedures available before the PTO.<sup>316</sup> In these circumstances, the district court proceedings would not be automatically stayed; rather the parties would litigate invalidity issues concurrently.<sup>317</sup>

This leaves several opportunities for inconsistent judgments. First, where a speedy district court makes its invalidity determination before the PTO, it is unclear what preclusive effect, if any, the district court procedure has on the post-issuance proceeding.<sup>318</sup> Second, although the statute prohibits the petitioner from “*asserting*” any invalidity claims in district court that it could have brought before the PTO, it is unclear what effect this language has on invalidity claims *already asserted* in federal court. Because §§ 315’s and 325’s prohibition on asserting foreseeable invalidity claims only attaches for post-issuance proceedings that “result[] in a final written decision,”<sup>319</sup> it remains to be seen whether a final written decision issued by the PTO strips petitioners of similar

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314. Robert W. Hahn & Hal J. Singer, *Assessing Bias in Patent Infringement Cases: A Review of International Trade Commission Decisions*, 21 HARV. J.L. & TECH. 457, 481 (2008); see also Kumar, *supra* note 21, at 539 n.57 (discussing the *U.S. Phillips Corp. v. Princo Corp.*, 361 F. Supp. 2d 168 (S.D.N.Y. 2005), *vacated*, 173 Fed. App’x 832 (Fed. Cir. 2006) litigation).

315. 35 U.S.C. § 315(e)(2) (2012); see also *id.* § 325(e)(2) (using the same language).

316. Jennifer C. Bailey, *Lessons Learned from the First Year of Inter Partes Reviews*, 6 LANDSLIDE 13, 14 (2013–2014) (discussing a typical inter partes review case).

317. See 35 U.S.C. § 315(a)(2) (mandating stays only where the petitioner files a declaratory judgment claim for invalidity against the patent holder); *id.* § 325(a)(2) (same).

318. See Kristen Jakobsen Osenga, *Rethinking Reexamination Reform: Is It Time for Corrective Surgery, or Is It Time to Amputate?*, 14 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 217, 235 (2003) (“While it is clear that a court’s determination of patent invalidity is binding on the PTO, the binding effects of the PTO’s conclusions during [post-issuance examinations] are less clear.”).

319. 35 U.S.C. § 315(e)(2) (inter partes review); *id.* § 325(e)(2) (post-grant review).

invalidity counterclaims in active federal litigation, or whether the statute's language applies only to litigation filed *after* the PTO issues its written decision. And third, because the invalidity contentions for inter partes and post-grant reviews are limited to claims of anticipation and obviousness,<sup>320</sup> i.e., claims under sections 102 and 103 of the patent statute, district court litigation centering around other invalidity claims, such as enablement under section 112, may produce strange—and inconsistent—results.

### III. BETTER ADMINISTRATING PATENT LITIGATION

The solution to the problems of administering patent litigation is not to eliminate agency involvement in patent disputes. For all its faults, agency oversight over patent litigation forms a critical component of bringing regulated products to market,<sup>321</sup> ensures compliance with other areas of law,<sup>322</sup> and, sometimes, serves as an expedient to resolving litigation.<sup>323</sup> Eliminating agency oversight, wholesale, may not ultimately be worth the savings. Rather, the solution to the problems of administering patent litigation is to *better* administrate patent litigation; to allow administrative agencies to fulfill their functions without being subject to gamesmanship or capture and without producing litigation uncertainty or inconsistencies. This Part proposes several ways—cheap, easy, and politically viable solutions—to better administrate patent litigation.

#### A. *Enhancing Substantive Oversight*

Perhaps counterintuitively, many of the problems with agency administration of patent litigation come from the agencies' myopic view of their own powers. The FDA's "purely ministerial"<sup>324</sup> approach to policing its Orange Book listings leads to no shortage of regulatory gamesmanship.<sup>325</sup> The PTO, long hamstrung by its lack of "substantive authority," suffers from endless problems in its attempt to coordinate its

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320. *Id.* § 311(b) (inter partes review); *id.* § 321(b) (post-grant review).

321. *See supra* notes 50–57 and accompanying text (discussing the FDA's role in patent litigation concerning drugs under its purview).

322. *See supra* notes 95–113 and accompanying text (discussing the FTC's role in patent litigation that raises antitrust concerns).

323. *See* sources cited *supra* note 180 (discussing the speed of litigation in the ITC).

324. *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 237 (4th Cir. 2002) ("The FDA defends this purely ministerial conception of its role in the Orange Book listing process by explaining that it lacks both the resources and the expertise to police the correctness of Orange Book listings.").

325. *See supra* notes 205–217 and accompanying text.

post-issuance procedures with district court litigation.<sup>326</sup> And the U.S. Trade Representative has consistently abdicated its power to review the substance of section 337 litigation before the ITC, making it, albeit by design, the subject of political whim.<sup>327</sup>

There is no silver bullet to the problems associated with these narrow views of agency power in patent litigation. The variety of agencies involved in patent litigation have a variety of purposes,<sup>328</sup> and, as a consequence, expanding an agency's powers in one case may prove beneficial in some cases but disastrous in others. Furthermore, altering agency power or behavior in some instances may simply be practically impossible for political or statutory reasons. Rather, solving the problems that arise from chary views of administering patent litigation should ultimately depend on the *function* of the agency involved. Where additional agency oversight of patent litigation will better "secure the just, speedy, and inexpensive determination" of parties' disputes,<sup>329</sup> it should be crafted to do so as long as providing the agency with such powers is, itself, politically and economically feasible. Where additional agency oversight would only complicate, prolong, or increase the cost of private patent disputes, the agency should refrain from exercising such authority.

Litigation gatekeeping serves as the principal function for which agencies should possess more robust authority in patent disputes. Ideally, agencies best fulfill their roles as "retail" gatekeepers where they police "claims [that] are on net socially costly or stray beyond legislative purposes."<sup>330</sup> Doing so—properly—requires robust enough authority to determine precisely which claims are socially costly or statutorily corrupt.

In the FDA's case, greater oversight over patent listings in the Orange Book—including the power to "delist" improperly included patents on its own initiative<sup>331</sup>—would allow the FDA to better function as a litigation gatekeeper, and seemingly solve some of the problems, such as product hopping, that come with its current straitjacketed approach. Many of the newly listed patents in product-hopping scenarios often

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326. See Masur, *supra* note 11, at 295–304 (discussing the PTO's lack of authority along several metrics); Tran, *supra* note 8, at 831 (discussing the PTO's authority in light of administrative law principles).

327. See *supra* notes 274–276 and accompanying text.

328. See, e.g., *supra* notes 95–114 and accompanying text (discussing the many roles of the FTC in patent litigation).

329. Cf. FED. R. CIV. P. 1.

330. Engstrom, *supra* note 13, at 659.

331. See *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 236–37 (4th Cir. 2002) (discussing the FDA's supposed lack of power to delist Orange Book patents).

only dubiously cover the new formulation, or do not meet the FDA's own regulations regarding permissible listings.<sup>332</sup> Allowing this regulatory gamesmanship to occur—with its attendant costly and time-consuming patent disputes—does little to decrease social cost or fulfill the purposes of the Hatch-Waxman Act, let alone promote pharmaceutical innovation.<sup>333</sup> Investing the FDA with the power to properly function as a litigation gatekeeper—by weeding out dubious or improperly listed patents on its own initiative, without litigation—would at least remove some of the incentives to game the Orange Book.

Despite the FDA's long-standing practice to avoid “meddling” in patent disputes,<sup>334</sup> the agency could easily be empowered with greater authority to do so. Nothing in the operative statute, 21 U.S.C. § 355, explicitly prohibits the FDA from taking a more active role in policing Orange Book listings. To the contrary, § 355(b)(1)(G) conditions the publishing of patent information in the Orange Book on the condition of approving a New Drug Application,<sup>335</sup> which the FDA may delay or withhold if the application “failed to contain the patent information prescribed by [the statute].”<sup>336</sup> That information includes only patents that actually “claim[ ] the drug [or a method of using the drug] for which the applicant submitted the application . . . [that] could *reasonably* be asserted” against a generic rival.<sup>337</sup> A reasonable interpretation of these two provisions—one which the FDA could easily take—is that a New

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332. See *Mylan Pharm., Inc. v. Thompson*, 268 F.3d 1323, 1325 (Fed. Cir. 2001) (allowing Bristol-Myers Squibb Co. to list an Orange Book patent on an uncovered metabolite of the reference drug); Cotter, *supra* note 59, at 1079 (“[T]he FDA does not monitor Orange Book filings—thus providing little disincentive for patent owners to list weak patents, or until recently multiple patents covering different aspects of the same drug—and it is clear that patent owners may have a substantial incentive to ‘game’ the system by, for example, leveraging a weak patent or series of patents into extended protection against generic competition.”); Lao, *supra* note 59, at 995–96 (discussing this in the context of *In re Buspirone Patent Litig.*, 185 F. Supp. 2d 363 (S.D.N.Y. 2002)).

333. See Thomas F. Cotter, *Patents, Antitrust, and the High Cost of Health Care*, 13 ANTITRUST SOURCE 1, 3–4 (2014) (reviewing work suggesting that there may be a social cost to product hopping); Dogan & Lemley, *supra* note 18, at 709–10 (discussing gamesmanship's behavior in light of the purpose of the Hatch-Waxman Act, expediting generics to market while protecting brand pharmaceuticals' valid patents); Mark A. Lemley & Carl Shapiro, *Patent Holdup and Royalty Stacking*, 85 TEX. L. REV. 1991, 2012 (2007) (discussing the effects of similar behavior on promoting innovation).

334. See *Caraco Pharm. Lab. Ltd. v. Novo Nordisk A/S*, \_\_\_ U.S. \_\_\_, 132 S. Ct. 1670, 1677 n.2 (2012) (mentioning cases affirming the FDA's failure to police Orange Book listings).

335. 21 U.S.C. § 355(b)(1)(G) (2012) (“*Upon approval* of the application, the Secretary shall publish [the patent] information submitted [by the applicant.]” (emphasis added)).

336. *Id.* § 355(d)(6) (“If the Secretary finds . . . that . . . the application failed to contain the patent information prescribed by subsection (b) of this section . . . he shall issue an order refusing to approve the application.”).

337. *Id.* § 355(b)(1)(G) (emphasis added).



Drug Application that lists patents which do *not* cover the drug listed in the New Drug Application, or for which a *reasonable* claim of infringement could *not* be asserted against a generic competitor, fail to include the specific “patent information” required by the statute and therefore cannot be approved. This is not far removed from the FDA’s current interpretation, which construes the statute as prohibiting “[p]rocess patents, patents claiming packaging, patents claiming metabolites, and patents claiming intermediates” from being listed in the Orange Book.<sup>338</sup> Thus, a simple, interpretive change at the direction of the agency itself, could invigorate—and better—the FDA’s authority as a gatekeeper of patent litigation.

The ease and simplicity with which the FDA could better administrate patent litigation stands in stark contrast to the opportunities available to the PTO and the USTR. The PTO, unlike the FDA, possesses no authority to enact regulations interpreting the substantive provisions of the patent statute.<sup>339</sup> Rather, it is generally limited to rulemaking concerning the “conduct of proceedings” before it.<sup>340</sup> Scholars have long complained about this artificial and seemingly odd constraint.<sup>341</sup> Yet, the PTO’s lack of substantive authority is both embedded in statute and in a long line of judicial opinions excluding the agency from the rigors, and benefits, of traditional policymaking.<sup>342</sup> Congress has also had multiple opportunities to expand the PTO’s authority and, even with the recent, expansive overhaul of the patent statute, did little to vest the PTO with any more authority than it was previously given.<sup>343</sup> In the end, expanding the PTO’s authority to be a proper administrative gatekeeper of litigation seems to be statutorily, judicially, and politically troublesome. Expanding the PTO’s authority, here, may simply be too costly or socially problematic, or stray too far from the patent statute’s legislative framework to recoup whatever efficiency gains are otherwise lost by reorienting the agency around a new role.

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338. 21 C.F.R. § 314.53(b)(1) (2014).

339. *See* Tran, *supra* note 8, at 831.

340. *Id.* at 843 (discussing this limitation).

341. *See, e.g.*, John M. Golden, *The USPTO’s Soft Power: Who Needs Chevron Deference?*, 66 SMU L. REV. 541, 541 (2013) (“Nonetheless, in terms of recognized power to speak on substantive questions of law, the USPTO can seem an institutional mite.”); Masur, *supra* note 11, at 275–80; Arti K. Rai, *Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform*, 103 COLUM. L. REV. 1035, 1132 (2003) (expressing doubt the PTO has the expertise it needs); Tran, *supra* note 8, at 843.

342. *See* 35 U.S.C. § 2 (2012) (granting the PTO its limited powers); Tran, *supra* note 8, at 841–54 (discussing the line of cases interpreting § 2).

343. Tran, *supra* note 8, at 843–44 (noting that the America Invents Act did little to grant the PTO a slate of “traditional” substantive rule-making authority).

Similarly, the USTR seems hemmed in to its current role as a political subordinate, rather than an agency with experienced oversight of patent disputes before the ITC. This may be, simply, because the statute commands it as such. Section 337(j)(2) of the Tariff Act of 1930 allows only the President to disallow an ITC finding, and only for “policy reasons”;<sup>344</sup> it is otherwise pregnantly silent on whether the President may do so as a substantive check on litigation before the ITC. Furthermore, the current USTR’s involvement stems only from the President delegating his authority to the agency,<sup>345</sup> making its decisions—by their very nature—political ones. Expanding the USTR’s authority to function as a core gatekeeper of patent litigation, therefore, may actually defeat its own statute’s legislative purposes, even if they were to be administered for the purpose of better effectuating the patent statute.

### B. *Utilizing Expertise*

Industry capture of patent litigation often occurs in the shadows. Industry groups’ attempts to lobby Congress for private gain in their patent disputes may not be readily visible.<sup>346</sup> And agencies’ patent litigation decisions—even those that appear to have an element of purchase—may only circumstantially support the conclusion that they were issued for the benefit of particular industry players.<sup>347</sup> In some cases, proving political capture appears to be even more difficult, leaving the public only to guess whether controversial agency decisions were the subject of political spoilsmanship.<sup>348</sup>

Like corruption, an effective solution to these capture problems in patent litigation lies in opening agency and political decision-making to public scrutiny. In the famous words of Justice Louis B. Brandeis: “Publicity is justly commended as a remedy for social and industrial diseases. Sunlight is said to be the best of disinfectants; electric light the most efficient policeman.”<sup>349</sup> Publicized agency opinions concerning patent litigation should make their reversal through capture politically

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344. 19 U.S.C. § 1337(j)(2) (2012).

345. Assignment of Certain Functions Under Section 337 of the Tariff Act of 1930, 70 Fed. Reg. 43251 (July 21, 2005) (delegating the President’s authority under Section 337 to the USTR).

346. See *supra* notes 235–240 and accompanying text.

347. See Kieff, *supra* note 249, at 413 (discussing the *Rambus* litigation).

348. See *supra* notes 274–275 and accompanying text (discussing the USTR’s disallowance of the ITC’s import injunction against Apple).

349. *Buckley v. Valeo*, 424 U.S. 1, 67 (1976) (quoting LOUIS B. BRANDEIS, *OTHER PEOPLE’S MONEY AND HOW THE BANKERS USE IT* 62 (1933)).

painful.<sup>350</sup> Having the FDA on record, for example, as expressing concern over new antibiotics<sup>351</sup> should make its acquiescence on antibiotic-proliferating patent policy somewhat suspect.<sup>352</sup>

Administrative law scholars have often focused on repeated industry–agency interaction as one cause of industry and political capture.<sup>353</sup> But repeatedly utilizing administrative agencies’ scientific and technical expertise in patent litigation may actually *prevent* the sort of industry and political capture that affects other regulatory areas. First, utilizing scientific and technical agencies as litigation experts puts the agency “on record” for important and cutting-edge issues. Repeated testimony in a particular area of science or technology would be difficult to disclaim should the agency abruptly change its mind in the face of industry pressure.<sup>354</sup> Furthermore, because of the public nature of most patent disputes<sup>355</sup>—at least, more so than the traditional rule-making process<sup>356</sup>—the “information deficit” typically associated with

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350. Cf. Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613, 1645 (1995) (discussing the political fallout of EPA policy reversals during the Reagan administration).

351. See generally Paul H. Rubin, *The FDA’s Antibiotic Resistance*, REGULATION Winter 2004–2005 (discussing the FDA’s past disinclination toward approving new antibiotics).

352. Anthony So & Robert Weissman, *Generating Antibiotic Incentives Now: GAIN—Or Just Greed*, HUFFINGTON POST (June 6, 2012), <http://perma.cc/JY5H-LF6M> (investigating the FDA’s silence regarding the GAIN Act).

353. See, e.g., Elena Kagan, *Presidential Administration*, 114 HARV. L. REV. 2245, 2264–65 (2001) (“The view that firms subject to regulation had ‘captured’ the agencies gained wide currency beginning in the 1960s. . . . [F]ew could argue with its basic insight—that well-organized groups had the potential to exercise disproportionate influence over agency policymaking by . . . the long-term relations they maintained with agency officials.”); Rebecca M. Kysar, *Lasting Legislation*, 159 U. PA. L. REV. 1007, 1044 (2011) (“[C]ontinuous relationships are a double-edged sword: frequent interaction may lead to a capture scenario in which the legislator is acting for the interest group rather than a broader constituency, regardless of presented information.”); D. Daniel Sokol, *Limiting Anticompetitive Government Interventions That Benefit Special Interests*, 17 GEO. MASON L. REV. 119, 134 (2009) (“[B]ecause sector regulators focus on a specific industry, as repeat players they are more prone than antitrust agencies to capture by those in a particular industry with a vested interest in sector outcomes.”).

354. See, e.g., *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 57 (1983) (“An agency’s view of what is in the public interest may change, either with or without a change in circumstances. But an agency changing its course must supply a reasoned analysis . . .” (quoting *Greater Boston Television Corp. v. FCC*, 444 F.2d 841, 852 (D.C. Cir. 1970))); Holly Doremus, *Listing Decisions Under the Endangered Species Act: Why Better Science Isn’t Always Better Policy*, 75 WASH. U. L.Q. 1029, 1125–27 (1997) (discussing the political fallout of “agency about-faces” in the context of endangered species); Steve Lohr, *F.C.C. Is Deluged With Comments on Net Neutrality Rules*, N.Y. TIMES (July 15, 2014), <http://perma.cc/6APE-YW5V> (reporting on the public backlash against the FCC following its policy reversal on “net neutrality”).

355. See, e.g., sources cited *supra* note 95.

356. See Richard B. Stewart, *Administrative Law in the Twenty-First Century*, 78 N.Y.U. L. REV. 437, 447 (2003) (“Agencies increasingly turn to less formal, less accountable, and more opaque methods of making regulatory policy.”).

regulatory capture should shrink.<sup>357</sup> Second, because patent litigation—like all litigation—is adversarial, there should be less of a concern of industry capture as a whole. All things being equal, there is no reason to think that, for any given patent case, an agency would play favorites.<sup>358</sup> And third, and relatedly, if agency expertise in litigation is deployed early enough in an industry’s lifecycle—historically, when patent disputes often begin to arise<sup>359</sup>—the agency is less likely to be captured by established, well-heeled companies because few yet exist.<sup>360</sup> These factors all suggest that, in utilizing agency expertise in patent litigation, agencies have little incentive but to “get the science right.”<sup>361</sup>

An increase in utilizing agency expertise would also have the salutary effect of bettering the scientific information available to courts and juries in patent disputes. Generalist district courts famously struggle with the scientific and technical issues involved in patent cases.<sup>362</sup> In a now famous, off-hand remark, Chief Judge Patti B. Saris described patent litigation as “the neurosurgery of litigation: it is hard scientifically and it is hard legally.”<sup>363</sup> And while judges can avail themselves of a variety of procedures to educate them about the scientific issues in dispute,<sup>364</sup> there

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357. See Nicholas Bagley, Response, *Agency Hygiene*, 89 TEX. L. REV. SEE ALSO 1, 2 (2010) (“[Political branches] need information in order to establish whether capture has taken hold, to understand the contours of the relevant capture dynamic, and to suggest agency-specific strategies for ameliorating capture.”).

358. See JAMES Q. WILSON, *POLITICAL ORGANIZATIONS* 336 (1973) (describing this phenomenon in considering an industry with multiple, well-organized companies).

359. See Colleen V. Chien, *Reforming Software Patents*, 50 HOUS. L. REV. 325, 328–29 (2012) (discussing several “patent wars” in technologies’ early stages of development). The recent “patent troll” problem, however, has taken the reverse tack. Patent holders will wait until an industry fully matures—and where greater damages are available—before suing for infringement. See Robert P. Merges, *The Trouble with Trolls: Innovation, Rent-Seeking, and Patent Law Reform*, 24 BERKELEY TECH. L.J. 1583, 1591 (2009) (“Typically, the troll waits until a technology is fully entrenched before scouting around for patents to acquire or asserting the patents it holds.”).

360. See David A. Strifling, *Environmental Federalism and Effective Regulation of Nanotechnology*, 2010 MICH. ST. L. REV. 1129, 1174–75 (2010) (“By definition, emerging technologies are new, and thus capture seems less likely because of the absence of the factors that are typically thought to cause it: a well-established industry lobby; agency officials with previous experience in industry, and vice versa; and little or no local political pressure.”).

361. Cf. Wendy E. Wagner, *Importing Daubert to Administrative Agencies Through the Information Quality Act*, 12 J.L. & POL’Y 589, 593 (2004) (“Because of its vulnerability to multiple reprimands from the courts, Congress, the White House, and the public at large, agencies have many reasons to get the science right the first time, particularly when their science-based decisions have direct and significant consequences for public health and the economy.”).

362. See Lee, *supra* note 282, at 9–17 (discussing patent cases’ cognitive burdens on generalist judges).

363. Kathleen M. O’Malley et al., *A Panel Discussion: Claim Construction from the Perspective of the District Judge*, 54 CASE W. RES. L. REV. 671, 682 (2004) (statement of Hon. Patti B. Saris).

364. See Karson Thompson, Note, *Luddites No Longer: Adopting the Technology Tutorial at the Supreme Court*, 91 TEX. L. REV. 199, 221–25 (2012) (briefly discussing the courts’ employment of

is little guarantee that the parties will best explain the scientific and technical concepts most conducive to an impartial assessment of the facts.<sup>365</sup> If anything, the high-stakes nature of most patent litigation—especially pharmaceutical patent litigation—strongly encourages litigants to play fast and loose with scientific concepts in an effort to simply persuade fact-finders of their claims.<sup>366</sup> Having independent, neutral participants—like scientific or technical agencies—in patent disputes may, therefore, be helpful.<sup>367</sup> Traditionally, courts have focused their attention on individual court-appointed experts, special masters, or technical advisors.<sup>368</sup> These have, by and large, been successful—if quite underutilized—approaches to the “scientific capture” problem.<sup>369</sup> But that underutilization stems from their difficulty to implement: “compensation, judicial propriety, neutrality, difficulties in locating experts, timing, and ex parte communication” have all hampered the use of independent third-parties educating the court on matters of science or technology.<sup>370</sup> Enhancing agencies’ functions as experts, therefore, may provide another avenue to providing courts with independent assessments of scientific and technical facts in patent litigation.

At the same time, this is easier said than done. Mechanically, agencies are generally barred from intervening in private litigation by section 516 of the Judiciary Code, which reserves agencies’ litigation authority to the DOJ.<sup>371</sup> But section 516 serves as a floor rather than a ceiling for agency litigation. While the DOJ, writ large, is responsible for the

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scientific advisors, special masters, court-appointed experts, and technologies tutorials in “bridging the technological gap”).

365. See Rai, *supra* note 341, at 1099 (“It is by no means clear, however, that adversarial procedures that rely on a ‘battle of the experts’ represent the best mechanism for educating lay persons about the relevant science.”).

366. See *Developments in the Law—Confronting the New Challenges of Scientific Evidence*, 108 HARV. L. REV. 1481, 1586 (1995) (“[S]ome experts are willing to testify to virtually anything for the right price.”).

367. Cf. Bock, *supra* note 14, at 242–49 (describing the advantages of a neutral, third-party litigant in patent disputes to ameliorate contentiousness).

368. See Joshua R. Nightingale, *An Empirical Study on the Use of Technical Advisors in Patent Cases*, 93 TECHNICAL ADVISORS IN PAT. CASES 400, 408–19 (2011) (empirically examining courts use of these procedures); Thompson, *supra* note 364, at 221–25 (describing the procedures required).

369. See Nightingale, *supra* note 368, at 408–12 (describing each of these procedures as “rare” or “mysterious and foreign”).

370. *Id.* at 410 (quoting John Shepard Wiley, Jr., *Taming Patent: Six Steps for Surviving Scary Patent Cases*, 50 UCLA L. REV. 1413, 1427 (2003)).

371. 28 U.S.C. § 516 (2012) (“Except as otherwise authorized by law, the conduct of litigation in which the United States, an agency, or officer thereof is a party, or is interested, and securing evidence therefor, is reserved to officers of the Department of Justice, under the direction of the Attorney General.”); see also note 114 and accompanying text.

conduct of litigation involving agencies, it is not immune, by law or by practice, from conferring, employing, and even taking orders from agencies regarding the direction of litigation.<sup>372</sup> Agencies are therefore free to push the DOJ to allow it to intervene in patent litigation where their interests are not adequately represented, or where there exist concerns that the parties' descriptions of the technology at issue would cause harm to a regulated industry. As the National Institute of Health's interaction with the Solicitor General in the *Myriad* litigation demonstrates, this is neither unheard of nor unfeasible.<sup>373</sup> Many other agencies on the cutting-edges of science and technology—such as NASA, the National Science Foundation, and the Department of Energy—could play equally valuable roles in current, high-profile patent disputes.<sup>374</sup>

But, even where an agency's negotiation with the Solicitor General's office comes to naught, the agency could still provide its expertise to patent litigation cheaply and easily: through the agency white paper. As demonstrated by the FTC's and ITC's white papers on patent litigation, courts are receptive to agencies' positions in private litigation if the litigation directly concerns an agency interest. Where the white paper has the ability to provide the court with a public view of the scientific or technical issues in dispute, courts have seemed to pay attention.<sup>375</sup> Scientific white papers in patent litigation should be no exception.

To be clear, expanding scientific agency expertise into patent litigation is nothing close to a cure for the problems of industry or political capture—whether in patent litigation or outside of it. And it is frankly difficult to determine just how well employing such expertise would function when used by an agency that has already been thoroughly captured by industry or political interests.<sup>376</sup> But utilizing

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372. See Neal Devins, *Unitariness and Independence: Solicitor General Control over Independent Agency Litigation*, 82 CAL. L. REV. 255, 302 (1994) (“[I]ndependent agency autonomy likewise will ebb and flow.”); Neal Devins & Michael Herz, *The Uneasy Case for Department of Justice Control of Federal Litigation*, 5 U. PA. J. CONST. L. 558, 562–63 (2003) (“Should DOJ learn of possible [civil] violations warranting investigation, it forwards the information to the agency; an actual civil action will not go forward without a referral from the agency to DOJ.”); Anne Joseph O’Connell, *Bureaucracy at the Boundary*, 162 U. PA. L. REV. 841, 921 (2014) (“[W]hile litigation authority is usually defined in terms of the levels of the federal courts, some boundary organizations have more unusual arrangements.”).

373. See *supra* notes 110–116 and accompanying text.

374. See, e.g., *Par Pharm. Inc. v. TWI Pharm. Inc.*, CIV. CCB-11-2466, 2014 WL 694976 (D. Md. Feb. 21, 2014) (nanotechnology); *ViaSat Inc. v. Space Sys./Loral Inc.*, 3:12-CV-00260-H-WVG, 2013 WL 3927750 (S.D. Cal. May 17, 2013) (aerospace); *Ecolochem Inc. v. S. Cal. Edison Co.*, 863 F. Supp. 1165, 1168 (C.D. Cal. 1994), *aff’d in part, rev’d in part*, 91 F.3d 169 (Fed. Cir. 1996) (nuclear reactors).

375. See *supra* notes 122–130 and accompanying text.

376. Cf. Bagley, *supra* note 357, at 2 (questioning whether the solutions to capture are the same

agency expertise in patent litigation should at least make such capture more noticeable and, as a consequence, agency inconsistency on issues of science and technology more painful. Like traditional expert witnesses, being forced to speak loudly, clearly, and on the record, at least encourages openness and consistency.<sup>377</sup>

### C. *Diminishing Alternative Fora*

Many of the problems of administering patent litigation come from agencies' roles as alternative fora to patent disputes. The availability of alternative fora serves as a tool of gamesmanship by parties unsatisfied with district court proceedings; as loci of both industry and political capture; as a source of significant settlement uncertainty; and as a cause of inconsistent judgments in patent disputes.<sup>378</sup> Here, the spirit, if not the letter, of the Federal Rules of Civil Procedure is enlightening: “[t]here is one form of action—the civil action.”<sup>379</sup> Having a single form—and forum—of action to resolve patent disputes has been more sensible, efficient, and just since the Federal Rules merged law and equity almost eighty years ago.<sup>380</sup> Diminishing the availability of alternative fora to patent disputes should funnel patent disputes to federal district court—a generalized forum unencumbered by the procedural or remedial restrictions of administrative agencies—and ameliorate many of the problems associated with agency involvement in patent litigation. While abolishing alternative fora completely is likely politically untenable, courts, agencies, and potentially Congress, could make several simple fixes to various facets of alternative review in order to route patent litigation back to district court.

#### 1. *Narrowing Claimants*

The first step to diminishing alternative fora to patent litigation is to narrow the claimants for whom alternative fora are available. Each

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for agencies that have already been captured).

377. *Cf.* *Richmond Newspapers, Inc. v. Virginia*, 448 U.S. 555, 597 (1980) (“[O]pen examination of witnesses *viva voce*, in the presence of all mankind, is much more conducive to the clearing up of truth, than the private and secret examination . . . where a witness may frequently depose that in private, which he will be ashamed to testify in a public and solemn tribunal.” (ellipses in original) (quoting 3 W. BLACKSTONE, COMMENTARIES 373 (1768))).

378. *See supra* Part II (discussing each of these problems with respect to Section 337 proceedings before the ITC, and the PTO’s post-issuance procedures).

379. FED. R. CIV. P. 2.

380. *See* Amanda Frye, “*Inextricably Commingled*”: *A Restitution Perspective in Patent Remedies*, 26 HARV. J.L. & TECH. 669, 673–75 (2013) (discussing the difficulties with distinguishing law and equity in the patent context).

forum offers few restraints as to who can file a petition. Anyone, for example, may file a request that the PTO reexamine a patent.<sup>381</sup> Similarly, “nearly every patentee can bring [a section 337] ITC complaint,”<sup>382</sup> so long as the patentee demonstrates that there exists a “domestic industry” for the patented goods.<sup>383</sup> The PTO’s new post-issuance procedures—inter partes, post-grant, and CBM reviews—are slightly more restrictive, but barely so. Any person “other than the patent owner” may bring petitions for inter partes and post-grant reviews,<sup>384</sup> while CBM petitions may be brought by anyone merely threatened for infringement of the asserted patent.<sup>385</sup>

These loose restrictions on the availability of alternative fora to patent litigation make the procedures ripe for abuse. Opening reexam, inter partes, and post-grant reviews to anyone—whether or not they have a significant interest in the patents at-issue—allows business competitors to potentially drag patent holders through preemptive litigation, without word on how the patent holders will make use of their patents.<sup>386</sup> Analogously, allowing virtually any patent holder to file a section 337 complaint in the ITC threatens to hold up entire technologies and private markets irrespective of the degree of harm caused by the alleged infringement or the fraction of which the accused technologies fall

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381. 35 U.S.C. § 302 (2012) (“Any person at any time may file a request for reexamination by the Office of any claim of a patent on the basis of any prior art cited under the provisions of section 301.”).

382. Chien & Lemley, *supra* note 10, at 15.

383. 19 U.S.C. § 1337(a)(2) (2012) (banning the importation of patent infringing goods “only if an industry in the United States, relating to the articles protected by the patent . . . exists or is in the process of being established”); *see also* Taras M. Czebiniak, *When Congress Gives Two Hats, Which Do You Wear? Choosing Between Domestic Industry Protection and IP Enforcement in § 337 Investigations*, 26 BERKELEY TECH. L.J. 93, 115–16 (2011) (discussing the contours and history of the “domestic industry” requirement).

384. 35 U.S.C. § 311(a) (2012) (“[A] person who is not the owner of a patent may file with the Office a petition to institute an inter partes review of the patent.”); *id.* § 321(a) (“[A] person who is not the owner of a patent may file with the Office a petition to institute a post-grant review of the patent.”).

385. 37 C.F.R. § 42.302(a) (2014) (“A petitioner may not file with the [PTO] a petition to institute a covered business method patent review of the patent unless the petitioner, the petitioner’s real party-in-interest, or a privy of the petitioner has been sued for infringement of the patent or has been charged with infringement under that patent.”).

386. Raymond A. Mercado, *Ensuring the Integrity of Administrative Challenges to Patents: Lessons from Reexamination*, 14 COLUM. SCI. & TECH. L. REV. 558, 602 (2013) (discussing patent holders’ view of reexam as “gamesmanship”); Wayne B. Paugh, *The Betrayal of Patent Reexamination: An Alternative to Litigation, Not A Supplement*, 19 FED. CIR. B.J. 177, 214 (2009) (“Ex parte reexam would still be able to function effectively as an option over the lifetime of the patent, but it should be curtailed as a method of litigation ‘gamesmanship’ through congressional action.”).



within the patents' claims.<sup>387</sup> At their core, these abuses are forms of regulatory gamesmanship.<sup>388</sup>

Ideally, these alternative fora for patent disputes should be tailored to limit complainants to those the procedures were designed to protect.<sup>389</sup> But the nature and purpose of many of these procedures is not entirely clear. With respect to the America Invents Act's new post-issuance procedures in the PTO, some were designed seemingly without an ideal complainant in mind.<sup>390</sup> And, in section 337 proceedings before the ITC, the historical loosening of the "domestic industry" requirement has seemed to "destroy section 337's protective purpose, because the broader domestic industry definition under the new section 337 gives foreign owners of U.S. intellectual property rights the same ease of access to the ITC."<sup>391</sup> A better approach would be instrumental. That is, to the extent these alternative fora to patent disputes simply serve as another means to obtain substantive opinions of patents' validity, the availability of alternative review should be narrowed to ensure that patent disputes are quickly docketed and disposed of in district court.

Siphoning patent cases away from alternative fora and into court could be accomplished in several ways. First, where it appears that petitioners for inter partes and post-grant reviews are using the procedures simply for the purpose of "gaming" parallel district court litigation, the Director of the PTO should exercise her discretion to deny those petitions. Under section 314, the Director may deny petitions for inter partes review unless the petitioner shows "a reasonable likelihood that [it] would prevail with respect to at least 1 of the claims challenged in the petition."<sup>392</sup> Similarly, under section 324, the Director may only grant petitions for post-grant review if "the information presented in the petition . . . would demonstrate that it is more likely than not that at least

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387. See Chien & Lemley, *supra* note 10, at 24–25 ("Patent holdup tends to occur in complex, multicomponent products, particularly in information technology industries. . . . The social harm in this latter case is disproportionate to the social benefit, as many productive, noninfringing components will be shut down to give the patentee control over only a single, small component.").

388. See Dogan & Lemley, *supra* note 18, at 687 (describing regulatory gamesmanship as "private behavior that harnesses procompetitive or neutral regulations and uses them for exclusionary purposes").

389. *Cf. Ass'n of Data Processing Serv. Orgs., Inc. v. Camp*, 397 U.S. 150, 153 (1970) (limiting standing to "the zone of interests to be protected or regulated by the statute or constitutional guarantee in question").

390. See Iancu & Haber, *supra* note 78, at 486 ("[I]t is unclear how a Post-grant Review will relate to Inter Partes Review.").

391. Anne L. Spangler, Note, *Intellectual Property Protection and Import Trade: Making Section 337 Consistent with the General Agreement on Tariffs and Trade*, 43 HASTINGS L.J. 217, 222 (1991).

392. 35 U.S.C. § 314 (2012).

[one] of the claims challenged in the petition is unpatentable.”<sup>393</sup> In either case, the Director should take into consideration the high bar to invalidating patents—“clear and convincing evidence”<sup>394</sup>—and should deny those petitions that, because of their procedural posture, appear likely to fail to carry that burden. Even when such petitions are “close calls,” the Director should still deny those petitions if federal court remains an available venue to contest issues of the patents’ validity. Where the patent disputes are substantial enough to merit federal litigation—likely, given that the fees for inter partes and post-grant reviews are a whopping \$27,200 and \$35,800, respectively—this should drive those disputes to federal court, where the court can resolve all issues of invalidity and infringement in a single forum. While denying petitions on such grounds may be controversial, the Director should take solace that denials of inter partes and post-grant reviews are “final and nonappealable.”<sup>395</sup>

Second, with respect to CBM review, the Director has substantial authority to determine whether the patent at-issue constitutes a “covered business method” patent—and by extension, to deny CBM petitions where the petitioner has failed to “demonstrate that the patent for which review is sought is a covered business method patent.”<sup>396</sup> For the same reasons, the Director should deny those petitions that are “close calls” under the PTO’s own definition of “covered business method patent,”<sup>397</sup> and take comfort in the fact that denials are also final and nonappealable.<sup>398</sup>

Lastly, reforming the class of claimants in the ITC will likely be more difficult than narrowing petitions to post-issuance proceedings before the PTO. Namely, this is because the best option for slimming section 337 complaints—strengthening the domestic industry requirement—has long been bloated from gross expansion and general disuse.<sup>399</sup> As noted by Colleen V. Chien and Mark A. Lemley, however, the ITC’s discretion over determining whether a section 337 complaint has merited the

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393. *Id.* § 324(a).

394. *See* *Microsoft Corp. v. i4i Ltd.*, \_\_ U.S. \_\_, 131 S. Ct. 2238, 2242 (2011) (“We consider whether § 282 requires an invalidity defense to be proved by clear and convincing evidence. We hold that it does.”).

395. 35 U.S.C. § 314 (inter partes review); *id.* § 324 (post-grant review).

396. 37 C.F.R. § 42.304(a) (2014).

397. *See* 37 C.F.R. § 42.301(a) (defining “covered business method patent”).

398. *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 18(a)(1), 125 Stat. 284, 329 (2011) (requiring CBM review to “employ the standards and procedures of, a post-grant review”); 35 U.S.C. § 324 (making post-grant review “final and nonappealable”).

399. *See* Czebiniak, *supra* note 383, at 115–16 (discussing the expansion of the domestic industry requirement).

“public interest” is broad.<sup>400</sup> Under 19 U.S.C. § 1337(d)(1), the ITC may refuse to enjoin the importation of patent infringing products if the injunction would negatively affect “the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, [or] United States consumers.”<sup>401</sup> Such determinations, sadly, are typically pro forma, reflexively favor the patentee, and come *after* the ITC has made its Initial Determination regarding invalidity and infringement.<sup>402</sup> But there is no reason why the ITC cannot give these statutory public interest factors more teeth—and more specifically, decide them *before* the parties’ principal section 337 dispute. Indeed, if the public interest factors are negative, such a conclusion would seem to obviate patent disputes in the ITC in the first instance: without the possibility of a remedy, there is little point in carrying on litigating. Such an approach would salvage an agency increasingly under attack,<sup>403</sup> save ITC litigants time and money, and ultimately, shuttle the most problematic patent disputes to district court. Furthermore, making such a determination about the availability of remedies prior to assessing issues of invalidity or infringement would not be unprecedented in patent litigation. A growing number of patent cases proceed through bifurcation of damages—an assessment of damages *before* litigating invalidity or infringement.<sup>404</sup> The reasons for the popularity of the procedure are simple enough: it “discourage[s] patent holders from bringing suits in instances where the potential damages are minimal compared to litigation costs . . . [and] encourage[s] earlier settlement.”<sup>405</sup> As with traditional federal litigation, the absence of a remedy in the ITC may simply make section 337 complaints disappear—or at least, find their way to district court.

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400. Chien & Lemley, *supra* note 10, at 19–20 (discussing the statutory public interest factors).

401. 19 U.S.C. § 1337(d)(1) (2012).

402. Chien & Lemley, *supra* note 10, at 19–21 (discussing this state of affairs).

403. See Thomas F. Cotter, *The International Trade Commission: Reform or Abolition? A Comment on Colleen V. Chien & Mark A. Lemley, Patent Holdup, The ITC, and The Public Interest*, 98 CORNELL L. REV. ONLINE 43, 43–44 (2013), <http://cornelllawreview.org/files/2013/05/Cotterfinal.pdf> (calling for, and assessing the movement, to abolish the ITC).

404. See, e.g., *Yamaha Hatsudoki Kabushiki Kaisha v. Bombardier Inc.*, 59 U.S.P.Q.2d 1088, 1090 (C.D. Cal. 2001) (“Bifurcation, while perhaps not routine, is nonetheless common in patent litigation.”); Steven S. Gensler, *Bifurcation Unbound*, 75 WASH. L. REV. 705, 725 (2000) (“Bifurcation is also common in patent litigation . . . .”); Matthew B. Lowrie, *Critical Issues in Managing Patent Litigation*, 44 IDEA 267, 279 (2004) (“A key strategic decision for the accused infringer to make is whether to ask to bifurcate the issue of willfulness of infringement (and, with it, damages) for discovery and trial.”).

405. Jason Rantanen, *Reverse Bifurcation in Practice*, PATENTLY-O (July 31, 2011), <http://perma.cc/4FQW-3DNV>.

## 2. *Strengthening Estoppel*

Strengthening the estoppel provisions of alternative fora to patent disputes would also go a long way to solve some of the problems inherent in the procedures, and to make better sense of their purpose relative to federal litigation. Currently, the estoppel provisions of PTO and ITC proceedings comprise a riot of standards. Reexamination proceedings have no estoppel effect on district court or ITC litigation, unless of course, the PTO cancels any of the reexamined claims.<sup>406</sup> Petitioners in inter partes and post-grant reviews are estopped from asserting, in both district court and ITC proceedings, “any ground that the petitioner raised or reasonably could have raised,”<sup>407</sup> while CBM petitioners may not assert, in district court or ITC proceedings, “any ground that the petitioner [*actually*] raised during that [CBM] proceeding.”<sup>408</sup> Section 337 proceedings before the ITC, meanwhile, “have no preclusive effect in other forums,”<sup>409</sup> even on issues actually raised before the ITC.<sup>410</sup> Like the differences among the classes of potential claimants in alternative fora, the quirks of estoppel in these procedures make them ripe for gamesmanship.<sup>411</sup> But, more significantly, they lead to inconsistent judgments and create a cloud of uncertainty regarding settlement.<sup>412</sup>

Reforming these problems, however, may prove difficult. For reexam and the new post-issuance procedures before PTO, the standards for estoppel are chiseled into the statute.<sup>413</sup> Altering them would require an affirmative act of Congress—unlikely given Congress’s recent enactment of the procedures.<sup>414</sup> And, although the estoppel effect of

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406. Andrei Iancu et al., *Inter Partes Review Is the New Normal: What Has Been Lost? What Has Been Gained?*, 40 AIPLA Q.J. 539, 577 (2012) (discussing the estoppel provisions of reexams).

407. 35 U.S.C. § 315(e)(2) (2012); *id.* § 325(e)(2).

408. Leahy-Smith America Invents Act, Pub. L. No. 112–29, § 18(a)(1)(D), 125 Stat. 284, 330 (2011). For an interpretation of the “actually raised” estoppel language, see Iancu & Haber, *supra* note 78, at 488.

409. *Tex. Instruments, Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1569 (Fed. Cir. 1996).

410. *Id.* at 1568.

411. See Kumar, *supra* note 14, at 1573–75 (2011) (describing the lack of preclusion from section 337 proceedings, and its effects on litigants, as “illogical”); Robert L. Stoll, *Maintaining Post-Grant Review Estoppel in the America Invents Act Revisited: A Call for Legislative Restraint*, 23 FED. CIR. B.J. 15, 51–53 (2013) (describing potential forms of gamesmanship under the post-issuance procedures’ estoppel provisions).

412. See *supra* notes 296–320 and accompanying text.

413. See, e.g., 35 U.S.C. § 315(e)(2) (2012) (inter partes); *id.* § 325(e)(2) (post-grant); Leahy-Smith America Invents Act § 18(a)(1)(D) (covered business method).

414. See Stoll, *supra* note 411, at 19–25 (discussing Congress’s consideration of the estoppel provisions).

section 337 proceedings before the ITC is judicially rather than statutorily mandated,<sup>415</sup> the Federal Circuit has repeatedly ruled against binding federal courts with decisions from the ITC.<sup>416</sup>

The solution, therefore, to these bizarre procedural circumstances lies—somewhat counterintuitively—in the courts themselves. While it may be an operative truth that some of the litigation alternatives in the PTO and ITC do not technically bind federal courts as to issues of invalidity or infringement, district courts can certainly take such judgments as persuasive authority.<sup>417</sup> District courts may, therefore, substantially rely on the decisions of the PTO and ITC in making their own determinations if they choose.

In some notable instances, this has already occurred. In *Old Reliable Wholesale, Inc. v. Cornell Corp.*,<sup>418</sup> the Federal Circuit “acknowledged [the PTO’s] expertise in evaluating prior art and assessing patent validity” after the PTO issued a reexamination certificate confirming the validity of all of the appellant’s patent’s claims.<sup>419</sup> The court concluded that “[t]he fact that the PTO, after assessing the relevant prior art, confirmed the patentability of all claims of the [asserted] patent undercut[ the appellee’s] contention that [the patent holder] had no reasonable basis for its assertion that its patent was not anticipated.”<sup>420</sup> Thus, although the Federal Circuit was clearly not bound by the results of the PTO’s reexamination, it considered the agency’s determination to be “probative evidence” on the defendant’s collateral claims.<sup>421</sup> Similarly, in *Solomon Technologies, Inc. v. Toyota Motor Corp.*,<sup>422</sup> the district court was faced with reviewing a patent dispute already decided by the ITC in the accused infringers’ favor.<sup>423</sup> Although the court

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415. See *Tex. Instruments*, 90 F.3d at 1568–69 (describing its decision as one relying on legislative history, rather than statute).

416. See, e.g., *Cognex Corp. v. Int’l Trade Comm’n*, 550 F. App’x 876, 881 n.2 (Fed. Cir. 2013) (denying review of the ITC’s finding that the asserted patent was ineligible for protection because “decisions of the ITC involving patent issues have no preclusive effect in other forums”); *Powertech Tech., Inc. v. Tessera, Inc.*, 660 F.3d 1301, 1308 (Fed. Cir. 2011) (noting that “the resolution of the ITC action will not have preclusive effect on either the district court in Texas or the district court in this case”); *Fuji Photo Film Co., Ltd. v. Benun*, 463 F.3d 1252, 1254 (Fed. Cir. 2006) (refusing to “question the authority of a federal district court to prohibit importation of infringing goods after the Commission has refused to issue a section 1337 general exclusion order”); *Tex. Instruments*, 90 F.3d at 1568–69.

417. See Kumar, *supra* note 14, at 1575 (suggesting this fix in regards to the ITC).

418. 636 F.3d 539 (Fed. Cir. 2011).

419. *Id.* at 548.

420. *Id.*

421. *Id.* at 549.

422. No. 8:05-cv-1702, 2010 WL 715243 (M.D. Fla. Jan. 26, 2010).

423. *Id.*

acknowledged that “the ITC’s prior decision cannot have claim preclusive effect in the district court,”<sup>424</sup> it forcefully concluded “that a district court may consider as persuasive an ITC’s decision.”<sup>425</sup> Finding “no ‘powerful incentive’ to deviate from the Federal Circuit’s prior decision,” it framed the dispute as “the same parties argu[ing] whether two of the same hybrid vehicles infringe the same claim in the same patent as they argued previously before both [tribunals].”<sup>426</sup>

*Old Reliable Wholesale* and *Solomon*, therefore, provide working examples of how courts can—and should—follow the practice of finding the PTO’s and ITC’s determinations persuasive, even if not technically binding. Giving substantial credence to agency decisions of validity and infringement removes the incentives to litigate in parallel, provides a clear avenue to settlement once the agency proceedings are complete, and erodes the potential for inconsistent judgments. Furthermore, generalist district courts—already seemingly burdened by the time and complexity of patent litigation<sup>427</sup>—would benefit from the agencies’ expertise.<sup>428</sup> As mentioned by the Federal Circuit in *Old Reliable Wholesale*, the PTO obviously possesses “expertise in evaluating prior art and assessing patent validity.”<sup>429</sup> Putting that expertise in practice requires little more than judicial notice.<sup>430</sup> And lastly, such a practice, if properly and routinely implemented, would be a boon to busy district courts’ attempts to manage their docket, allowing judges to resolve some issues of patent invalidity early and easily.

To be clear, to the degree that litigants prefer having their disputes primarily heard in the PTO and the ITC rather than district court, reforming the practice (and not the letter) of these estoppel provisions gives them no greater incentive to litigate in federal court rather than the agencies. In that sense, these proposals do not diminish the availability of alternative patent litigation fora in the same way as narrowing the classes of those fora’s claimants. But these proposals, if deployed widely, would solve the problem of at least having some litigants attempt to take two bites of the same apple. Some litigants clearly do prefer district court to administrative practice, and seem only to litigate

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424. *Id.* at \*4 (quoting *Bio-Tech. Gen. Corp. v. Genentech Inc.*, 80 F.3d 1553, 1564 (Fed. Cir. 1996)).

425. *Id.*

426. *Id.*

427. *Lee*, *supra* note 282, at 9–17 (discussing patent cases’ burdens on the judiciary).

428. *See Old Reliable Wholesale, Inc. v. Cornell Corp.*, 635 F.3d 539, 548 (Fed. Cir. 2011); *Kumar*, *supra* note 14, at 536–37 (discussing the ITC’s expertise in patent disputes).

429. 635 F.3d at 548.

430. *Id.* (taking judicial notice of the PTO’s reexamination, even though the outcome of the proceedings was not before the district court).

in parallel as a means to hedge their bets on the dispute's ultimate outcome.<sup>431</sup> Removing the incentives to such hedging should defang much parallel litigation and, in that sense, diminish at least some litigation in alternative fora.

### 3. *Streamlining Litigation Stays*

Currently, the differing procedures regarding stays in alternative fora of patent litigation are ripe for abuse. Litigants may take a wait-and-see approach to district court litigation—filing pleadings and engaging in discovery—before filing parallel litigation in the PTO or ITC in attempt to stall things in federal court.<sup>432</sup> At their core, these strategies—allowed by statute, and permitted by practice—are forms of gamesmanship.<sup>433</sup> But, because it may be difficult to determine how the agency will rule in parallel proceedings—and whether the district court will take the agency's decision into account<sup>434</sup>—stays may also make some district court settlements uncertain.<sup>435</sup>

Like the estoppel provisions governing PTO and ITC proceedings, resolving these problems may prove difficult because they are deeply embedded in the governing statute or litigation practice.<sup>436</sup> In concurrent ITC and district court litigation, district courts must stay their proceedings by operation of 28 U.S.C. § 1659(a).<sup>437</sup> And, in parallel proceedings before the PTO, district courts routinely stay cases pending the Office's decision.<sup>438</sup> District courts should, therefore, take a nuanced, case-by-case approach to determining whether to grant litigants' request

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431. See Stoll, *supra* note 411, at 33 (discussing the potential for hedging).

432. See Scott M. Daniels & Kate Addison, *Why Wait for Oppositions?*, 47 IDEA 343, 355 (2007) (discussing litigants strategies regarding dual-track filings in district court and the PTO); Hahn & Singer, *supra* note 314, at 482 (“When a case is pursued in both venues, the district court often stays the district court case for the duration of the ITC process, after which the parties may move to have the court vacate the stay. A patent holder could learn through the ITC determination that its case is strong or weak, and then settle the district court case accordingly.”).

433. See Hahn & Singer, *supra* note 314, at 482; J. Jason Williams et al., *Strategies for Combatting Patent Trolls*, 17 J. INTELL. PROP. L. 367, 373 n.23 (2010) (“Gamesmanship may include uses where there is a perceived lack of cooperation between parties or where the stay appears primarily only to delay trial.”).

434. See *supra* notes 413–416 and accompanying text

435. See, e.g., Matthew A. Smith, *Stay, Suspension and Merger: Considerations for Concurrent Proceedings Involving Inter Partes Reexamination*, 90 J. PAT. & TRADEMARK OFF. SOC'Y 657, 664 (2008) (“As for the likelihood of settlement, the patent owner will argue that a trial setting is more likely to induce settlement than a stay of litigation where the third party requester has nothing to lose.”).

436. See *supra* notes 72–92 and accompanying text.

437. See *supra* notes 72–77 and accompanying text.

438. See *supra* notes 79–92 and accompanying text.

for stays pending the outcome of agency proceedings—in particular, taking into account the preclusive effect (or the persuasive value) of the agency’s opinion. Where litigation has substantially commenced in federal court, and where it is unlikely the agency proceeding will have a preclusive or persuasive effect, district courts should deny litigants’ requests for stays the best they can. Doing so—while setting firm trial dates—will likely “resolve cases and reduce litigation costs.”<sup>439</sup> Oppositely, where federal litigation is relatively nascent, and where litigants will likely be estopped from asserting certain issues in district court depending on the outcome of the agency proceeding, courts should freely grant stays. And, where courts are commanded by statute to stay proceedings—as with contemporaneous litigation before the ITC and some select instances of inter partes and post-grant review—courts should even more strongly consider granting those agencies’ decisions preclusive effect.

Using this rubric, courts would essentially force litigants to order venues along two axes: from most developed (in terms of discovery and motions) to the least, and from the most persuasive (or binding) to the least. In doing so, courts would also end many of the abuses that stem from the various stay standards in parallel proceedings. By refusing stays for far-along litigation in federal court, courts would essentially encourage patent litigants to resolve their disputes by trial or settlement in federal court, before many agency decisions can likely be reached.<sup>440</sup> Similarly, by granting stays for recently filed federal litigation—and by threatening the parties that any agency decision will either preclude or decide their dormant federal claims—litigants would be encouraged to resolve all of their outstanding issues in the agency proceeding, or dismiss it entirely.<sup>441</sup> By combining reforms to courts’ consideration of parallel stay and agency estoppel provisions, courts can effectively streamline requests for stays while, ultimately, diminishing the use of alternative fora of patent litigation.

## CONCLUSION

Commentators have typically viewed patent litigation—and,

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439. *See* *Soverain Software LLC v. Amazon.com, Inc.*, 356 F. Supp. 2d 660, 663 (E.D. Tex. 2005).

440. *See* Lemley, *supra* note 224, at 415 (noting that the average patent dispute is resolved within a year).

441. *See, e.g.*, Hahn & Singer, *supra* note 314, at 482 (“When a case is pursued in both venues, the district court often stays the district court case for the duration of the ITC process, after which the parties may move to have the court vacate the stay. A patent holder could learn through the ITC determination that its case is strong or weak, and then settle the district court case accordingly.”).



consequently, patent reform—as an essentially private law matter, with administrative agencies forming only the occasional backdrop to substantive control over litigation. But a synoptic view of the functions administrative agencies play in patent disputes suggests that administrative agencies—the PTO included—do manage, run, or see to a wide variety of patent disputes. In short, administrative agencies “administrate” patent litigation.<sup>442</sup> Agencies serve as gatekeepers of litigation by overseeing patent listings or controlling the timing of litigation in federal court. Agencies also provide courts, in a variety of ways, with scientific and technical expertise important in patent disputes. In some instances, agencies serve as panels of review of already-completed patent litigation. And in others, agencies operate as patent tribunals themselves, offering parallel and competing fora to patent litigation before federal courts.

The interaction of these functions with courts themselves is complex and, in many instances, yields several significant problems. Agencies involved in patent disputes may be the subject of regulatory gamesmanship, where litigants use neutrally crafted regulations to artificially exclude competition. Agencies may also be the objects of capture—both by industries routinely involved in patent litigation and politicians looking to control patent litigation for public gain. And, lastly, contemporaneous agency administration of patent disputes with federal litigation may cloud opportunities for settlement and lead to inconsistent judgments between the two.

Resolving these problems—i.e., “patent litigation reform”—requires a longitudinal approach that cuts across agency functions. First, where agencies do act as litigation gatekeepers, agencies should exercise their powers with greater, and more nuanced, substantive oversight in an effort to quell gamesmanship. Second, agencies with scientific and technical expertise should make more forceful use of their talents in federal court, either by conferring with the DOJ in more patent disputes with the public’s interest at stake, or by deploying soft expertise that courts can later rely on. And lastly, because the bulk of problems associated with agency administration of patent litigation come from agencies acting as alternative fora to patent disputes, agencies—and courts—should streamline their efforts to diminish agencies’ power (and efforts) as separate venues of patent litigation. Collectively, these reforms demonstrate the importance of public law solutions to what have, traditionally, been viewed as private law problems. They seek, ultimately, to better administrate patent litigation.

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442. Cf. 1 OXFORD ENGLISH DICTIONARY, *supra* note 12, at 163 (defining “administrate” to mean “[t]o manage or direct (affairs)”).