THE COOPERATION OF MANY MINDS: DOMESTIC PATENT REFORM IN A HETEROGENEOUS REGIME

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* Assistant Professor, Marquette University Law School. I would like to dedicate this Article to my parents, Saundra Murray Nettles and Donald Gaines Murray, Jr., for their wonderful example as scholars and leaders. I would also like to thank Lucy Franklin Murray and Ronald Bailey for their support. I thank the Lamar Order of the University of Mississippi School of Law and Marquette University Law School for providing summer research grants. I would like to thank David L. Schwartz for his perceptive and helpful comments to my final draft. I would like to thank the 6th Annual Intellectual Property Scholars Conference as well as the Marquette Faculty Workshop for allowing me to present early drafts of this work. I would like to thank J. Frank Hogue, a research assistant, who made me recall the benefits of working at the law firm. Additional invaluable research assistance was also provided by Tiphany Baker-Dickerson and Gabrielle H. Ju.

Typically, suggested patent reforms have focused on streamlining administrative duties at the United States Patent and Trademark Office. Such reforms, however, may ignore the important role played by many different administrative agencies in formulating patent policies as to various issues important to a wide range of constituencies. By minimizing the roles of these secondary patent regulators, such reforms may not take into account their competing views of the relevant patent statutes and the overall goals of the patent regime. For example, in its roles of regulating patent imports, the International Trade Commission may offer competing views on the scope of infringement under the Patent Act. Undertaking a new approach, this Article contends that patent law should be seen as a heterogeneous regime that attempts to structure patent law through the competitive roles played by diverse agencies. This Article examines two issues. First, this Article will "map" the roles played by the diverse actors in the patent regime. Second, after exploring the "landscape" of patent law, this Article will examine how the boundaries of this regime are policed by different judicial doctrines. This Article contends that, while doctrinal competition may be necessary and administrative patent reform may need to recognize the importance of heightening the competitive relationships of patent law, the actions of some agency actors may deserve heightened scrutiny.

I. INTRODUCTION

Attending a museum exhibit of maps,[1] I became fascinated with a series of maps that depicted South America from 1507 to 1674. The first map, prepared by Martin Waldsemuller in 1507, seemed indecipherable. What we now identify as South America is depicted as a single coastline surrounded by unidentified bodies of waters—an alien landscape beyond comprehension. The second map, completed in 1524, portrays Tenochitlan, the capital of the Aztec Empire, as if it was a medieval European city on a lake. The cartographer resorted to a familiar landscape in the face of an unfamiliar one. A map from the 1570 compilation of the cartographer Abraham Ortellius, depicting the same coastline, offers a view closer to our current understanding of the North and South American continents. Three landmasses—North, Central and South America—are named on the map. Significant anomalies still present themselves; for instance, the landmass of what is now California is shown only as the Baja Peninsula. The last map in the series, prepared in 1674 by Herbert Jaillot as a present to King Louis XIV, is notable in its familiarity. The countries of Peru, Chile, Brazil and Paraguay are identified in roughly the same locations as their modern equivalents. Any child schooled in basic geography would now recognize the land depicted on the map as South America.

The shifting perspectives observed in these maps—from an entirely alien landscape to one close to our own experience—reveal the gradual acceptance of new paradigms. Much like this series of maps of the early Americas, the impact of administrative law on the U.S. patent regime is gradually taking a comprehensible form. Two events have made the "map" of the administrative aspects of patent law possible. First, the administrative efficacy of the current patent regime has been challenged due to a claimed decline in the quality of patents issued by the United States Patent and Trademark Office (PTO).[2] Sec-

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1 The Ethnologisches Museum in Berlin, Germany held the exhibit Vermessen, Kartograhie der Tropen from May 2006 until August 2006. Information on this exhibit is available at http://www.kartographie-der-tropen.de/44-0-freundeskreis.html. For additional discussions on the impact of cartography during the early modern period, see generally DAVID BUISSERET, THE MAPMAKERS' QUEST: DEPICTING NEW WORLDS IN RENAISSANCE EUROPE *passim* (2003); MILES HARVEY, THE ISLAND OF LOST MAPS: A TRUE STORY OF CARTOGRAPHIC CRIME *passim* (2000); JOHN LARNER, MARCO POLO AND THE DISCOVERY OF THE WORLD *passim* (1999); NORMAN J.W. THROWER, MAPS AND CIVILIZATION: CARTOGRAPHY IN CULTURE AND SOCIETY *passim* (2d ed. 1999).

2 *See generally* ADAM B. JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS: HOW OUR BROKEN PATENT SYSTEM IS ENDANGERING INNOVATION AND PROGRESS AND WHAT TO DO ABOUT IT 1–13 (2004) (providing an overview of ongoing criticism related to the administrative efficiency of the current patent system).

ond, patent law has become more closely aligned with administrative law as a result of the Supreme Court's holding in *Dickinson v. Zurko*,[3] in which the Court held that the Federal Circuit must apply the standard of review, outlined by Section 706(2) of the Administrative Procedure Act (APA), to factual findings of the PTO.[4] These trends have accelerated significantly in light of increased patent reform efforts. The recent controversy over the PTO's regulatory authority to reform continuation practices[5] under 35 U.S.C. § 120 reveals the increasing importance of administrative law principles to patent law.[6]

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3 527 U.S. 150, 154 (1999).

4 Notably, in *Dickinson*, the Supreme Court did not specify which standard of review under 5 U.S.C. § 706 applied to the factual findings of the Board of Patent Appeals and Interferences (BPAI). 527 U.S. at 165. A reviewing court may make a decision using either the "arbitrary and capricious" standard of § 706(2)(A) or the "substantial evidence" standard of § 706(2)(E). Administrative Procedure Act (APA), 5 U.S.C. § 706(2) (2006). A court owes less deference to the factual findings undertaken by an agency under the second standard. Thomas G. Field, Jr., Zurko*,* Gartside *and* Lee*: How Might They Affect Patent Prosecution?*, 44 IDEA 221, 227 (2004). The Federal Circuit subsequently asserted in *In re Gartside*, 203 F.3d 1305, 1315 (Fed. Cir. 2000), that this less deferential standard would be used to review factual findings undertaken by the PTO so as to avoid anomalous standards of review under the Patent Act. *See also* Brand v. Miller, 487 F.3d 862, 868 (Fed. Cir. 2007) ("We first considered that in *Gartside*, an appeal from Board Interference proceeding. We noted that APA § 706 provides that '[t]he reviewing court shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be . . . unsupported by the substantial evidence in a case subject to section 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute.' We then noted that 35 U.S.C. § 144 directs us to review 'on the record' the decisions of the Board."). This Federal Circuit interpretation has raised significant criticism. *See* Peter J. Corcoran, III, *Administrative Procedure Act Standards Governing Judicial Review of Findings of Fact Made by the Patent and Trademark Office*, 7 RICH. J.L. & TECH. 1, pt. IV (2000), *available at* http://law.richmond.edu/jolt/v7i1/article1.html (asserting that the factual findings undertaken by the PTO should be reviewed under the "substantial evidence" standard).

5 *See* Gary C. Ganzi, *Patent Continuation Practice and Public Notice: Can They Coexist?*, 89 J. PAT. & TRADEMARK OFF. SOC'Y 545 (2007) (proposing continuation practice reforms that do not infringe on the rights of patent applicants); Stephen T. Schreiner & Patrick A. Doody, *Patent Continuation Applications: How the PTO's Proposed New Rules Undermine an Important Part of the U.S. Patent System With Hundreds of Years of History*, 88 J. PAT. & TRADEMARK OFF. SOC'Y 556 (2006) (proposed continuation application rule is an "end-run" around Congressional policy); Brian E. Mack, Note, *PTO Rulemaking in the Twenty-First Century: Defining the Line Between Strategic Planning and Abuse of Authority*, 75 FORDHAM L. REV. 2105 (2007) (arguing that the PTO lacks the authority to adopt the proposed continuation application rule); Laxman Sahasrabuddhe, Note, *Is the PTO Authorized to Promulgate the Proposed Rule Change to the Continuation Practice?*, 22 BERKELEY TECH. L.J. 193 (2007) (proposed continuation application rule exceeds PTO rulemaking authority).

GlaxoSmithKline (GSK) recently scored a victory in its court challenge to the United States' Patent and Trademark Office's (USPTO's) final rules regarding continuation practices. Ta-

These trends can be seen as central in laying the groundwork for a considered reassessment of the importance of administrative law within the larger patent regime. Arguably, however, the map lacks one key element: an appreciation for the administrative patent regime within a multi-institutional context. Studies of agencies administering patent law have typically focused on the judicial oversight of *one* particular agency, such as the PTO or the Food and Drug Administration (FDA).[7] Such analyses, however, treat agencies as if they are hermetically sealed off from one another. In fact, agency actors and their interested constituencies often act, react and respond to how other agencies are approaching a particular issue.[8] Moreover, the content of particular regulatory regimes may foster competition between agencies.[9]

A key characteristic, then, of the current patent regime, is its *heterogeneity*. By heterogeneity, I refer to an administrative regime that is, broadly

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fas v. Dudas, No. 1:07cv846 (JCC), 2008 WL 859467 (E.D. Va. Apr. 1, 2008); *see also* Tafas v. Dudas, 511 F. Supp. 2d 652 (E.D. Va. 2007). In *Tafas*, the court determined that the USPTO's powers under section 2(b)(2) of Title 35 to regulate the proceedings of the Office did not extend substantive rulemaking powers. *Tafas*, 2008 WL 859467, at *4–6.

6 *See* Stuart Minor Benjamin & Arti K. Rai, *Who's Afraid of the APA? What the Patent System Can Learn from Administrative Law*, 95 GEO. L.J. 269 (2007) (use of administrative principles will create significant efficiencies in patent law).

7 Thomas G. Field, Jr., *Direct Judicial Review of PTO Decisions: Jurisdictional Proposals*, 42 IDEA 537 (2002) (proposing expansion of judicial review for PTO decisions); Mary E. Wictorowicz, *Emergent Patterns in the Regulation of Pharmaceuticals: Institutions and Interests in the United States, Canada, Britain, and France*, 28 J. HEALTH POL. POL'Y & L. 615, 632-33 (2003) (focusing on oversight of the FDA).

8 For instance, both generic and name-brand pharmaceutical companies have strategically used the administrative procedures of the FDA to attempt to control the enforcement scope of a patent. *See* FED. TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 1 (2002), *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf; *see also* Barbara J. Williams, *A Prescription for Anxiety: An Analysis of Three Brand-Name Drug Companies and Delayed Generic Drug Market Entry*, 40 NEW ENG. L. REV. 1, 6 (2005) ("Some generic companies contend that brand-name drug companies list patents unrelated to the active drug ingredient in the Orange Book for purposes of delay. This argument is countered by the fact that if there is enough innovation, the [PTO] may allow a patent based upon the improvement. Two courts have held that the generic companies have no private right of action to secure the delisting of the Orange Book patent listing. The FTC found recently that for high earning brand-name drugs, more patents per drug are being listed in the Orange Book and they are being listed after the generic Abbreviated New Drug Application (ANDA) application(s).").

9 For instance, William Kovacic and Andreas Reindl have noted the goals of an intellectual property regime and competition regime may differ since a granted IPR right may distort competition in a given area. William E. Kovacic & Andreas P. Reindl, *An Interdisciplinary Approach to Improving Competition Policy and Intellectual Property Policy*, 28 FORDHAM INT'L L.J. 1062, 1062, 1066 (2005).

speaking, concerned with the ability of different actors to contest the meaning of a regulated resource at multiple administrative sites.[10] I start from the working premise that administrative law is present in patent law; we need to describe how these subject areas work together in practice.[11] Thus, this Article, then, is not so much about a reform, but rather about recognition. I contend that an important aspect of administrative patent law is the relationship between various agency actors and the subsequent ways in which judicial oversight maintains the appropriate boundaries between agencies. In doing so, I undertake a process of "institutional cartography," seeking to outline the ways in which patent law is formed by the interactions between different regulatory actors.

In Section II, I identify a key characteristic of the current patent regime—its basic heterogeneity—and then trace how this heterogeneity is expressed. The presence of heterogeneity in the patent regime can create significant conflicts between the relevant agency actors, and in Section III, I explore ways of resolving those conflicts. Finally, in Section IV, I analyze the impact of a heterogeneous administrative regime on efforts to reform the current administrative system. I conclude that seeing patent law in a heterogeneous landscape points to some of the difficulties of resolving the PTO's role in current parent reform. Indeed, any patent reform must take into account the heterogeneity already present in our current system.

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[10] The concept of heterogeneity has been studied within the context of analyzing legal orders within nation-states. *See*, *e.g.*, Boaventura de Sousa Santos, *The Heterogeneous State and Legal Pluralism in Mozambique*, 40 LAW & SOC'Y REV. 39, 45 (2006) ("Each has its own legal norms and rationale, with the result that relations between them are very often tense and conflicting. These tensions and conflicts tend to increase as the articulations between the different legal orders and the different scales of law multiply and deepen."); *see also* BOAVENTURA DE SOUSA SANTOS, TOWARD A NEW COMMON SENSE: LAW, SCIENCE AND POLITICS IN THE PARADIGMATIC TRANSITION *passim* (1995).

[11] Orin Kerr has argued that the use of administrative law is disruptive to the overall goals of the patent regime because the patent system does not operate through public law regulation but rather through the private mechanisms of tort and contract law. Orin S. Kerr, *Rethinking Patent Law in the Administrative State*, 42 WM. & MARY L. REV. 127, 129 (2000). While Kerr's thesis has been attacked on a number of substantive grounds, *see* Arti K. Rai, *Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform*, 103 COLUM. L. REV. 1035, 1054 n.83 (2003), viewing patent law within a multi-institutional framework deepens its reliance on administrative law. In such a multi-institutional framework, administrative law is useful for its ability to draw boundaries between the different agencies and for its guidance as the appropriate deference owed to agency decisions.

II. MAPPING THE HETEROGENEOUS PATENT REGIME

Administrative law lends itself to the use of an extensive literature of political science as both disciplines seek to draw appropriate boundaries between the legislative, judicial and executive branches.[12] Recent scholarship in administrative law has incorporated one rich strand of political science: the study of ex ante and ongoing controls used by the legislature to maintain ongoing supervision over administrative agencies.[13] These studies are relevant here, because, as I contend below, a key aspect of administrative patent law is its reliance on another type of control—heterogeneity—to ensure a diverse range of administrative perspectives in patent law. After briefly outlining the theoretical insights drawn from relevant political science literature, I will identify the third type of control, heterogeneity, and argue that such heterogeneous control is essential to understanding key tensions within the patent regime. I will then identify two characteristics of a heterogeneous regime and trace how the patent regime incorporates these characteristics.

A. Heterogeneous Control in the Patent Administrative State

Elsewhere I have contended that participatory mechanisms such as expanded constituency standing and citizen enforcement can be seen as tools that empower interest groups to monitor agency behavior.[14] But while serving to empower particular constituencies, these participatory mechanisms also serve another goal: limiting agency deviations from legislative goals.[15] Seen in this

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12 *See*, *e.g.*, Matthew C. Stephenson, *Legislative Allocation of Delegated Power: Uncertainty, Risk, and the Choice Between Agencies and Courts*, 119 HARV. L. REV. 1035, 1040–48 (2006) (examining the political science literature addressing the legislative choice to delegate primary interpretative authority to an agency or a court); *see also* Barry Friedman, *Legislative Findings and Judicial Signals: A Positive Political Reading of* United States v. Lopez, 46 CASE W. RES. L. REV. 757, 780 (1996) (arguing that positive political theory offers a way to read judicial interpretations of legislative intent); Daniel B. Rodriguez, *The Positive Political Dimensions of Regulatory Reform*, 72 WASH. U. L.Q. 1, 43 (1994) (assessing "the potential intersections between positive political theory and [administrative law]"); Daniel B. Rodriguez & Barry R. Weingast, *The Positive Political Theory of Legislative History: New Perspectives on the 1964 Civil Rights Act and Its Interpretation*, 151 U. PA. L. REV. 1417, 1447 (2003) (using a theory of legislative rhetoric to evaluate legislative intent under the Civil Rights Act of 1964).

13 *See infra* note 22 and accompanying text.

14 Kali N. Murray, *Rules for Radicals: A Politics of Patent Law*, 14 J. INTELL. PROP. L. 63, 69 (2006).

15 Political scientists have tended to treat these purposes as mutually exclusive. *See*, *e.g.*, Stephen J. Balla, *Administrative Procedures and Political Control of the Bureaucracy*, 92 AM.

light, these mechanisms act as controls on the independence of agency action. As to the nature of these controls, recent scholarship has struggled with two issues: (1) identifying the precise nature of these controls; and (2) analyzing why such controls are in place (a far more controversial issue).

Preliminarily, scholars have identified two types of controls: ex ante controls and ongoing controls.[16] Ex ante controls are those mechanisms associated with the design of the agency contained in the initial authorizing legislation.[17] These mechanisms include, among other items, establishment of reporting and consultation requirements, empowerment of key constituencies, and design of agency criteria.[18] Ongoing controls are those continuing mechanisms that check agency action after initial authorization.[19] These mechanisms include congressional oversight conducted by direct monitoring through committee hearings and appropriations, judicial oversight conducted through a variety of tribunals, and executive oversight conducted through regulatory review and the appointment of political operatives.[20] Ex ante and ongoing controls do not operate independently of each other.[21] Thus, the legislative inclusion of ex ante mechanisms, like consultation requirements (such as an environmental impact statement), may later aid constituency oversight of agency behavior.[22]

POL. SCI. REV. 663, 664 (1998) (reviewing how the purposes of administrative procedures interact with legislative goals or "bureaucratic discretion"). These mechanisms, however, may serve complementary purposes. For instance, expanded standing will place more pressure on an agency to conform to norms underlying the authorizing legislation, by allowing interested constituencies to police the underlying goals of the legislation.

16 David Epstein & Sharyn O'Halloran, *Administrative Procedures, Information, and Agency Discretion*, 38 AM. J. POL. SCI. 697, 698 (1994).

17 *Id.*

18 *Id.*

19 *Id.* at 698–99.

20 *Id.* at 699.

21 *Id.*

22 *Id.* While identifying the types of controls at issue has been a relatively straightforward process, determining why these controls exist has been a more problematic exercise. A number of scholars, most prominently, Mathew McCubbins, Roger Noll, and Barry Weingast assert that legislators make deliberate choices about the structure and process of administrative decision-making to place pre-emptive controls on agency decision-making that falls outside the boundaries of legislative authorization. Mathew D. McCubbins et al., *Structure and Process, Politics and Policy: Administrative Arrangements and the Political Control of Agencies*, 75 VA. L. REV. 431, 444–45 (1989) [hereinafter McCubbins et al., *Structure and Process*]; *see also* Mathew D. McCubbins et al., *Administrative Procedures as Instruments of Political Control*, 3 J.L. ECON. & ORG. 243 *passim* (1987). These ex ante controls tend to reflect three preferences: (1) the suggested administrative procedures mirrors the political environment that sought passage of the initial authorizing legislation; (2) the suggested adminis-

While a variety of ongoing and ex ante controls have been identified within the relevant literature, an analysis of the patent administrative regime reveals yet another type of control—heterogeneity. Heterogeneous administrative regimes have two key characteristics: (1) a competitive relationship between diverse actors; and (2) diffuse judicial oversight that results from those competitive relationships. Initially, heterogeneous administrative regimes allow various regulatory actors to compete in regulating activities within an identified role framework.[23] Three types of roles can be played within a heterogeneous

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trative procedures favor the enacting coalition; and (3) the agency itself is structured to continual benefit of the enacting coalition. McCubbins et al., *Structure and Process*, *supra* at 444–45.

Mathew McCubbins, Roger Noll, and Barry Weingast's framework, which is commonly identified as positive political theory (PPT), or "structure and process" theory, has been criticized on a number of grounds. *See* David B. Spence, *Administrative Law and Agency Policy-Making: Rethinking the Positive Theory of Political Control*, 14 YALE J. ON REG. 407, 409 (1997) [hereinafter Spence, *Administrative Law*] (outlining use of names to discuss this theory). Initially, critics have contended that PPT typically underestimates the role played by the executive in controlling agency action through political appointments and its own interpretations of the relevant statutory powers. *See generally* Terry M. Moe & Scott A. Wilson, *Presidents and the Politics of Structure*, 57 LAW & CONTEMP. PROBS. 1 (Spring 1994). Moreover, critics have contended that PPT significantly underestimates the impact of three competing elements of institutional design. First, PPT underestimates the amount of control exercised over interpretative choices by agency actors themselves, given their professional expertise and control over the agenda. *See* Spence, *Administrative Law*, *supra* at 421-46; *see also* Balla, *supra* note 15, at 670 (concluding that the procedural controls imposed by notice and comment rulemaking did not impact agency-decision-making on physician payment reform under Medicare); David B. Spence, *Agency Discretion and the Dynamics of Procedural Reform*, 59 PUB. ADMIN. REV. 425, 425 (1999) (analyzing the effectiveness of procedural controls on agency decision-making by the Federal Energy Regulatory Commission). Second, PPT overestimates the amount of policy foresight exercised by busy legislators. *See* Spence, *Administrative Law*, *supra* at 426. Finally, PPT fails to recognize sufficiently the important role played by "idealist" normative theory in administrative law Glen O. Robinson, *Commentary on "Administrative Arrangements and the Political Control of Agencies": Political Uses of Structure and Process*, 75 VA. L. REV. 483, 495–98 (1989) (judicial review leads to uncertainty over whether structural decisions made by legislatures can be upheld).

In response to these criticisms, a modified account of structure and process of agency decision-making is useful. This account would emphasize the importance of the use of ex ante and ongoing controls in agency decision-making, but re-evaluate the initial thesis that asserted that such controls impact almost *all* agency decision-making.

[23] I have derived this concept of administrative heterogeneity is derived from studies of the competitive regulators within the context of deposit insurance in Germany. *See generally* Jens-Hinrich Binder, *Financial Markets Regulation in Germany: A New Institutional Framework*, [2000–01] Y.B. OF INT'L FIN. & ECON. L. 401 (analyzing the impact of regulatory competition on the overall performance of financial supervision); Jens-Hinrich Binder,

administrative regime. First, an agency can serve as a primary regulatory actor tasked with regulating the resource on an ongoing basis. The PTO (and the subsequent review of its actions by federal district courts) ultimately plays a dominant role in assessing the validity and enforceability of a patent under the Patent Act.[24] The PTO's dominance in the patent regime should not be understated since it is responsible for issuing patents.[25] Thus, in some sense, the PTO's actions trigger the responsibilities of others.[26]

Second, an agency can serve to replicate, in a narrower role, the interpretative duties of the primary interpreter of a given regime.[27] For example, the International Trade Commission (ITC) replicates the role of district court decision-maker within the narrower context of import controls.[28] Third, an agency can act as an expert on a given set of issues, thus affecting doctrinal issues beyond the scope of its initial enumerated powers.[29] The patent regime has a number of institutional actors, such as the FDA, which acts within the context of pharmaceutical patents, and the Federal Trade Commission (FTC), which acts within the context of antitrust actions that undertake such an expert role.[30]

Vesting a range of actors with different types of roles—primary, replicative, and expertise—fosters the second characteristic of the heterogeneous

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Regulatory Competition Between the Deposit Insurer and a Single Financial Regulator—The Case of Germany, 39 INT'L LAW. 3 (2005) (same).

24 *See* 35 U.S.C. § 2(a)(1)–(2) (2006) (stating that the PTO is responsible for "granting and issuing" patents and "disseminating to the public information" about the same). The Patent Act contemplates the internal heterogeneity in judicial review of patent validity and enforceability, allowing two avenues for appeal of a final decision issued by the BPAI. *Compare* 35 U.S.C. § 141 (2006) (a dissatisfied applicant can seek review of a BPAI determination at the Federal Circuit) *with* 35 U.S.C. § 145 (2006) (a dissatisfied applicant can file a civil action against the director of the PTO in a federal district court).

25 35 U.S.C. §154 (2006) (outlining the procedures associated with issuance of patents).

26 *See infra* notes 128-131 and accompanying text.

27 *See infra* notes 32–39 and accompanying text.

28 *Id.*

29 *See infra* notes 63–71 and accompanying text. I focus here on the FTC's power to interpret the Patent Act simply because its consequences have been less explored within the relevant literature. The other pre-eminent example of an expertise agency is the FDA's role in examining and assessing the consequences of approval of a patented drug. The FDA has assumed significant authority to review the use and enactment of pharmaceutical patents. *See In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 190–91 (2d Cir. 2006) (outlining the statutory duties of the FDA under the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act")); *see also* Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1296–98 (11th Cir. 2003); Andrx Pharms., Inc., v. Biovail Corp. Int'l, 256 F.3d 799, 801–02 (D.C. Cir. 2001).

30 *See infra* notes 63–71 and accompanying text.

regime, the possibility of diffuse oversight. By vesting agency actors with additional powers based on their identified roles, legislators can limit agency overreach by diffusing interpretative power through different administrative and judicial sites. This legislative design of a heterogeneous regime achieves two key results. First, a heterogeneous administrative regime, by fostering competition between agencies, creates internal "checks and balances" over a regulated resource prevents agency overreach on any given issue; thus, the heterogeneous administrative regime sets up a competitive interplay between agencies. This interplay can potentially enrich interpretative treatment of given subject matter. Second, by opening up multiple sites of administrative access, a heterogeneous administrative regime creates diverse avenues for interested constituencies to participate in the regulatory process. Such diversity is amplified by the fact that constituencies can use multiple avenues, such as notice and comment rulemaking, administrative tribunals, or less formalized procedures, to achieve policy outcomes. Current patent reform remains problematic to the extent that it treats problems within a singular context.[31] Such treatment fails to take into account that reform might have to address the actions of multiple actors.

B. Patent Law as a Model Heterogeneous Administrative Regime

Patent law as a whole reflects the characteristics of a heterogeneous administrative regime. I initially address the first characteristic of a heterogeneous regime, the diverse roles—replicative and expertise—assigned to actors within patent law. As discussed supra, however, this heterogeneity often remains unacknowledged and thus may undermine any attempt to reform the role of the PTO, the nominal primary actor in the patent regime. I next examine the second characteristic, the diffuse nature of judicial review in a heterogeneous context. This diffusion, in turn, may undermine a dominant trend toward a uniform approach to patent law.

1. Role-Playing in a Heterogeneous Administrative Regime

i) Replicative Actor: The International Trade Commission

While the PTO plays a unique role in the issuance of a patent, diverse regulatory actors compete to shape the doctrinal consequences of that grant.

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[31] For instance, the Patent Reform Act of 2007 has primarily focused on reforming the scope of Section 2 of the Patent Act, which regulates the governance powers of the USPTO. *See infra* note 245 and accompanying text.

These agencies can serve as "replicative" actors, supplementing the roles played by the primary regulatory actor. For instance, while the PTO and subsequent district court review play an important role in determining the validity and scope of a patent, the ITC plays a replicative role in assessing these same related issues within the narrower context of potentially infringing imports. Section 1337 empowers the ITC to regulate potentially unfair acts or unfair acts that may occur in the import of a number of intellectual property goods.[32] Specifically, the ITC can: (1) exclude products that destroy or substantially injure a domestic industry; (2) prevent the establishment of a domestic industry; and (3) regulate unfair methods of competition if the effect thereof is to restrain or monopolize trade and commerce in the United States.[33] The ITC can exclude a range of intellectual property articles: (1) articles that infringe a valid and enforceable U.S. patent;[34] (2) articles that infringe a valid and enforceable U.S. copyright;[35] and (3) articles that infringe valid and enforceable trademarks, mask works or designs.[36]

The ITC's replicative role appears to result from two legislative developments. First, under the Trade Act of 1974,[37] Congress granted the ITC the power to interpret all legal and equitable defenses that a party can raise.[38] Second, in the Omnibus Trade and Competitiveness Act of 1988, Congress amended § 1337(a)(1)(B)(i) to specify that it is "unlawful" to import a product that is covered by a U.S. patent that is "valid and enforceable."[39] Such language

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32 *See* 19 U.S.C. § 1337(a)(1)(A)(i)–(iii) (2006).

33 *Id.*

34 § 1337(a)(1)(B)(i).

35 *Id.*

36 § 1337(a)(1)(C)–(E).

37 Trade Act of 1974, Pub. L. No. 93–618, 88 Stat. 1978 (1975) (codified in scattered sections of 19 U.S.C.).

38 § 1337(c); *see also* Lannom Mfg. Co. v. ITC, 799 F.2d 1572, 1576–79 (Fed. Cir. 1986) (reviewing the major amendments in the Trade Act of 1974, including the ability of the ITC to review validity and infringement claims); J. Stephen Simms, Comment, *Scope of Action Against Unfair Import Trade Practices Under Section 337 of the Tariff Act of 1930*, 4 NW. J. INT'L L. & BUS. 234, 243 (1982) ("[T]he 1974 additions to subsection (c) of Section 337 provided that respondents in Section 337 investigations could present all 'legal and equitable defenses' and that parties who were adversely affected by Commission determinations could appeal to the United States Court of Customs and Patent Appeals.").

39 Omnibus Trade and Competitiveness Act of 1988 § 1342(a)(1)(B)(i), 19 U.S.C. § 1337(a)(1)(B)(i). The ITC's jurisdiction over counterclaims remains limited. 19 U.S.C. § 1337(c) (2006) ("[A]fter a counterclaim is received by the Commission, the respondent raising such counterclaim shall file a notice of removal with a United States district

eliminated the need to prove substantial injury to a domestic industry in the United States.[40] Both of these statutory subsections reflect congressional intent to create an alternative administrative site where patent owners can enforce their respective patents within the context of overseas manufacture.

The usefulness of a replicative actor, such as the ITC, in the patent regime is considerable. Initially, the ITC can offer an alternative understanding of the relevant doctrines within a specialized context. Unlike many district court judges,[41] who may address patent law sporadically at best, the administrative judges of the ITC can develop an overall understanding of doctrinal changes in the law that comes from seeing the same issues (and often the same parties) over time. Moreover, the ITC can develop a patent jurisprudence that is responsive to the overall *trade* context. The ITC is important as a site that connects the internal domestic market with external international markets. Indeed, the ITC's importance as a replicative site has only grown in light of the overall changes in the American economy as domestic companies rely on external supply chains to import major products.[42] Finally, adding more administrative sites allows competitors more opportunity to challenge the validity and enforcement of a patent. This creates additional strategic opportunities for owners to enforce their patents.

Judicial support of the replicative functions of the patent system has been highly controversial. The controversy surrounding *Kinik Co. v. ITC*,[43] in which the Federal Circuit upheld the ITC's refusal to apply the defenses contained in section 271(g) of the Patent Act, exemplifies this trend.[44] In *Kinik*, the ITC examined whether or not the abrasive articles imported by Kinik Company infringed upon a 3M process claimed in U.S. Patent No. 5,620,489.[45] In doing so, the ITC determined that Kinik could not claim that its imported articles that used a patented process fell within the two defenses outlined in 35

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court in which venue for any of the counterclaims raised by the party would exist under section 1391 of Title 28.").

40 Terry Lynn Clark, *The Future of Patent-Based Investigation Under Section 337 After the Omnibus Trade and Competitiveness Act of 1988*, 38 AM. U. L. REV. 1149, 1160-73 (1989).

41 Kimberly A. Moore, *Forum Shopping in Patent Cases: Does Geographic Choice Affect Innovation?*, 79 N.C. L. REV. 889, 903–04 (2001) (noting that five district courts disposed of 29% of all district court patent cases during the study period).

42 *Shining Examples: How Three Large and Successful Companies Are Using Their Supply Chains to Compete*, The Economist, June 15, 2006, *available at* http://www.economist.com/surveys/displaystory.cfm?story_id=7032179.

43 362 F.3d 1359 (Fed. Cir. 2004).

44 *Id.* at 1361.

45 *Id.*

U.S.C. § 271(g).[46] The ITC claimed that the Process Patent Amendments Act of 1988 stated infringers could not raise these available defenses in claims made before the agency.[47] Of course, limiting the defenses outlined in § 271(g) would necessarily constrain the full range of remedies available to a potential infringer under the Patent Act.

The Federal Circuit, applying the deference accorded to the agency's interpretative choices under *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*,[48] upheld the ITC's position for three primary reasons. First, the text of § 9006(c) had to be read in light of the broader purposes of 35 U.S.C. § 271(g), which served to expand the scope of infringing actions that could be considered by a district court, but did not impact the actions of the ITC.[49] Second, the legislative history of the Process Patent Amendments Act, as demonstrated by the relevant Senate Report, indicated that Congress intended to preserve the ability of the process patent owners to obtain full remedies under existing law.[50] Third, in an earlier case, *Amgen, Inc. v. U.S. ITC*,[51] the Federal Circuit had previously held that the congressional failure to change the text of § 1337 in 1988 indicated that the scope of remedies available to patent owners before the ITC has not been reduced, despite the enactment of § 271(g).[52] Accordingly, the Federal Circuit concluded that each of these reasons—the text, the legislative history, and the recent precedent—reinforced the ITC's interpretation of the scope of § 271(g).

The Federal Circuit's holding in *Kinik* has been perceived as "muddying" the patent landscape in a number of ways.[53] Critics contend that *Kinik* un-

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46 *Id.* Two defenses are outlined in § 271(g). Under § 271(g), an imported product that is made using a patented process will not be infringing if: (1) the product is "materially changed by subsequent processes;" or (2) "it becomes a trivial and nonessential component of another product."

47 *Kinik*, 362 F.3d at 1362 (citing the Process Patent Amendments Act of 1988, Pub. L. No. 100–418, § 9006(c), 102 Stat. 1107 (1988)).

48 467 U.S. 837, 843 (1984).

49 The ITC contended that the language contained in section 9006(c) of the Process Patent Amendments Act of 1988, which stated that "[t]he amendments made by this subtitle shall not deprive a patent owner of any remedies available . . . under section 337 of the Tariff Act of 1930," should be interpreted to mean that a patent owner would be allowed a full range of remedies before the Commission. *Kinik*, 362 F.3d at 1362.

50 *Id.* at 1362–63 (citing Process Patent Amendments Act of 1987, S. Rep. No. 100–83, at 60–61 (1987)).

51 902 F.2d 1532 (Fed. Cir. 1990).

52 *Id.* at 1540 n.13.

53 *See* John M. Eden, *Unnecessary Indeterminacy: Process Patent Protection After* Kinik v. ITC*,* 2006 DUKE L. & TECH. REV. 0009, 1, 9 (2006); Anne Elise Herold Li, Note, *Is the Fed-*

dermines a unified patent regime by allowing the ITC to pursue an interpretative route that prevents foreign defendants from raising defenses under § 271(g). This interpretative choice is seen as one that unduly favors plaintiffs.[54] Moreover, *Kinik* is subject to intense criticism because the Federal Circuit appears to accord *Chevron* deference to the ITC's interpretation of the Patent Act.[55] According to such critics, only the PTO and subsequent district court review are tasked with interpreting the scope of the Patent Act, and therefore, the ITC's reading of § 271(g) should have only been assessed for its persuasiveness.[56]

These criticisms, however, illustrate why *Kinik* accurately represents the current patent administrative landscape in two key respects. First, in *Kinik*, the Federal Circuit appears to recognize that Congress may intend to create a non-uniform approach to a given interpretative problem. Diverse administrative approaches may more properly serve interested constituencies. Here, congressional desire to protect the rights of process patent claimants at the expense of foreign manufacturers, while accompanied by more than a whiff of expediency, may serve otherwise legitimate goals of responding to a transnational trade context. Indeed, as the Federal Circuit noted, while this created a minor anomaly "in the defenses available in different tribunals, before this enactment there was an even greater distinction, for overseas manufacture could not be reached at all in the district courts."[57] Second, a diverse approach to agency policy making does not have to be unmediated. *Kinik*, as discussed below, posits that such heterogeneity needs to be supported by explicit statements from Congress; otherwise, such judicial support of heterogeneity may not necessarily exist. Likewise, as discussed supra, the scope of the ITC's decision-making can be policed through a refusal to apply the determinations of the ITC in subsequent district court proceedings.

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eral Circuit Affecting U.S. Treaties? The ITC, § 271(g), GATT/TRIPS & the Kinik *Decision*, 16 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 601, 636-37 (2006).

54 Eden, *supra* note 53, at 15.

55 *Id.* at 19 ("The main problem is that *the ITC is not the agency charged with interpreting the Patent Act*. Thus, on a defensible interpretation of the Chevron doctrine, the particular interpretive choices the ITC made in this instance do not deserve any deference."). Of course, as I discuss below, such criticism may ignore the fact that considerable ambiguity exists over which agency is actually tasked with interpreting the Patent Act. *See infra* Fn 219 and accompanying text.

56 *Id.*

57 Kinik Co. v. ITC, 362 F.3d 1359, 1363 (Fed. Cir. 1990).

ii) Expertise Actor: The Federal Trade Commission

An agency within a heterogeneous administrative regime can also play an "expertise" role that may come from the broader role undertaken by an agency, or in a specific task allocated to an agency. This responsibility of an expert agency can often expand in response to perceived needs. Expertise actors have performed well as "gap-fillers" in assessing the impact of patents on unfair competition and antitrust law. A primary example of an agency playing an expertise role in patent law is the FTC, which has been given significant responsibilities to analyze the antitrust and consumer consequences associated with the grant of a patent.

The Federal Trade Commission Act of 1914 established the FTC for the predominant purpose of becoming an expert agency that assessed anticompetitive and consumer behavior.[58] The broad mission of the FTC derives from section 5 of the FTC Act, which provides that the agency can regulate two key areas.[59] Initially, section 5 directs the FTC to address "unfair methods of competition in or affecting commerce,"[60] which has been interpreted to allow the FTC to interpret and prevent, respectively, violations of the Sherman, Clayton, and Robinson-Patman Acts.[61] This power has established the FTC's competency in antitrust law. Section 5 of the FTC Act further directs the FTC to prevent "unfair or deceptive acts or practices in or affecting commerce," which allows the FTC to regulate behavior that unfairly impacts consumers.[62] This responsibility has established the FTC's competency in a variety of consumer protection areas.[63]

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58 D. Bruce Hoffman & M. Sean Royall, *Administrative Litigation at the FTC: Past, Present, and Future*, 71 ANTITRUST L.J. 319, 320 (2003) (analyzing the development of the FTC's expertise role as response to ongoing controversies over the appropriate scope of antitrust laws); Marc Winerman, *The Origins of the FTC: Concentration, Cooperation, Control, and Competition*, 71 ANTITRUST L.J. 1, 54–84 (2003) (same). *See generally* 1 THE FTC AS AN ANTITRUST ENFORCEMENT AGENCY: THE ROLE OF SECTION 5 OF THE FTC ACT IN ANTITRUST 20–25 (1981) (noting that the legislative history of Section 5 indicates that congressional drafters believed that an expertise role for the FTC was necessary to the extent that an expert agency could resolve broad issues with promptness and definiteness).

59 Federal Trade Commission Act § 5, 15 U.S.C. § 45(a)(1) (2006).

60 *Id.*

61 *See* Sherman Act, 15 U.S.C. §§ 1–7 (2006); Clayton Act, 15 U.S.C. § 12 (2006); Robinson-Patman Act, 15 U.S.C. §§ 13, 21(a) (2006).

62 15 U.S.C. § 45(a)(1) (2006).

63 The scope of the FTC consumer competency is broad and covers at least seven different categories. First, the FTC can seek to cancel improperly granted or maintained trademarks. *See*, *e.g.*, Lanham Act § 14, 15 U.S.C. § 1064 (2006) (granting the FTC the power to seek

The FTC's power to undertake these core competencies is reinforced in three key ways. First, the FTC can exercise its powers over a wide range of subjects.[64] Second, the FTC can exercise its powers in an equitable fashion, thus regulating a broad range of competitive and consumer behavior. The Supreme Court noted in *FTC v. Sperry & Hutchinson Co.*[65] that the scope of the FTC's equitable powers under section 5 of the FTC Act are broad, stating that:

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cancellation of generic, abandoned, functional, or incorrectly granted certification marks). Second, the FTC can regulate the labeling on a number of different products. *See*, *e.g.*, Wool Products Labeling Act, 15 U.S.C. § 68d (2006); Fur Products Labeling Act, 15 U.S.C. § 69f (2006); Textile Fiber Products Identification Act, 15 U.S.C. § 70e (2006); Federal Cigarette Labeling and Advertising Act, 15 U.S.C. § 1333 (2006); Fair Packaging and Labeling Act, 15 U.S.C. § 1455 (2006). Third, the FTC can regulate the transparent disclosure of financial information. *See*, *e.g.*, Bankruptcy Abuse Prevention and Consumer Protection Act of 2005 (BAPCPA), Pub. L. 109–8, § 1301, 119 Stat. 23, 205 (2005) (codified in scattered sections of 11 U.S.C); Federal Deposit Insurance Corporation Improvement Act of 1991, Pub. L. 102–242, § 40, 105 Stat. 2236, 2283 (1991) (codified in scattered sections of 12 U.S.C.); Truth in Lending Act, 15 U.S.C. § 1607 (2006). Fourth, the FTC regulates the proper conduct of the telecommunications industry. *See*, *e.g.*, Telephone Disclosure and Dispute Resolution Act, 15 U.S.C. § 5711 (2006); Crimes Against Charitable Americans Act of 2001, 15 U.S.C. §§ 6102, 6106 (2006) (requiring the FTC to include fraudulent charitable solicitations in the telemarketing rules' definition of deceptive telemarketing practices); Telemarketing and Consumer Fraud and Abuse Prevention Act, 15 U.S.C. §§ 6102, 6107 (2006) (requiring the FTC to promulgate regulations prohibiting deceptive telemarketing practices and restricting the manner of telemarketing operations). Fifth, the FTC regulates the potentially fraudulent behavior on-line. *See*, *e.g.*, Children's Online Privacy Protection Act, 15 U.S.C. §§ 6502, 6505 (2006) (authorizing the FTC to enforce this Act, which prohibits deceptive or misleading, unsolicited commercial email, and also requiring the FTC to issue rules involving the required labeling of sexually explicit commercial email); Controlling Assault of Non-Solicited Pornography and Marketing Act of 2003 (CAN-SPAM Act), 15 U.S.C. § 7706 (2006) (authorizing the FTC to enforce this Act, which requires operators of commercial websites and online services to give parents the tools to control what information is collected from their children on line).

64 Banks, savings and loans institutions, common carriers, domestic and foreign air carriers, and livestock and meat packing industries are exempted from its authority. 15 U.S.C. § 45(a)(2) (2006).

65 405 U.S. 233 (1972). The unspecified power to determine what constitutes an "unfair" consumer practice, announced by the Supreme Court in *Sperry,* subsequently came under significant criticism. *See, e.g.*, Ernest Gellhorn, *Trading Stamps,* S & H*, and the FTC's Unfairness Doctrine*, 1983 DUKE L.J. 903, 904 (1983). The scope of the "unfairness" doctrine was refined by 15 U.S.C. § 45(n). *See* Caswell O. Hobbs, *Antitrust and Consumer Protection: Exploring the Common Ground*, 72 ANTITRUST L.J. 1153, 1154 n.8 (2005) (examining the development of 15 U.S.C. § 45(n) in response to criticism that the unfairness doctrine of *Sperry* did not provide impacted parties with clear guidance as to the scope of the doctrine).

> [T]he Federal Trade Commission does not arrogate excessive power to itself if, in measuring a practice against the elusive, but congressionally mandated standard of fairness, it, like a court of equity, considers public values beyond simply those enshrined in the letter or encompassed in the spirit of the antitrust laws.[66]

Finally, the FTC has a broad range of administrative methods for enforcing its statutory powers. The FTC can investigate a variety of disputed practices.[67] Such initial investigation can exert pressure on a business to comply without the FTC resorting to additional measures.[68] After conducting an investigation into a disputed practice, the FTC can announce its interpretation by party-by-party adjudication,[69] or by issuing industry-wide rules.[70] The range of permissive actions vested in the FTC is remarkable in its flexibility and scope.

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66 *Sperry*, 405 U.S. at 244.

67 15 U.S.C. § 46(a) (2006); *see also* 16 C.F.R. §§ 2.1–2.51 (2007) (describing the investigatory procedures undertaken by the FTC). The FTC's investigatory power under Section 6 may include investigations of behavior that are beyond the scope of administrative actions contemplated in Section 5. 2 THE FTC AS AN ANTITRUST ENFORCEMENT AGENCY: ITS STRUCTURE, POWERS AND PROCEDURES 15 n.46 (1981). Beyond the broad scope of the investigated in Section 6(a), the FTC can also investigate: (1) continuing compliance with antitrust decrees; (2) violations of antitrust statutes; (3) foreign trade practices, involving associations, combinations, or practices, which may affect the foreign trade of the United States; and (4) possible violations of foreign antitrust laws. *See* 15 U.S.C. § 46(c),(d),(h),(i) (2006).

68 The FTC can utilize a variety of powers during the course of its initial investigation. First, the FTC can require the investigated party to file an annual report that discusses the investigated practice. *See* 15 U.S.C. § 46(b) (2006). Second, the FTC can issue subpoenas that require investigated parties to produce the relevant documents and appear before the administrative tribunal. *See* 15 U.S.C. § 49 (2006). Third, the FTC has a more limited ability to access and examine the records independent of its subpoena power. *Id.*

69 The FTC can initiate a complaint against an individual company (typically referred to as the respondent) after the initial investigatory period. 15 U.S.C. § 45(b); 16 C.F.R. § 2.1 (2007). The respondent can either elect to settle (by signing a consent order) or contest the order by appearing before an administrative law judge (ALJ). *See* 16 C.F.R. § 2.34 (2007).

A respondent that elects to settle does not have to admit liability but cedes the right to appeal the settlement. 16 C.F.R. § 2.32 (2007). The consent order is then placed on record for public comment for 30 days (or any other period specified by the FTC). 16 C.F.R. § 2.34(c) (2007). The Commission next decides whether to make the order final upon the close of the designated time period. 16 C.F.R. § 2.34(e) (2007).

If, on the other hand, the respondent chooses to adjudicate the complaint, a hearing must be held at least thirty days after the service of the complaint. 16 C.F.R. §§ 3.11, 3.41 (2007). After the hearing, the ALJ produces an initial decision consisting of fact-findings, conclusions of law, and a recommended action. 16 C.F.R. § 3.51 (2007). Both parties (the respondent and the Complaint Counsel) can appeal the initial decision before the FTC. 16 C.F.R. § 3.52(a) (2007). The appellate process is similar to that of other types of judicial proceedings—the parties provide briefs, oral arguments and then the FTC issues its majority

Consistent with the scope of its statutory and administrative mission, the FTC has claimed that its powers to craft appropriate remedies under section 5 of the FTC Act extend to an independent ability to undertake a legal and factual determination of whether or not a patentee has violated the Patent Act itself. The FTC first asserted this power in *In re American Cyanamid Co.*[71] in 1962, and reaffirmed this power in *In re Union Oil Co. of California*[72] in 2004. In *In re American Cyanamid*, the FTC determined that six pharmaceutical companies that sold and distributed tetracycline, a broad-spectrum antibiotic, engaged in a number of unfair trade practices.[73] A key claim of the complaint was that two of

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opinion and accompanying order. 16 C.F.R. § 3.54 (2007). After issuance of the order, the non-prevailing party has 14 days to petition for review of the order. 16 C.F.R. § 3.55 (2007). The order becomes final if both parties do not petition for appellate review within 60 days of service. 16 C.F.R. § 3.56 (2007). The appellant must petition in a circuit court of the United States Court of Appeals where the accused practice occurred or where the petitioner resides or carries on business. 15 U.S.C. § 45(c) (2006).

70 Section 18 of the Act gives the Commission authority to prescribe rules and general policy statements on unfair and deceptive practices. *See* 15 U.S.C. § 57a(a)(1) (2006). The types of rules include interpretive rules, general statements, and rules defining specific acts the FTC believes are unfair or deceptive. *Id.* This section also requires the FTC to use notice and comment rulemaking outlined by the Administrative Procedures Act. *Id.*; *see* 5 U.S.C. § 553 (2006). Although used within the consumer protection context, the FTC has not used this rulemaking authority with respect to antitrust issues in over thirty years. David Balto, *Returning to the Elman Vision of the Federal Trade Commission: Reassessing the Approach to FTC Remedies*, 72 ANTITRUST L.J. 1113, 1118 (2005) (reviewing the FTC's use of remedial powers under its rulemaking authority).

71 63 F.T.C. 1747 (1963), 1963 FTC LEXIS 77, *vacated on other grounds*, Am. Cyanamid Co. v. FTC, 363 F.2d 757 (6th Cir. 1966). *In re American Cyanamid* rightly can be called the Bleak House of administrative patent law. The FTC initiated proceedings against the relevant companies in 1998, which prompted a significant case history of related criminal prosecutions. *See* United States v. Chas. Pfizer & Co., 367 F. Supp. 91, 101–02 (D.C.N.Y. 1973) (granting motion for acquittal on indictment due to governmental failure to establish its burden under Section 1 and Section 2 of the Sherman Antitrust Act); United States v. Chas. Pfizer, 281 F. Supp. 837, 840, 851 (D.C.N.Y. 1968) (denying a motion for judgment notwithstanding the verdict due to alleged prejudicial pre-trial publicity), *aff'd* 404 U.S. 548 (1972) (reversal of trial verdict due to imprecise jury instructions); United States v. Chas. Pfizer & Co., 245 F. Supp. 801, 819 (D.C.N.Y. 1965) (dismissing individual indictments because of previously-issued immunity grants); United States v. Chas. Pfizer & Co., 217 F. Supp. 199, 203 (D.C.N.Y. 1963) (denying motion to strike potentially prejudicially statements from criminal indictments). Another set of cases arose around the state prosecution of related antitrust claims. *See generally* North Carolina v. Chas. Pfizer & Co., 537 F.2d 67 (4th Cir. 1976) (analyzing antitrust claims).

72 2004 WL 1632816 (F.T.C. 2004).

73 The six companies were Chas. Pfizer & Co. (Pfizer), American Cyanamid Co., Bristol-Myers Co., Bristol Laboratories Inc., Olin Mathieson Chemical Co., and The Upjohn Co. *See In re* Am. Cyanamid, 63 F.T.C. 1747, 1963 FTC LEXIS 77 at *3–*4. The disputed trade practices

the companies, American Cyanamid and Pfizer, had engaged in material misrepresentations before the PTO so as to unlawfully obtain a patent for a variant of a method of making tetracycline that used a direct fermentation process.[74] As a specific remedy for this behavior, the FTC ordered Pfizer and Cyanamid to offer compulsory licenses at a pre-determined royalty, based on its previous net sales for the relevant patents.[75]

In particular, the FTC found that Pfizer and Cyanamid acted improperly during the prosecution of the relevant patent, U.S. Patent Number 2,482,055.[76] Two key issues complicated the FTC's analysis in *American Cyanamid*. First, the FTC confronted a complex prosecution history during which separate companies made potentially misleading statements at two different points.[77] Second, the FTC confronted the question of the scope of its jurisdictional authority under the Patent Act.[78]

The intense dispute between the FTC and the relevant companies resulted, in many ways, from a complex prosecution history. Initially, in October 1954, the patent examiner conducted an interference proceeding under section 102(g) of the Patent Act between Pfizer, Cyanamid and Bristol.[79] A central issue of the prosecution was whether two previously issued patents disclosed an

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included allegations that the six companies: (1) maintained fixed prices as to the sale of tetracycline; (2) established cross licenses with the purpose of "foreclosing and preventing competition in the production and sale of tetracycline"; (3) "foreclosed access to substantial markets" in the sale of tetracycline; (4) "fixed and maintained prices, terms, and conditions of sale"; (5) "established and maintained illegal resale price maintenance agreements"; (6) "attempted to monopolize the antibiotics industry"; and (7) "attempted to monopolize and have monopolized the manufacture, sale and distribution of tetracycline." *See id.* at *11, *14–15.

74 *Id.*

75 *Id.* at *332–48. *American Cyanamid* has often been used to illustrate the scope of the FTC's power to issue a royalty-free compulsory license. *See*, *e.g.*, Colleen Chien, *Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?*, 18 BERKELEY TECH. L.J. 853, 891–92 (2003) (suggesting that compulsory licenses fashioned with caution do not negatively impact investment in innovation, "contrary to the prevalent assumption that compulsory licensing categorically harms innovation"); Lawrence Schlam, *Compulsory Royalty-Free Licensing as an Antitrust Remedy for Patent Fraud: Law, Policy and the Patent-Antitrust Interface Revisited*, 7 CORNELL J.L. & PUB. POL'Y 467, 529–30 (1998) (suggesting that the antitrust remedy of royalty-free compulsory patent licensing is the most useful and effective one compared to other remedies).

76 *In re* Am. Cyanamid, 63 F.T.C. 1747, 1963 FTC LEXIS 77 at *24.

77 *Id.* at *208–15, *224–28.

78 *Id.* at *228–29.

79 *Id.* at *139–40. Two interferences were conducted in relation to the disputed patents. The first interference resulted in a settlement between Pfizer and American Cyanamid. *Id.* at *138–39.

invention that would have inherently produced the tetracycline claimed by all three patent applications.[80] These two patents, respectively, disclosed the characteristics of the relevant antibiotic (but not its actual molecular structure), and a process for creating the relevant antibiotic.[81] The FTC found that Cyanamid failed to disclose information about the presence of tetracycline in its preexisting products. This disclosure would have indicated that the chemical compound was inherently produced by the prior art.[82] In November 1954, the patent examiner rejected all three patent applications, concluding that while the prior two patents did not directly disclose tetracycline, it could have been inherently produced from the processes disclosed by the previous patents.[83]

After this initial rejection, the prosecution of the patent narrowed to an ex parte examination of Pfizer's patent application.[84] Pfizer's counsel met with the patent examiner and, during the course of the meeting, contended that tetracycline could not be produced by the previous prior art. In response, the patent examiner stated that he would reexamine his conclusions as to the product claims if Pfizer could demonstrate that the tetracycline could not be produced from the processes disclosed in the previous patents.[85] The FTC found that Pfizer, in responding to this request, failed to disclose two key items. First, Pfizer failed to disclose to the patent examiner previously conducted tests that indicated that tetracycline could be produced from the relevant prior art references.[86] Second, Pfizer did not fully disclose aspects of a number of additional test results that undermined its claims that the prior art references did not disclose aspects of its claims.[87]

The FTC also confronted the scope of its jurisdictional authority to interpret the provisions of the Patent Act in the course of its duties under section 5. A key anomaly in the record—that the patent examiner failed to articulate under which provision of 35 U.S.C. § 102 the relevant applications were deficient—triggered this inquiry.[88] The administrative law judge decided that the statements of Cyanamid and Pfizer were not material to the issuance of the '055 patent, since the patent examiner rejected the relevant application under 35

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80 *Id.* at *139.

81 *Id.* at *142–43.

82 *Id.* at *140.

83 *Id.* at *142–43.

84 *Id.* at *143.

85 *Id.* at *148–49.

86 *Id.* at *152–53.

87 *Id.*

88 *Id.* at *157.

U.S.C. § 102(b) in light of the previous public sale of Cyanamid's commercial product, Aureomycin.[89] The full Commission, however, disagreed with that assessment. Instead, the FTC found that the patent examiner considered the key issue to be whether, under 35 U.S.C. § 102(e), the product tetracycline was inherently produced by products and processes previously disclosed in the applications of two other patents.[90] In doing so, the full Commission of the FTC analyzed one issue: the state of the law associated with the doctrine of inherent anticipation.

In response, Pfizer, Cyanamid and Bristol challenged the FTC's jurisdictional authority under 28 U.S.C. § 1338.[91] Section 1338 states that the "district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents, copyrights, and trademarks" and, moreover, that such jurisdiction is "exclusive of the courts of the states in patent and copyright cases."[92] The FTC dismissed this challenge on two grounds. First, the FTC asserted that while § 1338 precluded *state* courts from asserting jurisdiction over patent or copyright claims (unless in incidental or collateral claims), § 1338 did not apply to *federal* executive agencies such as the FTC.[93] Second, the FTC argued that the breadth and flexibility embodied by section 5 reinforced the FTC's power to interpret subsidiary issues related to the Patent Act.[94]

These two interpretations of the FTC's expertise role, outlined in *American Cyanamid,* remain consistent throughout its later jurisprudence. Although a portion of the decision was vacated on other grounds, the Court of Appeals for

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89 *Id*. at *160.

90 *Id*. at *171.

91 *Id.* at *228.

92 17 U.S.C. § 1338(a) (2006).

93 *In re* Am. Cyanamid, 63 F.T.C. 1747, 1963 FTC LEXIS 77 at *230–31. Earlier precedent supported the FTC's interpretative gloss of the scope of section 5. The District of Columbia Circuit had upheld the issuance of the cease-and-desist order by the FTC that sought to prevent a patentee making a number of potentially false claims related to the exhaust mechanism of an automobile. Decker v. FTC, 176 F.2d 461, 462 (D.C. Cir. 1949). The patentee claimed that the advertisements enjoyed immunity from such an order because the claims were included in the issued patent. *Id.* at 462. The majority affirmed the FTC's order, because an advertisement is not considered when determining the scope of a patent and this issue involved only advertisements. *Id.* at 463. In dissent, Chief Judge Stephens contended that the FTC had impermissibly rendered the patent at issue inoperative. *Id.* at 465 (Stephens, C.J., dissenting). He criticized the majority's opinion on two grounds. First, he contended that the majority ignored that a statement made in a patent is assumed be to true upon issuance of the patent. *Id.* Second, he further argued that the FTC order substantially stripped the patentee's benefits by rescinding its ability to claim the features disclosed in the patent. *Id.*

94 *In re* Am. Cyanamid Co., 63 F.T.C. 1747, 1963 FTC LEXIS 77 at *230–32.

the Sixth Circuit in *American Cyanamid Co. v. FTC*[95] affirmed the decision of the FTC that the Commission had jurisdiction under section 5 to interpret the Patent Act.[96] The Sixth Circuit reemphasized the FTC's power to substantively interpret the Patent Act for two main reasons. Initially, the Sixth Circuit stressed that the Supreme Court's holding in *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp*[97] indicated that a full range of antitrust remedies—including section 5 of the FTC Act—could constrain improper patent monopolies.[98] Furthermore, the Sixth Circuit claimed the FTC's power under section 5 was strengthened by its ability to assess the facts that were not available to the Patent Office.[99] Notably, however, the Sixth Circuit suggested that the FTC did not have the power to invalidate a patent or order a compulsory license without the availability of royalty payments to the patent owner.[100] Although its reasoning on this issue is not clear, the Sixth Circuit may have seen these functions as singularly within the scope of primary regulatory actors, such as the PTO and the federal district courts. Additionally, such an expanded role could undermine the usefulness of an expertise agency's focus on its designated subject matter. Despite reinforcing this broad jurisdictional authority, the Sixth Circuit vacated the holding and remanded the decision.[101] The FTC, therefore, had to conduct a new evidentiary hearing, since the FTC had not sufficiently proven that the patent examiner had granted the patent because of the parties' misleading statements.[102] Upon remand, the FTC reaffirmed its previous determination, a decision ultimately upheld by the Sixth Circuit in 1968.[103]

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95 Am. Cyanamid Co. v. FTC, 363 F.2d 757 (6th Cir. 1966).

96 *Id.* at 771.

97 Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172 (1965).

98 Am. Cyanamid Co., 363 F.2d at 770–71.

99 *Id.* at 771.

100 *Id.* at 772.

101 *Id.* at 779.

102 *Id.*

103 Charles Pfizer & Co. v. FTC, 401 F.2d 574 (6th Cir. 1968).

After a period of relative non-use,[104] the FTC has recently re-invigorated *American Cyanamid* to explore the outer boundaries of its jurisdictional authority under section 5. In *In re Union Oil Company of California*,[105] the FTC examined whether or not the Union Oil Company of California ("Unocal") had engaged in unfair methods of competition by failing to disclose to the California Air Resources Board and its competitors that it had pending patent rights that overlapped in key respects with a number of proposed regulations.[106] The administrative law judge (ALJ) held that Unocal had not engaged in anticompetitive practices as a matter of law for two key reasons. First, Unocal's behavior did not fall within any relevant exceptions of the Noerr-Pennington doctrine, which provides antitrust immunity for potential misconduct that involves petitioning a relevant governmental body.[107] Second, the grant of exclusive jurisdiction to district courts in patent cases under § 1338 precluded the FTC's exercise of its jurisdictional powers in the same way. The FTC reversed the ALJ's initial decision on both grounds.[108] While the outcome as to the first issue—the FTC's expansion of the exceptions that apply to remove antitrust immunity under the Noerr-Pennington doctrine[109]—has received more scholarly

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104 *American Cyanamid* has been used as precedent in three ways. First, the Sixth Circuit's opinion in *American Cyanamid* is typically cited for its separate holding that an official's prior participation in a case could disqualify the official from participating in separate administrative hearings. *See*, *e.g.*, *In re* Grand Jury Subpoenas, 573 F.2d 936, 944 (6th Cir. 1978). Second, the FTC has regularly used *American Cyanamid* for its ultimate holding that the FTC could order compulsory licensing of a product. *See, e.g.*, *In re* Borden, Inc., 92 F.T.C. 669, 1978 WL 206107 (F.T.C. 1978). Third, the FTC has also used *American Cyanamid* as precedent to outline the appropriate burden of proof placed on a party that has made a false or misleading statement about a patent. The FTC recently determined that the Complaint Counsel in an FTC adjudicatory proceeding has only to prove that a false or misleading statement was made by a preponderance of the evidence if the statement was made outside of the patent procurement process. *See In re* Rambus, Inc., No. 9302, 2006 W.L. 2330117, at *51 (F.T.C. Aug. 2, 2006). Previously, relying on *American Cyanamid*, the FTC had determined that clear and convincing evidence must be used to demonstrate that false and misleading statement had been made during the course of the patent procurement process. *See In re* VISX, Inc., No. 9286, 1999 WL 33577396, at *97 (F.T.C. May 27, 1999).

105 No. 9305, 2004 FTC LEXIS 115 (F.T.C. July 7, 2004).

106 *Id.* at *1–2.

107 *Id.* at *2.

108 *Id.*

109 In its reversal, the FTC also recognized that a deliberate misrepresentation that substantially affects the outcome of a proceeding can remove the antitrust immunity enjoyed under the Noerr-Pennington doctrine. *Id.* at *25–70.

attention,[110] its holding as to the second issue is equally important within the context of a multi-institutional regime.

Relying on its affirmed holding in *American Cyanamid*, the FTC asserted that its jurisdictional authority rested on three grounds in *Unocal*. Initially, the FTC held that section 5 conferred broad power to prevent unfair methods of competition, including those related to patent enforcement.[111] Next, the FTC dismissed the ALJ's initial decision, which stressed that § 1338 vested district courts with sole jurisdiction over patent matters.[112] Finally, the FTC concluded that its power to interpret substantive questions of the Patent Act was a subsidiary one, since its ultimate holding would neither address invalidity nor infringement, but instead considered whether certain technologies were likely to infringe on Uncoal's patent and, therefore, may not have provided a significant anticompetitive check on Unocal's behavior.[113] Based on these three grounds, the FTC in *Unocal* appears to not only reaffirm its broad interpretative powers under section 5 of the FTC Act, but also offers a reading of § 1338 that asserts that administrative agencies such as the FTC enjoy an equal importance within the context of a heterogeneous regime. Arguably, the FTC attempts to limit the consequences of its interpretative choices by emphasizing the provisional nature of its decisions. This argument, however, ignores the significant additional remedies that the FTC may enjoy under the relevant antitrust statutes.[114]

Beyond its own claims to a broader role within the context of patent law, Congress has recently strengthened the FTC's "expertise" role in patent law.[115] For example, in the Medicare Prescription Drug, Improvement and

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110 *See* M. Elaine Johnston, *Antitrust Liability for Acts and Omissions in Dealing With Government Entities*, 832 PRAC. L. INST. 465, 483 (2005); James B. Kobak, Jr. & Robert P. Reznick, *Antitrust Liability for Statements about Intellectual Property: Unocal, Unitherm, and New Uncertainty*, ANTITRUST, Fall 2004, at 88; Robert E. Kohn, Commentary, *New Antitrust Remedies for Lying to Government Rule Makers*, FED. LAW., Feb. 2005, at 25.

111 *In re* Union Oil Co. of Cal., 2004 FTC LEXIS 115 at *121.

112 *Id.* at *126.

113 *Id.* at *132–34.

114 Herbert Hovenkamp, FEDERAL ANTITRUST POLICY: THE LAW OF COMPETITION AND ITS PRACTICE 596–97 (3d ed. 2005) (remarking that the FTC used section 5 to condemn conduct beyond the bounds of other antitrust laws).

115 Congress has also delegated to the FTC other "expertise" tasks in at least eleven other statutes. *See* Hart-Scott-Rodino Antitrust Improvements Act of 1976, 15 U.S.C. § 18a (2006) (requiring companies to notify the FTC before any proposed merger); Webb-Pomerene Act, 15 U.S.C. §§ 61–66 (2006) (requiring the FTC to examine the issues related to export trade associations); National Cooperative Research and Production Act of 1993, 15 U.S.C. §§ 4301–4306 (2006) (regulating the assessment of joint research and development ventures); International Antitrust Enforcement Assistance Act of 1994, 15 U.S.C. §§ 46, 57b-1,

Modernization Act (MMA) of 2003, Congress, seeking to limit the ability of brand-name patent owners to collude with generic drug producers, created a new statutory assessment of settlement agreements.[116] The MMA provides for two types of review: (1) a review of settlement agreements between generic and brand companies as to the manufacture, marketing or sale of a brand name or generic drug listed in an Abbreviated New Drug Application; and (2) a review of the settlement agreements related to the 180-day period of exclusivity.[117] If this review finds a potential antitrust violation, the FTC or the Department of Justice (DOJ) may conduct an investigation.[118] The FTC's role in reviewing settlement agreements demonstrates the additional difficulty that can result from a designated "expertise" role within a particular regulatory context, as this review adds another layer of complexity to the review of patented pharmaceutical drugs. A patented drug, then, is subject to three levels of control: (1) the PTO assesses the validity of the patent; (2) the FDA reviews the efficacy and safety of the patented drug; and (3) the FTC reviews the anti-competitive consequences associated with the drug. Notably, each of these reviews has a significant impact on the competitive value of a patented drug.

The FTC's role as an "expertise" agency affects the patent regime by offering interested constituencies, for a lack of a better word, flexibility. This flexibility can arise in many ways. Obviously, the FTC enjoys substantive institutional flexibility. Moreover, while the FTC has not taken significant advantage of its ability to undertake notice-and-comment proceedings under section 553 of the APA, the FTC has used its "softer" power to issue study reports under section 46(f) of the FTC Act to advocate for significant changes to the current patent system.[119] Significantly, these "softer" powers appear to be broader

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1311, 1312, 6201, 6202 (2006) (outlining procedures that permit the FTC to coordinate international review of antitrust issues); Deepwater Port Act of 1974, 33 U.S.C. §§ 1501–1524 (2006) (requiring the FTC to evaluate the antitrust consequences of proposed deepwater port licenses); Conservation Service Reform Act of 1986, 42 U.S.C.§ 8201 (2006) (requiring the FTC to assess any antitrust consequences of the supply and installation of residential energy measures); Outer Continental Shelf Lands Act (OCSLA), 43 U.S.C. §§ 1337–1356a (2006) (requiring companies to prepare reports that detail the competitive effects of proposed oil and gas leases on the Continental Shelf).

116 Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066.

117 *Id.* § 1112.

118 21 U.S.C. § 355 (j)(5)(D)(i)(V) (2006).

119 15 U.S.C. § 46(f) (2006). The FTC has most prominently used its section 46(f) powers when it issued its study TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY (2003), *available at* http://www.ftc.gov/os/2003/10/innovationrpt.pdf. In the aftermath of this study, the FTC has

than the type of powers enjoyed by the PTO to conduct notice-and-comment rulemaking procedures under section 2(b)(2)(A) of the Patent Act.[120]

Despite the institutional and theoretical flexibilities enjoyed by the FTC, its "expertise" role can be problematic within the context of a heterogeneous patent regime. Unlike replicators, expertise actors may not be attuned to the substantive goals of the patent regime, since they do not address these issues in a consistent manner. More fundamentally, an expertise actor may privilege the theoretical framework of its substantive area of law, thus "overreaching" in its expertise. Concerns over institutional overreach appear to be at the heart of the Court of Appeals for the Eleventh Circuit's ("Eleventh Circuit") controversial holding in *Schering-Plough Corp. v. FTC*.[121] In *Schering-Plough*, the Eleventh Circuit vacated the FTC's determination that Schering-Plough and two of its generic competitors violated section 1 of the Sherman Antitrust Act due to their use of a reverse payment settlement to settle a patent dispute under the Hatch-Waxman Act.[122]

In *Schering-Plough*, the Eleventh Circuit attempted to prevent institutional overreach on the part of the FTC in a number of ways. First, throughout its opinion, the Eleventh Circuit questioned the methodology undertaken by the Commission in its holding. The Eleventh Circuit faulted the full Commission for ignoring the factual evidence presented to the administrative law judge and, therefore, contended that it owed a lesser level of deference to the Commission than under the "substantial evidence" standard of section 553 of the APA.[123] Second, the Eleventh Circuit refused to accept the FTC's inference that two of the parties, Schering-Plough Corp. and Upshur, were motivated by significant economic concerns in coming to the reverse payment settlement.[124] In its petition for writ of certiorari to the Supreme Court, the FTC argued that this criticism did not take into account its institutional expertise.[125] The FTC stated that

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continued to advocate for substantive changes in the practices criticized. For instance, the FTC recently submitted comments related to the USPTO's proposed changes in continuation practices. Comments of the FTC, *In re* Changes to Practices for Continuing Applications, Requests for Continued Examination Practice, and Applications for Containing Patentably Indistinct Claims, No. 2-5-P-066, (U.S.P.T.O. May 3, 2006), *available at* http://www.uspto.gov/web/offices/pac/dapp/opla/comments/fpp_continuation/ftc.pdf.

120 35 U.S.C. § 2(b)(2)(A) (2006).

121 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 126 S.Ct. 2929 (U.S. 2006).

122 *Id.* at 1073–76.

123 *Id.* at 1062–63.

124 *Id.* at 1068–71.

125 Petition for Writ of Certiorari at *28, FTC v. Schering-Plough Corp., No. 05-273, 2005 WL 2105243 (U.S. August 29, 2005).

"[b]usiness practices and the economic incentives facing businesses are at the heart of the FTC's institutional expertise, and . . . the Commission is entitled to rely on 'common sense and economic theory' in its administrative adjudications."[126]

This exchange demonstrates what the parties considered one of the key issues at stake in *Schering-Plough*: should the behavior of patentees be assessed within a specialized context? In many respects, the Eleventh Circuit's holding in *Schering-Plough* can be seen as a rebuke to the FTC in its attempt to assimilate patentee behavior into a generalized antitrust framework. While many aspects of *Schering-Plough* remain controversial, in some sense, it can be seen as a dialogue about the appropriate role of the expertise actor.

2. Diffuse Review of Patent Validity and Enforcement

The presence of replicative and expertise actors within a multi-institutional framework creates the possibility of diffuse administrative and judicial review of a given issue. I review this diffusion in two different contexts: (1) the primary level, where an initial examiner and, potentially, the ultimate internal reviewing authority review a given issue; and (2) the secondary level, where an external judicial authority reviews the initial decision making of the agency. Each level of review can provoke a different approach to a given issue, thus increasing the availability of competing views of a given patent issue.

i) Primary Review of Patent Validity and Enforcement

The ability of administrative actors (other than the PTO) to initially review core patent issues arises in two ways. First, Congress can include an explicit power to review these relevant patent issues. For example, as discussed infra, Congress amended section 1337 of the Tariff Act to allow the ITC to review all legal and equitable defenses—including the validity of a patent—under the Patent Act.[127] However, this power to review the relevant issues is limited in significant ways. For example, in *Lannom Manufacturing Co., Inc., v. ITC*,[128] the Federal Circuit held that, while the ITC can review challenges to validity or enforcement of a patent raised by a relevant party, the ITC could not raise the same issues sua sponte.[129] In *Lannom,* the ITC attempted to review the validity

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126 *Id.*

127 *See supra* note 37 and accompanying text.

128 Lannom Mfg. Co. v. ITC, 799 F.2d 1572 (Fed. Cir. 1986).

129 *Id.* at 1579.

of a patent after the relevant parties had settled their dispute.[130] In her opinion, Justice Newman emphasized that the ITC could not exercise its interpretative powers without a corresponding claim by an interested party because "[s]pontaneous administrative duplication of the work of one agency by another, to avoid 'mischief' if the first agency erred, shall not be inferred or implied."[131]

Reading *Lannom* and *Kinik* together (both authored by Justice Newman) suggests one perspective of the heterogeneous regime. First, a multi-institutional actor can only be created by an *explicit* grant by Congress. An agency acting within its explicit powers enjoys significant leeway to determine its particular course as to a given regulated resource. That agency, however, cannot overreach the terms of its explicit grant. This prevents potential over-reach by the secondary actor. Under this theory, then, a heterogeneous regime functions best where Congress clearly demarcates the roles that should be played by the secondary actor. Indeed, the ITC has subsequently used *Lannom* as precedent in refusing to examine additional issues, such as inequitable conduct, when a complainant has withdrawn or terminated an action before the agency.[132] Moreover, an explicit grant is more consistent with the idea that Congress uses heterogeneity—the diffusion of administrative responsibility within a particular patent regime to a number of relevant actors—as a type of control over subsequent agency behavior. Discerning legislative intent to create a secondary actor remains the primary difficulty in relying on an explicit congressional grant to define the boundaries of a multi-institutional regime.

The vision laid out in *Lannom* and *Kinik*, however, is inconsistent with the second method used by agency actors to assert primary review of patent validity and enforcement. *American Cyanamid* and its progeny suggest that an agency does not need explicit congressional authorization, but instead can rely on implicit powers contained in other, unrelated statutory grants. An implicit claim relies on two key inferences. First, an implicit claim of primary review relies on expansive interpretation of 28 U.S.C. § 1338(a). Section 1338(a) has typically been interpreted to provide federal district courts with exclusive jurisdiction to review patent and copyright claims, thus precluding state court review of the same matters.[133] Whether § 1338(a) applies to the review of patent valid-

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130 *Id.* at 1573.

131 *Id.* at 1579.

132 *See*, *e.g.*, *In re* Certain Rubber Antidegradants, Components Thereof, and Products Containing Same, 2005 WL 2600632 (U.S.I.T.C. 2005).

133 *See*, *e.g.*, Scherbatskoy v. Halliburton Co., 125 F.3d 288, 291 (5th Cir. 1997) (outlining the jurisdictional limits of § 1338).

ity and enforcement by *federal* administrative actors remains unclear.[134] The FTC has argued that its actions as a federal agency do not fall within the jurisdictional limits of § 1338. For instance, in *Unocal*, the FTC contended that its regulated administrative proceedings were not "civil actions" as stated by § 1338, but rather "proceedings" that fall outside the scope of § 1338.[135] Such a reading of § 1338 is logical in light of the FTC's inability to assess damages under the Patent Act, a power held solely by federal district courts.[136] Thus, the FTC's ability to render decisions on substantive questions of patent law remained provisional. Second, as discussed previously, an implicit claim rests on an aggressive reading of an agency's enacting statute. This aggressive reading may create significant overlap with other actors within a given field, creating some incoherency in articulating the overall goals of the regime.

ii) Secondary Review of Patent Validity and Enforcement

A key consequence of this increased administrative heterogeneity is the rise of secondary judicial actors overseeing agency behavior. The question of decentralization of judicial review within the patent context has recently become the subject of intense academic debate. Craig Allen Nard and John F. Duffy have argued that uniform judicial review of patents by the Court of Appeals for the Federal Circuit should be decentralized to provide a peer, competitive assessment of major patent issues, such as claim interpretation, non-obviousness and written description.[137] Nard's and Duffy's account of the benefits of decentralization is persuasive, particularly if such benefits are viewed in light of a heterogeneous patent regime. Assessing patent law in a multi-institutional perspective supports the view that decentralization is an achievable norm, since secondary judicial review of patent issues may already exist within the current regime. Viewing patent law as a heterogeneous regime thus supplements the Nard and Duffy thesis; however, these perspectives differ in one key respect. Policy-makers seen as subsidiary within a Nard and Duffy framework—namely congressional and agency actors—are crucial in driving the diffusion of judicial

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134 Considerable uncertainty exists over whether other federal courts, such as the Court of International Trade, can exercise jurisdiction over subsidiary patent matters without an explicit grant of jurisdictional authority. *See generally,* K Mart Corp. v. Cartier, Inc., 485 U.S. 176 (1988) (examining the scope of Court of International Trade's jurisdiction under 28 U.S.C. § 1581).

135 *In re* Union Oil Co. of Cal., No. 9305, 2004 FTC LEXIS 115,*125–26 (F.T.C. July 7, 2004).

136 35 U.S.C. § 284 (2006).

137 Craig Allen Nard & John F. Duffy, *Rethinking Patent Law's Uniformity Principle*, 101 NW. U. L. REV. 1619 (2007).

roles.[138] Judicial policy-making in such a perspective is neither isolated nor dominant, but rather intimately involved in policing more active agency and congressional regulators.

Secondary review of the ITC as a replicative actor is straightforward: the Federal Circuit has the power to review any relevant appeals.[139] Again, the FTC serves as a useful counter-example. Two provisions govern the appeal of actions before the FTC. Section 45(c) of the FTC Act provides that a party seeking review of a final order of the FTC can file in the court of appeals within any circuit: (1) "where the method of competition or the act or practice in question was used"; or (2) "where such person, partnership, or corporation resides or carries on business."[140] Additionally, section 45(d) of the FTC Act provides that the designated court of appeal has exclusive jurisdiction over any actions related to the relevant appeal.[141] These two provisions allow more than one circuit to address a relevant issue within the patent regime. For example, the Eleventh Circuit in *Schering-Plough* and the Court of Appeals for the Second Circuit in *In re Tamoxifen Citrate Antitrust Litigation*[142] disagreed with the Sixth Circuit in *In re Cardizem CD Antitrust Litigation*[143] over whether reverse settlement payments were per se unlawful under the relevant antitrust statutes.[144] The resulting

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138 In many ways, the preceding characterization arises from Justice Plager and Lynn E. Pettigrew's useful response to Nard and Duffy's proffered framework. *See* S. Jay Plager & Lynne E. Pettigrew, *Rethinking Patent Law's Uniformity Principle: A Response to Nard and Duffy*, 101 NW. U. L. REV. 1735, 1735–58 (2007). Plager and Pettigrew contend that Nard and Duffy over-privilege judicial policy-making at the expense of other policy-makers that determine the course of patent policy. *Id.* at 1743. A heterogeneous perspective attempts to mediate between these perspectives by arguing that the stronger role being played by subsidiary actors necessarily leads to judicial review of patent-related issues is becoming more diffuse.

139 28 U.S.C. § 1295(a)(6) (2006) (The Federal Circuit has the jurisdiction "to review the final determinations of the United States International Trade Commission relating to unfair practices in import trade, made under section 337 of the Tariff Act of 1930").

140 15 U.S.C. § 45(c) (2007).

141 15 U.S.C. § 45(d) (2007).

142 466 F.3d 187 (2d Cir. 2006).

143 332 F.3d 896 (6th Cir. 2003).

144 *Compare In re* Cardizem CD Antitrust Litig., 332 F.3d at 900 ("The Agreement whereby HMR paid Andrx $40 million per year not to enter the United States market for Cardizem CD and its generic equivalents is a horizontal market allocation agreement and, as such, is *per se* illegal under the Sherman Act and under the corresponding state antitrust laws."), *with In re* Tamifloxen, 466 F.3d at 206 ("[W]e decline to conclude (and repeat that the plaintiffs do not ask us to conclude) that reverse payments are *per se* violations of the Sherman Act such that an allegation of an agreement to make reverse payments suffices to assert an antitrust violation."). *See generally*, Thomas B. Leary, *Antitrust Issues in Settlement of Pharma-*

multiple, and sometimes differing, peer assessments demonstrate the competitive interplay on a given issue between sister circuits; an interplay that Nard and Duffy find necessary.[145]

An interesting jurisdictional question arises given the ability of various circuits to assert jurisdiction to review final orders under § 45 of the FTC Act. In *American Cyanamid* and its progeny, the FTC asserted its ability to review issues related to patent validity and enforcement under § 1338. The Sixth Circuit in *American Cyanamid*, however, reviewed the FTC's ultimate determination under § 45.[146] Notably, however, *American Cyanamid* took place prior to the establishment of the Federal Circuit in 1982 and its exclusive jurisdiction under 28 U.S.C. § 1295.[147] Potentially, an *American Cyanamid* claim would raise the question of whether such a claim would "arise under" patent law, thereby potentially subjecting appellate review of any resulting order to the Federal Circuit under § 1295, rather than section 45 of the FTC Act. Of course, this is further complicated by the ongoing struggle over the scope of the Federal Circuit's "arising under" jurisdiction amongst the federal circuits.[148] While the Supreme Court in *Christianson v. Colt Industries Operating Corp.*[149] held that a claim arises under federal patent law if "a well-pleaded complaint establishes

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ceutical Patent Disputes, Part II, 34 J. HEALTH L. 657 (2001) (outlining disputes between the circuits over "per se unlawful" reverse payments); Thomas B. Leary, *Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes*, *Part III*, 30 SEATTLE U. L. REV. 377 (2007) (outlining disputes between the circuits over "per se unlawful" reverse payments).

145 Nard & Duffy, *supra* note 137.

146 Am. Cyanamid Co. v. FTC, 363 F.2d 757, 761 (6th Cir. 1966).

147 28 U.S.C. § 1295(a)(1) (2006) (The Federal Circuit has jurisdiction over "of an appeal from a final decision of a district court of the United States . . . if the jurisdiction of that court was based, in whole or in part, on section 1338 of this title.").

148 The scope of the Federal Circuit's ability to assert exclusive jurisdiction over patent matters is a source of ongoing controversy. The Supreme Court rejected a contention that a counterclaim could serve as the basis for the exercise of jurisdictional authority under § 1295. Holmes Group, Inc. v. Vornado Air Circulation Sys., Inc., 535 U.S. 826, 830 (2002). This controversy is particularly acute within the context of antitrust law. *See*, *e.g.*, Peter M. Boyle et al., *Antitrust Law at the Federal Circuit: Red Light or Green Light at the IP-Antitrust Intersection?*, 69 ANTITRUST L.J. 739, 740 (2002) (analyzing the impact of broadened jurisdictional claims by the Federal Circuit on antitrust law); Ronald S. Katz & Adam J. Safer, *Should One Patent Court Be Making Antitrust Law for the Whole Country?*, 69 ANTITRUST L.J. 687, 688 (2002) (analyzing the impact of broadened jurisdictional claims by the Federal Circuit on antitrust law); Scott A. Stempel & John F. Terzaken III, *Casting a Long IP Shadow Over Antitrust Jurisprudence: The Federal Circuit's Expanding Jurisdictional Reach*, 69 ANTITRUST L.J. 711, 712 (2002) (analyzing the impact of broadened jurisdictional claims by the Federal Circuit on antitrust law).

149 486 U.S. 800 (1988).

either that federal patent law creates the cause of action or that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law,"[150] this has not necessarily prevented other circuits from asserting jurisdiction over core patent issues. For instance, the Second Circuit, in *In re Tamoxifen*, rejected a party's claim that the court did not have jurisdiction over a complaint that raised issues related to patent validity and enforcement.[151] The Second Circuit argued that its jurisdictional authority was appropriate for two reasons. First, the availability of jurisdiction within a given circuit depended on the content of a plaintiff's complaint; and if the complaint did not properly outline the relevant defense, then jurisdiction could not be based on the *potential* use of patent-related defenses.[152] Second, no "arising under" jurisdiction under § 1338 exists where there is not at least one patent claim pleaded (such as on the attached countervailing claim).[153]

The claim of jurisdictional authority in patent-related matters made by the Second Circuit in *In re Tamoxifen* demonstrates how the presence of expertise actors could potentially alter the parameters of the patent regime. *In re Tamoxifen* offers a framework in which the FTC could potentially avoid the review of patent issues by the Federal Circuit—a claim intensified by the potentially parallel and equal basis of jurisdiction available under 15 U.S.C. § 45(d). Here, the FTC benefits once again from the flexibility of its competitive and consumer missions, which increases its ability to raise alternative theories in a given complaint. This ability could potentially shift a number of patent issues to competing sister circuits; indeed this diffusion may only grow as expert actors, such as the FTC, increase their policy and adjudicative roles. Such diffusion, critics have said, may undermine the uniformity of review that has been a major goal of the current patent regime. Such diffusion, however, may be beneficial to the overall functioning of the patent regime. Indeed, as Justice Stevens noted in his concurrence to *Holmes Group, Inc. v. Vornado Air Circulation Systems, Inc.*:

> Necessarily, therefore, other circuits will have some role to play in the development of this area of the law. An occasional conflict in decisions may be useful in identifying questions that merit this Court's attention. Moreover, occasional decisions by courts with broader jurisdiction will provide an antidote to the risk that the specialized court may develop an institutional bias.[154]

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150 *Id.* at 809.

151 *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 198–99 (2d Cir. 2006).

152 *Id.* at 199 (citing *Christianson*, 486 U.S. at 809).

153 *Id.*

154 *Holmes Group, Inc.*, 535 U.S. at 839 (Stevens, J., concurring).

III. POLICING THE HETEROGENEOUS ADMINISTRATIVE REGIME

Heterogeneous regimes face a key challenge in resolving potential challenges between different agencies. Two methods can be used to resolve competing agency agendas. First, legislative enactment can seek to unify competing agency interests, either by requiring coordinated cooperation by a designated agency mediator, or merging the diverse agencies into one super-agency.[155] Each type of legislative enactment, however, can be undermined by any number of factors. For example, a legislative enactment that designates one agency to coordinate between all the relevant agencies may increase information sharing between them, but may not succeed in reducing interagency conflict if the coordinating agency is not allocated independent power to resolve conflicts.[156] Likewise, a legislative enactment that designates a "super-agency" may face significant challenges in merging different agency functions; or worse, this type of legislation may undermine the goals of a particular subordinate agency.[157]

A more flexible alternative, perhaps, than permanent legislative enactment is continuing judicial oversight that seeks to draw boundaries between agencies as circumstances warrant. Continuing judicial oversight offers one significant advantage over legislative enactment in that judicial oversight does

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155 The Homeland Security Act of 2002 serves as a useful example of this phenomenon. Homeland Security Act of 2002, 6 U.S.C. § 101 (2006). The Act merged a substantial number of formerly independent agencies or units of other agencies into the new Cabinet-level Department of Homeland Security (DHS), including the Transportation Safety Administration, the U.S. Customs & Border Protection, the U.S. Citizenship & Immigration Services, the U.S. Immigration Customs Enforcement Agency, the U.S. Secret Service, the Federal Emergency Management Agency and the U.S. Coast Guard. *See*, *e.g.*, 6 U.S.C. § 313 (2006) (outlining the transfer of various emergency preparedness functions to the DHS); 6 U.S.C. § 203 (2006) (outlining the transfer of transportation functions to the DHS).

156 For example, the FTC and the DOJ are both responsible for administering the antitrust laws. However, neither is in a position to override the actions of the other, and the agencies can stake out opposing positions on the same issue. This manifested itself in *Schering-Plough Corp.*, where the DOJ urged the Supreme Court to reject the FTC's petition to review the Eleventh Circuit's ruling. *See* Brief for the United States as Amicus Curiae, FTC v. Schering-Plough Corp., 126 S. Ct. 2929 (2005) (No. 05-273), 2006 WL 1358441.

157 The recent problems FEMA has faced in carrying out its mission are a prime example of the unintended effects of merging a subordinate agency into a "super-agency." Some of the formerly independent agencies have suffered under DHS rule, even though the Homeland Security Act of 2002 commands that the roles of the absorbed agencies should not be "diminished or neglected." 6 U.S.C. § 111(b)(1)(E) (2006). A 2005 report by Homeland Security Inspector General Richard L. Skinner criticized the actions of FEMA since its absorption into DHS. *See* Dan Eggen, *Homeland Security Is Faulted in Audit: Inspector General Points to FEMA, Cites Mismanagement Among Problems*, WASH. POST, Dec. 29, 2005, at A1 (discussing the audit of the DHS released by Inspector General Skinner).

not prescribe how agencies should act towards one another. Rather, judicial oversight protects against agency overreach in asserting a particular interpretative choice. Judicial oversight, however, is retrospective in nature and cannot proactively coordinate agency behavior in any significant manner.

The patent regime usually attempts to solve the issues of heterogeneity by continuing judicial oversight. I will examine the two avenues that have been used to address issues related to heterogeneity. First, this section will examine how the two types of preclusion—issue and claim preclusion—serve to mark the boundaries between the primary and replicative agencies in a heterogeneous regime. I will next analyze how the use of deference to agency decision-making could be used to police heterogeneous agency behavior.

A. Policing the Boundaries I: Issue and Claim Preclusion in a Heterogeneous Regime

Two key methods of preserving boundaries within a heterogeneous regime are claim and issue preclusion. Claim preclusion[158] bars a second suit between the same parties on the same cause of action or claim,[159] where a valid final judgment has been entered on the merits.[160] Issue preclusion[161] prevents subsequent litigation on an issue of fact or law that was previously litigated and determined by a valid and final judgment, and such determination was essential to the judgment.[162] An analysis of use (or non-use) of these methods to police administrative boundaries reinforces our view of the overall statutory landscape in a heterogeneous regime. The use of claim and issue preclusion is relatively straightforward within the context of replicative actors, and more opaque within the context of expertise actors. Once again, this distinction occurs because

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158 Claim preclusion is also commonly referred to as res judicata. *See* Allen v. McCurry, 449 U.S. 90, 94 n.5 (1980) (discussing the doctrine of res judicata). I will use the term "claim preclusion" for ease of reference.

159 Parklane Hosiery Co. v. Shore, 439 U.S. 322, 326 n.5 (1979).

160 Balt. Luggage Co. v. Samsonite Corp., 727 F. Supp. 202, 205 (D. Md. 1989).

161 Issue preclusion is also commonly referred to as "collateral estoppel." *See* Allen, 449 U.S. at 94 n.5 (discussing the doctrine of collateral estoppel). I will use the term "issue preclusion" for ease of reference.

162 *Id.* The prerequisites for providing a preclusive effect for a decision on the grounds of collateral estoppel are: (i) the issue in the second action must be the same as the issue in the first action; (ii) the issue must have been actually litigated and decided in the first action; (iii) both parties must have had a full and fair opportunity to litigate the issue in the first action; and (iv) the disposition of the issue must have been essential to the judgment. RESTATEMENT (SECOND) OF JUDGMENTS § 27 (1982); 18 CHARLES ALAN WRIGHT, ARTHUR R. MILLER, & EDWARD H. COOPER, FEDERAL PRACTICE AND PROCEDURE § 4416 (1981).

Congress has explicitly defined the role of a replicative actor, whereas the role of an expertise actor arises from powers implicit in unrelated powers.

1. Claim and Issue Preclusion of Decision-Making by a Replicative Actor

The issue of whether or not to accord effect to the factual and legal determinations of preclusion by the ITC in subsequent district court proceedings has, until recently, been relatively controversial.[163] Suggested approaches include: (1) the decisions of the ITC should be given full preclusive effect in subsequent proceedings;[164] (2) the decisions of the ITC should be treated in a bifurcated manner, where factual, but not legal, determinations were given preclusive effect;[165] and (3) the decisions of the ITC should not be given any claim or issue preclusion. The Federal Circuit, in *Bio-Technology General Corp. v. Genentech, Inc.*[166] and *Texas Instruments, Inc. v. Cypress Semiconductor Corp.*,[167] appears to have settled the controversy by adopting the third approach.

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163 *See generally* Douglas P. Martin, *Preclusive Effect of Factual Determinations of the International Trade Commission with Regard to Patent Matters*, 62 U. CHI. L. REV. 885 (1995); Hal D. Baird, Note, *Res Judicata Effect of United States International Trade Commission Patent Decisions*, 6 BYU J. PUB. L. 345 (1992).

164 *See*, *e.g.*, Aunyx Corp. v. Canon, U.S.A., Inc., 978 F.2d 3 (1st Cir. 1992). In *Aunyx Corp.*, the First Circuit examined whether or not to give claim preclusion to a previous decision by the ITC finding for a manufacturer against a dealer in a dispute over copier toners. *Id.* at 5–6. The First Circuit held that the plaintiff was entitled to claim preclusion because the ITC acted in judicial capacity, and thus, its decisions were given res judicata effect. *Id.* at 7. Subsequent cases have limited the scope of *Aunyx Corp*. *See* Minn. Mining & Mfg. Co. v. Beautone Specialties Co., 117 F. Supp. 2d 72, 81 (D. Mass. 1999) (preclusive effect as to issue is accorded to ITC decision-making only within the context of anti-trust findings).

165 *See In re* Convertible Rowing Exerciser Patent Litig., 814 F. Supp. 1197, 1208 (D. Del. 1993) ("Here, as noted, the fact finding by the ITC underlying the legal determination of patent invalidity was necessary for the ultimate determination regarding whether an unfair trade practice had occurred. Because these factual findings represented intermediate 'links in the chain' necessary to the ITC's ultimate determination, they are properly given preclusive effect."); *In re* Convertible Rowing Exerciser Patent Litig., 721 F. Supp. 596, 598 (D. Del. 1989) ("This Court consequently holds that where the ITC makes a determination under section 337 of the Trade Reform Act of 1974 that a patent is invalid and is affirmed by the Federal Circuit, a federal District Court is not estopped from adjudicating the question of the validity of the same patent under its original and exclusive (as to the states) jurisdiction found in 28 U.S.C. § 1338 (1982)."). *See generally* Thomas R. Rouse, Note & Comment, *The Preclusive Effect of ITC Patent Fact Findings on Federal District Courts: A New Twist on* In re Convertible Rowing Exerciser Patent Litigation, 27 LOY. L.A. L. REV. 1417, 1462–63 (1994).

166 80 F.3d 1553 (Fed. Cir. 1996).

167 90 F.3d 1558 (Fed. Cir. 1996).

Bio-Technology and *Texas Instruments*, respectively, address claim preclusion and issue preclusion, and both concluded that ITC decisions need not be given preclusive effect. In *Bio-Technology,* the Federal Circuit examined whether or not to accord a claim-preclusive effect to a dismissal of a complaint with prejudice that the ITC had imposed on Genentech for violating a discovery order.[168] In *Bio-Technology*, the Federal Circuit held that, while the decisions of an administrative agency acting in a judicial capacity could have a claim-preclusive effect,[169] the decisions of the ITC in subsequent district court litigation could not have a claim-preclusive effect.[170] In doing so, the opinion stressed that the legislative history of the ITC indicated that the decisions of the ITC were not to have a preclusive effect, specifically referring to Senate Report No. 1298, which stated that:

> [I]n patent-based cases, the Commission considers, for its own purposes under section 337, the status of imports with respect to the claims of U.S. patents. The Commission's findings neither purport to be, nor can they be, regarded as binding interpretations of the U.S. patent laws in particular factual contexts. Therefore, it seems clear that any disposition of a Commission action by a Federal Court should not have a res judicata or collateral estoppel effect in cases before such courts.[171]

In *Texas Instruments*, the Federal Circuit applied the same reasoning to the doctrine of issue preclusion. The decision, in which the Federal Circuit analyzed whether or not to accord a preclusive effect to the ITC's interpretation of the claims of a disputed patent, also contended the legislative history of § 1337 indicated congressional intent to limit the impact of the ITC's determination on subsequent district court proceedings.[172] Like *Bio-Technology*, *Texas Instruments* stressed the importance of the legislative history in delineating why the ITC's factual and legal decisions are not to be given a preclusive effect. Indeed, *Texas Instruments* emphasized that the legislative intent, expressed in 1974, should trump a number of substantive changes to the procedures of the ITC that could have potentially strengthened the preclusive effect of its decision-making on subsequent proceedings.[173]

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168 *Bio-Technology*, 80 F.3d at 1563.

169 *Id.* (citing Univ. of Tenn. v. Elliott, 478 U.S. 788, 797–99 (1986)).

170 *Id.*

171 *Id*. (citing S. Rep. No. 93-1298 (1974)).

172 *Tex. Instruments, Inc.*, 90 F.3d at 1569.

173 *Id.*

This reasoning is consistent with *Lannom*[174] and *Kinik*[175] in that *explicit* congressional intent should play a central role in defining the limits of a heterogeneous regime. Read together, these four cases offer an instructional map of the role envisioned by the replicative actor. The authority of the replicative actor may be strong within its designated area, but any potential overreaching can be easily corrected by substantial judicial review. The secondary reasons listed in *Bio-Technology* and *Texas Instruments* support this reading. Both suggested institutional and instructional reasons for rejecting the preclusive effect of the ITC's decisions. Initially, in *Bio-Technology*, the Federal Circuit emphasized that the ITC itself accepted this limited reading of its authority in a previous case, *Corning Glass Works v. ITC*.[176] This acquiescence, the Federal Circuit suggested, revealed that the ITC accepted the expressed congressional intent.[177] Moreover, in *Texas Instruments*, the Federal Circuit suggested that its refusal to accord a preclusive effect to the decisions of the ITC served the greater purpose of preserving the Seventh Amendment right to a jury trial enjoyed by patent owners.[178] These outlined reasons suggest the ideal role of the replicator as seen by the Federal Circuit. The ideal replicator is easily confined to the realm of its congressionally mandated role, constrained by a variety of mechanisms from potentially arrogant overreach.

2. Claim and Issue Preclusion of Decision-Making by an Expertise Actor

Determining the preclusive effect of FTC decision-making on subsequent district court proceedings is far more difficult given its role within a generalized antitrust framework. First, the doctrine of claim preclusion is typically not applied in suits that follow FTC adjudication since a usual prerequisite to applying claim preclusion is the presence of the same parties or their privies in the second action.[179] The FTC is an active party in actions it brings, unlike the ITC, which, under § 1337, serves as a forum for determining rights between unrelated parties. Second, the doctrine of claim preclusion does not apply even

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174 Lannom Mfg. Co. v. ITC, 799 F.2d 1572 (Fed. Cir. 1986).

175 Kinik Co. v. ITC, 362 F.3d 1359 (Fed. Cir. 1990).

176 *Bio-Technology*, 80 F.3d at 1564 (citing Corning Glass Works v. ITC, 799 F.2d 1559, 1570 n.12 (Fed. Cir. 1986)).

177 *See id.* at 1564. ("We note that 'the ITC takes the position that its decisions have no *res judicata* effect in [district court] litigation.'").

178 *Tex. Instruments, Inc.*, 90 F.3d at 1569 n.10.

179 RESTATEMENT (SECOND) OF JUDGMENTS § 17 (1982).

when another executive branch agency files a subsequent suit.[180] Thus, for the most part, the doctrine of claim preclusion does not frequently arise as an issue in proceedings that follow administrative actions undertaken by the FTC.

Determining the appropriate role for the doctrine of issue preclusion for the FTC is more complex due to its interactions with the overall antitrust regime. The statutory directive outlined in section 5(a) of the Clayton Antitrust Act complicates the doctrine of issue preclusion within the antitrust regime.[181] Section 5(a) of the Act provides that a "final judgment or decree" in a civil or criminal proceeding brought by a governmental entity can be used as "prima facie evidence" in a subsequent action brought by a private litigant under statutorily enumerated antitrust laws.[182] Congress, in the Antitrust Procedural Improvements Act of 1980,[183] resolved a controversy over whether the "prima facie" standard of section 5(a) preempted the common law doctrine of collateral estoppel by amending section 5 to specify that the doctrine could be applied to every governmental actor *except* the FTC.[184] Thus, a final order[185] of the FTC under the Sherman, Clayton and Robinson-Patman Acts, as well as section 5 of the FTC Act, will not enjoy a preclusive effect in subsequent proceedings.

While section 5(a) prohibits the use of the doctrine of issue preclusion as to the final orders of the FTC, it generally has been interpreted to allow use of the weaker prima facie evidentiary standard for issues determined in previous FTC proceedings.[186] The use of the weaker prima facie evidentiary standard,

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180 *See* United States v. Angelica, 861 F.2d 268 (9th Cir. 1988) (unpublished table decision) (claim preclusion not applicable when FTC is not a party to second action by DOJ).

181 15 U.S.C. § 16(a) (2006).

182 *Id.*

183 Pub. L. No. 96-349, 94 Stat. 1154 (codified at 15 U.S.C. §§ 1311–14 (2006)); *see also* LOUIS ALTMAN & MALLA POLLACK, PARTIES, DEFENSES, REMEDIES AND PROCEDURE, 4 CALLMAN ON UNFAIR COMPETITION, TRADEMARKS AND MONOPOLIES § 23:5 (4th ed. 2007) (summarizing relevant background on this issue).

184 > Nothing contained in this section shall be construed to impose any limitation on the application of collateral estoppel, except that, in any action or proceeding brought under the antitrust laws, collateral estoppel effect shall not be given to any finding made by the Federal Trade Commission under the antitrust laws or under section 45 of this title which could give rise to a claim for relief under the antitrust laws.
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> 15 U.S.C. § 16(a).

185 In addition, section 5(a) does not provide either a prima facie effect or issue preclusion to "consent judgments or decrees entered before any testimony has been taken" issued by the FTC. *Id.*

186 For instance, in *Pool Water Products. v. Olin Corp.*, despite rejecting the use of section 5(a) in the matter before it, the Ninth Circuit held that private plaintiffs could use the prima facie

however, has been interpreted[187] to apply only to orders of the FTC issued under the three acts listed in section 4 of the Clayton Act: (1) the Clayton Act itself; (2) the Sherman Act; and (3) the Wilson Tariff Act and subsequent amendments.[188] Significantly, even the weaker prima facie evidentiary standard outlined in section 5(a) does not appear to apply to these FTC actions brought under section 5 of the FTC Act.[189] Only one case, *North Carolina v. Charles Pfizer & Co., Inc.*,[190] has specifically addressed whether or not the FTC's factual and legal conclusions as to potentially inequitable conduct under the Patent Act can have a preclusive effect in subsequent proceedings. *Chas. Pfizer*, yet another offshoot of *American Cyanamid*, involved the state of North Carolina's attempt to use the FTC's previous factual and legal conclusions under the doctrine of issue preclusion to support its claim that Pfizer, Cyanamid, Bristol, Squibb and Upjohn violated section 1 and section 2 of the Sherman Act by attempting to monopolize the broad-spectrum antibiotic market.[191]

The Fourth Circuit rejected this claim, holding the doctrine of issue preclusion could not apply to the FTC's previous determinations.[192] Initially, the Fourth Circuit contended that the administrative proceedings undertaken by the FTC were not similar to judicial trials and thus should not be accorded the same effect in subsequent proceedings.[193] This particular aspect of the Fourth Circuit's reasoning has not aged particularly well, as the last twenty years have seen a greater willingness to accord administrative proceedings the similar status as trials in subsequent proceedings.[194] Additionally, the Fourth Circuit explained that the strong regulatory powers accorded the FTC under section 5 dif-

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standard of section 5(a) of the Clayton Act in subsequent proceedings. Pool Water Prods. v. Olin Corp. 258 F.3d 1024, 1031 & n.3 (9th Cir. 2001).

187 *Id.* at 1032 n.4.

188 Clayton Act, 15 U.S.C. §§ 12–27, 29 U.S.C. §§ 52–53 (2006); Sherman Antitrust Act, 15 U.S.C. §§ 1–7 (2006); Wilson Tariff Act, 15 U.S.C. §§ 8–11 (2006).

189 *See* Yamaha Motor Co. v. FTC, 657 F.2d 971, 982 (8th Cir. 1981) (holding that "Section 7 is one of the 'antitrust laws' within the meaning of Sections 5(a) and 5(i) of the Clayton Act, while Section 5 of the FTC Act is not."); Nashville Milk Co. v. Carnation Co., 355 U.S. 373, 375–77 (1958) (determining that section 5(a) did not apply to the Robinson-Patman Act because it was not one of the four enumerated statutes outlined in section 4 of the Clayton Act).

190 537 F.2d 67 (4th Cir. 1976).

191 *Id.* at 69.

192 *Id.* at 73–74.

193 *Id.*

194 *See generally* Joel de Jesus, Comment, *Interagency Privity and Claim Preclusion*, 57 U. CHI. L. REV. 195 (1990) (analyzing preclusive doctrines as applied to federal administrative agencies).

ferentiated it from the other primary antitrust statutes—the Clayton Act and the Sherman Act.[195] The Fourth Circuit, relying on *Chas. Pfizer & Co.*,[196] emphasized that the Sherman Act's penal and civil remedies differed substantially from the regulatory remedies available under the Sherman Act.[197] In doing so, the Fourth Circuit stressed the broad scope of the FTC's investigative and interpretive powers under section 5, and thus its fundamental incapacity to fit comfortably within other regulatory regimes.[198]

Finally, the Fourth Circuit stressed that allowing the application of the doctrine of issue preclusion to FTC proceedings would cause inconsistent results within the antitrust regime given the language of section 5(e) of the FTC Act[199] and section 5(a) of the Clayton Act.[200] Because section 5(e) of the FTC Act provides that a Commission order or judgment does not "relieve or absolve any person, partnership, or corporation from any liability under the Antitrust Acts," the Fourth Circuit contended that:

> It would be strangely unfair to permit the Government to litigate under the Sherman or Clayton Acts an issue earlier decided against it in a Section 5 proceeding, and at the same time deny to a respondent the right to defend on the same issues in a subsequent antitrust suit brought by a plaintiff who was not even a party to the administrative proceeding.[201]

Moreover, the Fourth Circuit continued, allowing the use of the issue preclusion doctrine would give an improper advantage to proceedings conducted under section 5, as opposed to criminal proceedings conducted under the Sherman Act, which, at the time, could only rely on the weaker prima facie evidentiary standard outlined under section 5 of the FTC Act.[202]

This last issue, of course, was resolved by the congressional amendments in 1980,[203] and illustrates how, in many ways, *Chas. Pfizer & Co.* is an anachronism. Its concerns over the use of the doctrine of issue preclusion within the context of administrative proceedings are not particularly compelling concerns today. *Chas. Pfizer & Co.*, however, highlights a crucial way to cabin the FTC's expertise powers. The FTC's powers under section 5 can be treated

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195 537 F.2d at 74.

196 205 F. Supp. 94, 96 (S.D.N.Y. 1962).

197 *Chas. Pfizer & Co.*, 537 F.2d at 74.

198 *Id.*

199 15 U.S.C. § 45(e) (2006).

200 15 U.S.C. § 16(a) (2006).

201 *Chas. Pfizer & Co.*, 537 F.2d at 74.

202 *Id.*

203 *See supra* note 183 and accompanying text.

as uniquely sui generis—so utterly singular that their ultimate holdings cannot offer much guidance to subsequent proceedings. What precedent does exist indicates it is likely the administrative rulings of the FTC would not be accorded a preclusive effect (although this is a far from certain conclusion). In many ways, this uncertainty indicates the difficulty associated with an expertise actor within in a heterogeneous regime because such an expertise actor may assert its power intermittently, thus failing to build a consistent record over time on these issues.

B. Policing the Boundaries II: Judicial Review of Statutory Interpretation in a Heterogeneous Regime

Judicial review of agency interpretation is the second primary method of preserving boundaries within the context of a heterogeneous regime. Although questions of judicial deference can vary substantively in terms of what act is under review, a useful way of exploring this method of "policing the boundaries" within a heterogeneous regime is to examine one issue: the judicial deference accorded to various actors' substantive interpretations of the common interpretative statute—the Patent Act. As Stuart Benjamin and Arti Rai recently pointed out,[204] the PTO has not been given the substantial deference usually enjoyed by an agency that interprets its enacting statute under *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*,[205] since the PTO's powers are constrained by section 2 of the Patent Act.[206] The gap left in judicial deference creates interesting anomalies within the patent regime.

This refusal to accord the PTO full interpretive powers perversely allows the ITC, as a replicative actor, to enjoy *more* judicial deference for its substantive interpretations of the Patent Act. By contrast, however, *Chevron* deference has been applied less consistently to the interpretive choices of the FTC, once again reflecting the significant uncertainty that may accompany an exercise of the expertise actor's power within a heterogeneous regime. In any event, the method of "policing the boundaries" is in flux as Congress considers significantly revising the scope of the PTO's interpretive powers.[207] This reform, how-

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204 Benjamin & Rai, *supra* note 6, at 294–301.

205 467 U.S. 837 (1984).

206 The scope of the PTO's powers under section 2 of the Patent Act has itself been the source of ongoing controversy in light of its proposed changes in continuation practice. *See supra* note 242 and accompanying text.

207 *See infra* note 246 and accompanying text.

ever, should recognize the subsidiary roles played by other agencies in applying patent law.

1. Judicial Review of Decision-Making by a Replicative Actor

In recent years, the Supreme Court in three cases—*Christensen v. Harris County*,[208] *United States v. Mead Corp.*[209] and *Barnhart v. Walton*[210]—has revisited the impact of *Chevron* on judicial review of agency interpretations of a given interpretive statute. *Chevron* famously articulates a two-step inquiry that asks: (1) "whether Congress has directly spoken to the precise question at issue," which has been specifically interpreted to mean that congressional intent is "clear" and "unambiguously expressed"; and (2) if statutory ambiguity does exist, "whether the agency's answer is based on a permissible construction of the statute."[211]

Recently, the Supreme Court fitfully compromised *Chevron's* scope in *Christensen*, *Mead* and *Barnhart*, all of which argued that interpretations issued in less formalized agency decisions (e.g., opinion letters and tariff classifications) should not enjoy the type of deference enjoyed by more formalized agency decisions, such as rule-making and formalized adjudications.[212] Rather, those less formalized decisions should be interpreted based on the persuasiveness standard outlined in *Skidmore v. Swift & Co.*,[213] which accords deference on a number of factors, including, inter alia: (1) the thoroughness of the agency's consideration; (2) the validity of the agency's reasoning; and (3) the consistency of the agency's decision-making with earlier decisions and later pronouncements.[214]

Justice Newman's opinion in *Kinik Co. v. ITC*[215] frames the interpretive acts of the ITC, a replicative actor, as consistent under even a modified *Chevron* framework. *Kinik Co.* treats the relevant interpretation at stake as one in which the ITC interpreted its duties under § 1337—its relevant enacting statute—and therefore, "[t]o the extent that there is any uncertainty or ambiguity in the inter-

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208 529 U.S. 576 (2000).

209 533 U.S. 218 (2001).

210 535 U.S. 212 (2002).

211 *Chevron*, 467 U.S. at 842–43.

212 *See* Cass R. Sunstein, Chevron *Step Zero*, 92 VA. L. REV. 187, 212–19 (2006) (analyzing the "Step Zero" Trilogy and its creation of a modified *Chevron* framework).

213 323 U.S. 134 (1944).

214 *Id.* at 140.

215 362 F.3d 1359 (Fed. Cir. 2004).

pretation of § 337(a) and its successor § 1337(a)(1)(B)(ii), deference must be given to the view of the agency that is charged with its administration."[216] Moreover, even under a modified *Chevron* framework, an interpretive choice of the ITC under § 1337 would typically be accorded substantial judicial deference because the ITC issues its statutory interpretations through formalized adjudicatory procedures.[217]

Kinik Co., however, involves a subtle recasting of the actual interpretive choice faced by the ITC. Two statutory texts were at issue in *Kinik Co.*: (1) the text of § 1337(c); and (2) the text of § 271(g) in light of the amendments that attached to the Process Patent Amendment Act of 1988.[218] *Kinik Co.* neatly elides the interpretive choice faced by the ITC by emphasizing that the ITC interpreted the Patent Act as part as of its statutory duties under § 1337.[219] This treatment, however, ignores the central conundrum of § 1337 in that it is an enacting statute whose primary purpose appears to be to allow for a consistent interpretation of *another* statute: the Patent Act. Indeed, the inclusion of the language stating that the ITC can hear all valid "legal and equitable defenses"[220] indicates that for the ITC to properly undertake its duties under § 1337, it must necessarily engage in a series of interpretive choices about issues raised under the Patent Act that have little or nothing to do with a coextensive textual interpretation of § 1337.

Kinik Co. then, leads to an unsatisfactory result. It fails to fully acknowledge the ways in which the ITC is undertaking a substantive interpretation of the Patent Act. Two choices could potentially resolve this ambiguous treatment of the ITC's replicative role: (1) continue to offer deference under *Chevron* based on the ITC's statutory authority to interpret the Patent Act; or (2) offer limited *Skidmore* deference based on the persuasiveness of the given interpretation. The first option would necessarily require a significant revision of our understanding of the overall patent regime. Instead of perceiving the Patent Act as a statute enforced by one agency, the Patent Act should be perceived as one that it is enforced by multiple agencies. In that case, the ITC, as a replicative actor, would be treated as a co-equal enforcer of the Patent Act along with the PTO, and therefore would enjoy full *Chevron* deference for its ongoing interpretations of the Patent Act. Thomas W. Merrill and Kristin E. Hickman—in

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216 *Id.* at 1363 (citing Chevron, 467 U.S. at 843 (1984)).

217 19 U.S.C. § 1337(b) (2006).

218 Process Patent Amendment Act (PPAA) of 1988, 35 U.S.C. § 271(g); *Kinik Co.*, 362 F.3d at 1362.

219 *Kinik Co.*, 362 F.3d at 1362.

220 19 U.S.C. § 1337(c).

describing multi-enforcement schemes such as the DOJ and the FTC's joint enforcement of the antitrust statutes, the Americans with Disabilities Act, the Mine Safety and Health Act—contend that under such multi-enforcement schemes, more than one agency can be accorded full *Chevron* deference.[221] These agencies should enjoy such deference, because "[c]onceivably, Congress could give two or more agencies the power to issue binding regulations or adjudications. If so, then each of the agencies given the appropriate powers should be entitled to mandatory deference."[222]

Recasting the ITC's interpretative choices under the Patent Act would be consistent with the explicit congressional articulation that accompanies the roles of a replicative actor, a choice amplified by the ITC's use of formalized adjudicative processes. Moreover, such a reading is consistent with the Supreme Court's decision in *Barnhart*, which emphasizes that an administrative agency may be offered *Chevron* deference even if it previously reached its interpretations through less formalized procedures when:

> the interstitial nature of the legal question, the related expertise of the Agency, the importance of the question to administration of the statute, the complexity of that administration, and the careful consideration the Agency has given the question over a long period of time all indicate that *Chevron* provides the appropriate legal lens through which to view the legality of the Agency interpretation here at issue.[223]

Such a reading of the ITC's powers would recognize that, while it is not the "primary" agency actor tasked with interpreting the Patent Act, the other factors present—its ongoing expertise in intellectual property within the context of the trade regime, the linkage of its interpretation of the Patent Act with the goals of § 1337 and its consistent consideration of these over time—support *Chevron* deference to its interpretive choices under the Patent Act.

One central problem presents itself, however, if such *Chevron* deference would be given to ITC's interpretive choices under the Patent Act. The statutory text of the Patent Act itself fails to recognize other actors beyond the designated primary actors, thus leading to questions of whether or not Congress has expressly delegated to the ITC powers to interpret the Act.[224] For instance, in *Nutrinova Nutrition Specialties & Food Ingredients GmbH v. ITC*,[225] the Federal Circuit upheld a determination by an ITC ALJ that the timing of a determination

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221 Thomas W. Merrill & Kristin E. Hickman, Chevron*'s Domain*, 89 GEO. L.J. 833, 894 (2006).

222 *Id.*

223 Barnhart v. Walton, 535 U.S. 212, 222 (2002).

224 35 U.S.C. §§ 1–2 (2006).

225 224 F.3d 1356 (Fed. Cir. 2000).

related to a presumption granted to process patent owners under 35 U.S.C. § 295 could be held after discovery despite the fact that the text of § 295 refers only to a "court" making such a determination.[226] The Federal Circuit merely alluded to this textual problem in a footnote, concluding that because the ITC had not raised this issue as a particular problem, it would treat the matter as waived.[227] Thereafter, the Federal Circuit simply treated the ALJ as a trial court tasked with reviewing § 295.[228] *Nutrinova* demonstrates the difficulties of reconciling the explicit congressional expansion associated with the ITC's duties with the relatively static statutory text of the Patent Act. It is difficult to argue that *Chevron* deference would be owed to the ITC's interpretive choices under the Patent Act if the Act itself does not expressly delegate this role of the ITC. This disjoint may reflect the fact that the expansion of the ITC's role occurred after the passage of the Patent Act in 1952.[229]

If full *Chevron* deference is not appropriate, given the language of the Patent Act itself, a *Skidmore* type of deference may be appropriate for ITC decision-making under most circumstances. Using a *Skidmore* framework would still result in considerable deference because ITC procedures are formalized. Moreover, the ITC consistently applies the Patent Act in a designated expertise area. This type of deference may be more appropriate in a heterogeneous regime so as not to overwhelm the decision-making of the primary actors.

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226 *Id.* at 1359. "In actions alleging infringement of a process patent based on the importation, sale, offer for sale, or use of a product which is made from a process patented in the United States, if the *court* finds . . . ." 35 U.S.C. § 295 (2006) (emphasis added).

227 *Nutrinova*, 224 F.3d at 1360 n.1. "Trial courts are generally given discretion to determine when decisions concerning procedural matters are to be decided." *Id.* at 1360. *See*, *e.g.*, Ciena Corp. v. Jarrard, 203 F.3d 312, 319 (4th Cir. 2000) ("[B]road discretion is given to the district court to manage the timing and process for entry of all interlocutory injunctions . . . ."); *In re* Temporomandibular Joint (TMJ) Implants Prods. Liab. Litig., 113 F.3d 1484, 1492 (8th Cir. 1997) ("[P]laintiffs have failed to show that the District Court abused its discretion regarding the timing of its entry of summary judgment . . . ."). "Trial courts have this discretion because the facts of every case are different, and the appropriate time for a trial court to make a decision concerning a procedural matter depends on the circumstances." *Nutrinova*, 224 F.3d at 1360.

228 Subsequent cases have treated *Nutrinova* as precedent for the ability of a district court to determine its own procedural timing under the Patent Act. *See*, *e.g.*, Westvaco Corp. v. Viva Magnetics Ltd., No. 00CIV.9399LTSKNF, 2002 WL 31052870, at *2 (S.D.N.Y. Sept. 13, 2002).

229 *See supra* note 37 and accompanying text.

2. Judicial Review of Decision-Making by an Expertise Actor

While any discussion of the deference accorded the ITC's interpretative choices reflects a full range of options for a decision-maker, arguably the FTC may enjoy little or no deference, even under a *Skidmore* framework, for its interpretive choices under the Patent Act. Two reasons would support such a choice.

Initially, as previously discussed, the FTC's interpretive choices under the Patent Act arise from its implicit exercise of its unrelated statutory power under section 5. Considerable difficulties would then exist if the FTC sought *Chevron* deference to these interpretative choices. Congress, itself, has not expressed any clear guidance as to whether or not the FTC should even engage in the role it has undertaken for itself. This lack of congressional intent is further illustrated by the fact that Congress typically exercises less subsequent control over the actions of independent agencies such as the FTC.[230] And while this may mean that the FTC enjoys significant deference in its interpretation of the antitrust statutes or other statutes it explicitly administers,[231] the FTC's authority may weaken substantially as it moves away from these designated competencies.

Moreover, while the FTC has undertaken its interpretive choices within formalized adjudicative procedures (a choice given substantive weight in *Mead Corp.*[232]), it has done so intermittently over time. Such a failure to consistently interpret a developed precedent over time (similar to the ITC) necessarily weakens its claim of expertise on patent-related issues. Such a weakness arguably lessens the persuasive value of the FTC's decisions within the context of *Chevron* deference. Again, this difficulty highlights the weakness of an expertise actor within a heterogeneous regime because its role generally has been unacknowledged. More importantly, the potential lack of persuasive value of FTC

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230 Randolph J. May, *Defining Deference Down: Independent Agencies and* Chevron *Deference*, 58 ADMIN. L. REV. 429, 451 (2006).

231 For instance, the Court of Appeals for the District of Columbia held that, as part of the FTC's power under the Fair Credit Reporting Act, it could interpret an ambiguous provision of the Gramm-Leach-Bliley Act because "[w]here . . . Congress enacts an ambiguous provision within a statute entrusted to the agency's expertise, it has 'implicitly delegated to the agency the power to fill those gaps.'" Trans Union, LLC v. FTC, 295 F.3d 42, 50 (D.C. Cir. 2002) (citing County of Los Angeles v. Shalala, 192 F.3d 1005, 1016 (D.C. Cir. 1999).

232 United States v. Mead Corp., 533 U.S. 218, 229 (2001) ("We have recognized a very good indicator of delegation meriting *Chevron* treatment in express congressional authorizations to engage in the process of rulemaking or adjudication that produces regulations or rulings for which deference is claimed.").

decision-making in this area highlights the fact that judicial review of its decision-making can—and should—be searching.

Furthermore, an expertise actor may suffer, as does the FTC, given that the issue of *Chevron* deference remains unresolved in the statutory context from which the FTC derives its own expertise. The role of *Chevron* deference in the decisions of the FTC and DOJ within the context of antitrust law remains largely unresolved. The treatment of *Chevron* within the context of FTC decision-making has been quite varied. The FTC has enjoyed substantial deference under the *Chevron* framework as to those singular statutes, such as the Magnuson-Moss Warranty Trade Commission Act and the Fair Credit Reporting Act, which Congress has specifically entrusted to its expertise.[233]

Judicial review of its interpretive choices under section 5 of the FTC Act has been more searching. For example, in *FTC v. Indiana Federation of Dentists*,[234] the Supreme Court stated that the FTC's judgment over whether or not a particular commercial practice is deemed "unfair" under section 5 was due "some deference," a standard that it did not clarify in the rest of the opinion.[235] Subsequent precedent interpreted this statement to mean that the lesser *Skidmore*-type deference is owed to FTC decision-making based on its reasonableness, consistency and persuasiveness.[236] This choice has been criticized. Daniel A. Farber and Brett McDonnell contend that the FTC's interpretive choices may be owed a stronger level of deference, because of the congressional intent to "invest[] agencies, not courts, with wide discretion in such areas," and, more-

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233 The FTC has enjoyed full deference under the *Chevron* framework for its interpretive choices under the Fair Credit Reporting Act. *See*, *e.g.*, Trans Union, LLC, 295 F.3d at 50–51 (FTC's definition of "personally identifiable financial information" (PIFI) permissible given the congressional failure to determine the term); Trans Union Corp. v. FTC, 81 F.3d 228, 231 (D.C. Cir. 1996) (FTC interpretation of a disputed term accorded deference even under *Skidmore*'s limited deference framework); Estiverne v. Sak's Fifth Ave., 9 F.3d 1171, 1173 (5th Cir. 1993) (judicial deference to the FTC's interpretation of the term "consumer report" in the Fair Credit Reporting Act). More uncertainty exists over whether to accord full deference to the FTC in its interpretation of terms in the Magnuson Moss Warranty Act (MMWA). *Compare* Walton v. Rose Mobile Homes, LLC, 298 F.3d 470, 475 (5th Cir. 2002) (FTC interpretation of MMWA not accorded *Chevron* deference), *with* Higgs v. Warranty Group, No. C2-02-1092, 2007 WL 2034376, at *8 (S.D. Ohio July 7, 2007) (FTC interpretation of MMWA accorded full deference under *Chevron* framework).

234 476 U.S. 447 (1986).

235 *Id.* at 454.

236 *See*, *e.g.*, Detroit Auto. Dealers Ass'n v. FTC, 955 F.2d 457, 461 (6th Cir. 1992) ("In reviewing the FTC decision, we gave plenary review to its analysis of legal issues, but it is entitled, nevertheless, to some deference. . . . We must determine whether the interpretation of the statute in this case made by [the] FTC, a government agency, is 'reasonable, consistent, and persuasive.'" (citations omitted)).

over, because greater skepticism should be given to "judges trying to assert great discretionary authority in an area where Congress has given such authority to a specialized agency."[237] This logic may be reasonable in light of the FTC's enumerated roles within the antitrust and consumer regimes. Less deference may be owed to its forays into less core areas.

IV. CONCLUSION: REFORM CHOICES IN A HETEROGENEOUS LANDSCAPE

Significant parts of the "patent" landscape then, remain shifting and uncertain. Some conclusions, however, can be reached. Initially, a cautionary note must be sounded about the role of the expertise actor, such as the FTC, within the context of the patent regime. Significant conceptual and theoretical uncertainty may accompany the FTC's role. Its expertise arises from its implicit powers under section 5 of the FTC Act, and thus, does not arise out of the organic goals of the patent regime. These concerns, however, may be addressed by the methods of policing the boundaries—refusing to accord strong preclusive effect to its legal and factual decision-making, and searching judicial review of its interpretative choices under the Patent Act.

Additionally, viewing patent law within a heterogeneous landscape highlights two key aspects of the PTO's role as a primary actor. First, the PTO has been reluctant to acknowledge the role of other actors. What little precedent exists indicates that the PTO regards interpretations of the Patent Act by other actors with little deference. For instance, in *Ex parte Baker*,[238] the Board of Patent Appeals and Interferences (BPAI), examining an item of relevant prior art within the context of a re-examination proceeding, stated that it did not need to offer deference to any pre-existing ITC determinations.[239] The BPAI stressed that its re-examination was based on a different factual ground than the one conducted by the ITC,[240] and more importantly, "[w]e know of no authority and appellants have cited none, as was their responsibility, for the proposition that we are bound by the decisions of the ITC."[241] *Ex parte Baker* usefully reveals the uneasy relationship between the PTO—the primary regulatory actor—and the subsidiary actors. Other actors often operate with different statutory impera-

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237 Daniel A. Farber & Brett H. McDonnell, *"Is There a Text in This Class?" The Conflict Between Textualism and Antitrus*t, 14 J. CONTEMP. LEGAL ISSUES 619, 655 (2005).

238 1997 WL 1935474, *7–8 (B.P.A.I. 2007) (unpublished).

239 *Id.* at *8.

240 *Id.*

241 *Id.*

tives than the PTO. Thus, it may be difficult to fit the actions of subsidiary actors into the PTO's statutory framework.

Second, viewing its behavior within a heterogeneous landscape highlights the PTO's relative powerlessness as a policy-maker. For instance, the theoretical flexibility enjoyed by the FTC under section 5 demonstrates the corresponding inflexibility of section 2 under the Patent Act. Section 5 of the FTC Act gives the FTC the ability to craft expansive remedies that respond to actions of its regulated constituencies. A buffet is a useful metaphor to describe the potential agency behavior sanctioned by section 5. The agency can choose from a variety of options to implement its decision in a manner that protects the widest variety of interests.

By contrast, section 2 of the Patent Act significantly limits how the PTO can respond to overly aggressive constituent behavior or new policy concerns. Under section 2, agency behavior is channeled into discrete avenues that offer little maneuverability to the relevant agency actors. For instance, a correctly granted patent can only be rescinded through a series of doctrinal funnels such as reissue,[242] correction of mistakes[243] or reexamination.[244] The PTO does not have the power to respond to mistakes that fall outside of these avenues. The Patent Act, to extend the above metaphor, acts very much like a "prix-fixe" menu. The administrative actor is offered a set of already-determined choices that offers little flexibility in either initiating change or fashioning an appropriate remedy. The "prix-fixe" nature of the Patent Act is amplified by its failure to grant the PTO broad notice-and-comment rulemaking beyond its current power under section 2(b)(2)(A) of the Act.[245] The limited power of the PTO in a heterogeneous landscape creates significant disadvantages vis-à-vis more flexible institutional actors such as the FTC.

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242 35 U.S.C. § 251 (2006); *see also* Merck & Co. v. Kessler, 80 F.3d 1543, 1549–50 (Fed. Cir. 1996) ("As we have previously held, the broadest of the PTO's rulemaking powers—35 U.S.C. § 6(a)—authorizes the Commissioner to promulgate regulations directed only to 'the conduct of proceedings in the [PTO]'; it does NOT grant the Commissioner the authority to issue substantive rules. . . . Because Congress has not vested the Commissioner with any general substantive rulemaking power, the 'Final Determination' at issue in this case cannot possibly have the 'force and effect of law.'").

243 35 U.S.C. § 254 (2006) (correction of mistakes committed by the USPTO); 35 U.S.C. § 255 (2007) (correction of mistakes committed by the patent owner); 35 U.S.C. § 256 (2006) (correction of the named inventor).

244 35 U.S.C. §§ 301–307 (2006) (outlining the procedures related to ex parte reexamination procedures).

245 35 U.S.C. § 2(b)(2)(A) (2006).

Expanding the powers of the PTO—that is, allowing it to exercise significant, independent powers with a "buffet" of institutional flexibility under section 2—has been the subject of intense debate during the drafting of the Patent Reform Act of 2007.[246] The current patent debate has seen three attempts to rewrite the boundaries of section 2 of the Patent Act. For example, in the initial draft of the Senate's Patent Reform Act, section 11 would have allowed the PTO to issue any rules and regulations that were necessary: (1) to enact its responsibilities under the Patent Act; (2) to enact its duties under other relevant acts; and (3) to govern issues related to the Office.[247] Section 11 was remarkable for two key reasons. First, it granted the PTO broad notice-and-comment rulemaking under section 553—a clear shift from section 2(b)(2)(A), which only allows the PTO to govern the proceedings of the Office.[248] This would grant significant flexibility to the PTO to respond to a broader range of policy concerns.[249] Second, section 11(a) would have granted the PTO the power to interpret *other* relevant acts that impact its statutory duties.[250] Thus, under the newly revised section 11, the PTO would have the ability to address issues, such as competitive concerns, that may impact the use of an issued patent.[251] These two changes represented a significant shift from the "prix-fixe" model of administrative governance outlined by the Patent Act.

Congress, however, significantly reduced the scope of the proposed section 11 in subsequent versions of the Patent Reform Act of 2007. The final version of the Act of 2007, ultimately passed by the House, did not include the broad re-conceptualization of the PTO's powers contained in section 11.[252] Rather, the House's newly drafted section 14 amended section (2)(c) of the current Patent Act to allow the PTO to regulate continuation practice under sections 120, 121 and 365(c).[253] Section 14 is an obvious shift from section 11. Indeed,

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246 Patent Reform Act of 2007, S. 1145, 110th Cong. § 11 (as proposed on April 18, 2007). The companion House provision was initially substantially similar. H.R. 1908, 110th Cong. § 11 (as proposed on April 18, 2007).

247 S. 1145 § 11. Section 11(a) clearly contemplated that this statutory power would be broader than the current section 2(b)(2)(A) since section 11(c) also refers to the lesser-included power to govern the proceedings of the USPTO.

248 35 U.S.C. § 2(b)(2)(A).

249 For instance, the USPTO could conduct a rulemaking procedure that could address an international intellectual property policy issue given its advisory role outlined in section 2(b)(8) of the Patent Act. 35 U.S.C. § 2(b)(8) (2006).

250 *See* S. 1145 § 11(a).

251 *Id.*

252 Patent Reform Act of 2007, H.R. 1908, 110th Cong. (as passed by House, Sept. 7, 2007).

253 H.R. 1908 § 14(a).

the language of the House Report suggests that the amendment of section 14 was intended to "clarify and reiterate that the PTO has always had authority to promulgate rules that place limitations or conditions on patent applications, including continuation applications, that do not directly contradict any such limitations or conditions expressly stated in statute."[254] Section 9, the manager's amendment to the Senate version of the Patent Reform Act, even eliminates this additional ability to issue rules related to continuation proceedings before the PTO.[255] The congressional response to the debate over continuation practices reflects the intense debate over the proper role of the PTO in regulating—not simply issuing—patents. Even the modest claim by the PTO that it can write procedures as an aspect of its governance powers under section 2(b) of the Patent Act creates significant, if not vociferous, dissent on the part of the traditional patent constituency.[256]

The growing complexity of the patent regime, however, suggests that perhaps the PTO will have to act in potentially more aggressive ways to satisfy broader complaints from the public over the perceived inefficiencies in the overall patent regime. Indeed, in the debate over H.R. 1908, Representative Mel Watt, noted that:

> One of the changes that I think hasn't gotten much attention in this bill that I was surprised at as a member of the Financial Services Committee that has so many regulators of the various parts of our financial system which can promulgate rules, it seemed to me when I found out the Patent and Trade Office [sic] really didn't have the authority to promulgate any meaningful rules, that that was contributing to the problem, because innovations and ideas and inventions and communications are traveling so fast that the law can't always keep up with them. It is in that context that meaningful regulation is important.[257]

This concern will only be heightened by what may be an unintended consequence of patent reform. A primary interpretative actor may be necessary to resolve the significant interpretative ambiguities that will arise in the transition to a first-inventor-to-file regime.

Moreover, this attempt to reform the PTO's regulatory authority is complicated by its role in a heterogeneous landscape, which creates an ongoing tension because PTO's powers cannot be expanded in such a way that would interfere with the powers of other patent regulators. Notably, during the debate

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254 H.R. REP. NO. 110-314, at 45 (2007).

255 S. 1145 (as reported by S. Comm. On the Judiciary, July 20, 2007).

256 *See supra* note 5 and accompanying text.

257 153 Cong. Rec. H10277 (daily ed. Sept. 7, 2007) (statement of Rep. Watt).

over H.R. 1908, Representative Charles Rangel, chairman of the House Ways and Means Committee, wrote a letter to Representative John Conyers requesting to be placed on the Conference Committee so that any patent reform ultimately passed would take into account its impact on import trade.[258] Rangel's request demonstrates the importance that congressional legislators place on maintaining the powers of other patent regulators. While such battles may preserve the influence of regulators such as Rangel, the result of these debates is the diffusion of regulatory influence over patents throughout multiple agencies. This diffusion would ultimately lead to a less involved role for the PTO.

While the actions of Representative Rangel during the debate over H.R. 1908 indicate that congressional awareness of this heterogeneity is present, viewing patent reform in a heterogeneous landscape cautions against the incrementalist approach that undergirds much of the reform debate. Congress has undertaken patent reform in the last three years without significant discussion about whether a wholesale rewriting of the Patent Act is necessary in order to achieve the reform. Reform, then, has been conservative in its approach, seeking to engraft broad changes over the preexisting infrastructure of the Patent Act of 1952. Such reform may ignore the ways in which the statutory text of the current Patent Act, itself, is not serving the goals of a far more heterogeneous regime. Building a new super-structure on a preexisting statutory infrastructure, without resolving the roles of other heterogeneous actors, may further undermine the coherency of our current regime. In the end, perhaps, recognizing the current shape our patent landscape has taken suggests our map still remains provisional.

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[258] See Appendix for the entire discussion over the jurisdictional authority of the House Committee on Ways and Means.

APPENDIX

Discussion over the jurisdictional authority of the House Committee on Ways and Means, 153 CONG. REC. H10295–96 (daily ed. Sept. 7, 2007):

> Mr. SMITH of Texas. I want to thank the chairman of the Judiciary Committee for yielding me time.
>
> Mr. Chairman, I want to be unequivocal, first of all, in saying that I support this manager's amendment.
>
> I yield to my friend from California (Mr. HERGER) for purposes of a colloquy.
>
> Mr. HERGER. I would like to thank the ranking member for engaging in this colloquy.
>
> As you know, the manager's amendment was released yesterday afternoon, and it contains language concerning section 337 proceedings before the U.S. International Trade Commission.
>
> However, this language was not considered by the Committee on Ways and Means, even though it is squarely in our jurisdiction. I am aware that Chairman RANGEL and Chairman CONYERS have exchanged letters in which Chairman CONYERS has acknowledged that this issue is within the jurisdiction of the Ways and Means committee. I will support a request for conferees to be named from the Ways and Means committee.
>
> As you know, section 337 proceedings are very complex, and we must ensure that the full ramifications of this language are clearly understood.
>
> As ranking member of the Ways and Means Trade Subcommittee, I hope that you would agree with me that these provisions warrant further analysis and ask that you would work with me and other members of the committee in conference to ensure that these provisions are thoroughly understood as the bill moves through the legislative process.
>
> Mr. SMITH of Texas. Mr. Chairman, I want to thank my friend from California for pointing these provisions out, and I certainly do agree with them, and we will work towards that goal.
>
> Mr. CONYERS. Would the ranking member yield to me?
>
> Mr. SMITH of Texas. I yield to the chairman of the committee.
>
> Mr. CONYERS. Thank you. I want to assure the gentleman.
>
> Mr. Chairman, I would submit for the RECORD a letter dated September 7, 2007, between myself and the chairman of Ways and Means, CHARLES RANGEL.
>
> HOUSE OF REPRESENTATIVES,
> COMMITTEE ON WAYS AND MEANS,
> *Washington, DC, September 7, 2007.*

Hon. JOHN CONYERS, Jr.,
Chairman, Judiciary Committee,
Washington, DC.

DEAR JOHN: I am writing regarding H.R. 1908, the Patent Reform Act of 2007. During consideration of the bill by the Rules Committee, a manager's amendment was made in order that includes provisions affecting section 337 of the Tariff Act of 1930.

As you know, section 337 falls within the jurisdiction of the Committee on Ways and Means. The Ways and Means Committee has jurisdiction over all issues concerning import trade matters.

In order to expedite this legislation for floor consideration, the Committee will forgo action on this bill, and will not oppose the inclusion of this provision relating to section 337 of the Tariff Act within H.R. 1908. This is being done with the understanding that it does not in any way prejudice the Committee with respect to its jurisdictional prerogatives on this bill or similar legislation in the future.

I would appreciate your response to this letter, confirming this understanding with respect to H.R. 1908, and would ask that a copy of our exchange of letters on this matter be included in the RECORD.

Sincerely,

CHARLES B. RANGEL,
Chairman.

HOUSE OF REPRESENTATIVES,
COMMITTEE ON THE JUDICIARY,
Washington, DC, September 7, 2007.

Hon. CHARLES B. RANGEL,
Chairman, Committee on Ways and Means,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: Thank you for your recent letter regarding your committee's jurisdictional interest in H.R. 1908, the Patent Reform Act of 2007.

I appreciate your willingness to support expediting floor consideration of this important legislation today. I understand and agree that this is without prejudice to your Committee's jurisdictional interests in this or similar legislation in the future. In the event a House-Senate conference on this or similar legislation is convened, I would support your request for an appropriate number of conferees.

I will include a copy of your letter and this response in the CONGRESSIONAL RECORD during consideration of the bill on the House floor. Thank you for your cooperation as we work towards enactment of this legislation.

Sincerely,

JOHN CONYERS, Jr.
Chairman.

I completely agree that it was totally inadvertent, and we want the Ways and Means Committee to assert, and we will help them assert, their full rights in terms of jurisdiction in this matter. I thank him for bringing it to our attention.