TOWARDS FDA–USPTO COOPERATION

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The Food and Drug Administration ("FDA") and U.S. Patent and Trademark Office ("USPTO") play complementary roles in driving pharmaceutical innovation. Yet, for the most part, the agencies conduct their affairs without regard for one another. Recent calls for a "whole of government" approach to reduce this departmentalism have led to only modest initiatives. Collectively, the FDA and USPTO have announced mandates that they have no intention of enforcing; conducted cross-training in topics that their employees will most likely never use; and resisted proposed legislation that would formalize their relationship.

Current agency intransigence represents a lost opportunity to further the goals of the Hatch–Waxman Act: encouraging the labors that lead to pharmaceutical innovation, while also distributing the fruits of those labors to the public through low-cost, generic medications. At a minimum, agency cooperation could lead to consistent and accurate terminology. The FDA and USPTO should coordinate their policies toward adjusting patent terms to account for regulatory delays. They should also act jointly to enhance the Orange Book, an FDA publication that in part acts as a clearinghouse for pharmaceutical patents. The USPTO should issue patents along the lines of the inventive categories identified with the Hatch–Waxman Act. For its part, the FDA ought to take advantage of USPTO resources to maintain the integrity of the Orange Book by striving toward accurate patent listings.

The FDA's anomalous "use code" practice deserves reconsideration. The FDA does not assess the scope of patents claiming methods of medical treatment based on the instrument the USPTO granted. Rather, it relies upon brand-name drug companies to characterize these patents using 250 characters or less. Use codes defy foundational patent law principles and have been prone to abuse. This dubious approach to complex legal texts approved by a peer agency should be modified or abolished.

The FDA and USPTO are also well-positioned to consider the idiosyncratic and possibly unbalanced practices of pharmaceutical patent enforcement. During these cases, which for the most part arise in just 2 of the 94 federal districts in the United

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States, generic drug companies must explain at the outset why they don't infringe—even though the patent proprietor bears the burden of proving infringement. Congress also afforded brand-name drug companies the ability to sue a dozen or more generic drug companies in one courtroom at one time, for no other reason than that they allegedly infringe the same patent. These and other litigation practices bear reassessment.

Finally, the USPTO routinely issues patents with dozens or hundreds of claims. It also issues multiple patents covering the same drug. Such prolix USPTO work product has resulted in coping strategies by courts, which must encourage or cajole patent proprietors into choosing just a few of these claims to be subject to adjudication. That so many pharmaceutical patent claims remain unadjudicated breeds uncertainty, particularly with respect to FDA administration of regulatory exclusivities. These issues should be addressed through changes to agency practice or to the wording of the Hatch–Waxman Act.

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INTRODUCTION

Four decades ago, the Hatch–Waxman Act welded the patent laws and food and drug laws together.[1] Yet the Food and Drug Administration ("FDA") and U.S.

1. Pub. L. No. 98-417, 98 Stat. 1585 (1984). The Hatch–Waxman is more formally known as the Drug Price Competition and Patent Term Restoration Act. *See generally* George Encarnacion Jr., *The Future of Healthcare is Generic: Expanding Hatch-*

Patent and Trademark Office ("USPTO") have remained reluctant suitors.[2] They currently interact only when they increase the term of a patent to compensate for regulatory delays—and even here, the FDA refers to the concept as the "restoration" of the patent term,[3] while the USPTO prefers the term "extension."[4] That the two agencies cannot even agree on common terminology immediately suggests that they are not on the same page.

Given this degree of departmentalism, the Biden Administration called for a "whole of government" approach that seeks common solutions to pressing issues of public health.[5] The response of the FDA and USPTO has been muted. Collectively, they have announced mandates that they have no intention of enforcing;[6] conducted cross-training in topics that their employees will most likely never use;[7] and resisted proposed legislation that would formalize their relationship.[8]

The current indifference of the FDA and USPTO towards achieving valuable reforms, while regrettable, was predictable. It is reminiscent of the FDA's reaction to the Medicare Prescription Drug, Improvement, and Modernization Act ("MMA").[9] This 2003 legislation introduced multiple reforms involving patents and the Hatch–Waxman Act.[10] However, the FDA did not issue a final rule implementing these provisions until 2016—about 12 years and ten months later.[11] This glacial pace should not raise high hopes that the FDA will eagerly embrace the opportunity to partner with the USPTO.

Waxman to Equitably Regulate the Healthcare Products Industry, 24 DEPAUL J. HEALTH CARE L. 2 (2023); Winston Zou, *Fixing the Hatch-Waxman Imbalance: A Proposed Solution to the Problem Created by Inter Partes Review*, 47 AM. INTELL. PROP. L. ASS'N Q.J. 635 (2019); Shashank Upadhye, *There's a Hole in My Bucket Dear Liza, Dear Liza: The 30-Year Anniversary of the Hatch-Waxman Act: Resolved and Unresolved Gaps and Court-Driven Policy Gap Filling*, 40 WM. MITCHELL L. REV. 1307 (2014); Teresa J. Lechner-Fish, *The Hatch-Waxman System: Suffering a Plague of Bad Behavior*, 5 HOUS. BUS. & TAX L.J. 369 (2005).

2. *See, e.g.*, Rebecca S. Eisenberg & Daniel A. Crane, *Patent Punting: How FDA and Antitrust Courts Undermine the Hatch-Waxman Act to Avoid Dealing with Patents*, 21 MICH. TELECOMMS. & TECH. L. REV. 197, 198–204 (2015) (noting the distinct, solitary roles of the FDA and USPTO).

3. 21 C.F.R. § 60.2 (2023) ("The purpose of this part is to establish a thorough yet efficient process for the Food and Drug Administration review of patent term restoration applications.").

4. 37 C.F.R. § 1.710 (2022) ("Patents subject to extension of the patent term.").

5. *See* Exec. Order No. 14,036, 3 C.F.R. § 5(p)(vi) (July 9, 2021).

6. *See infra* Section III.A.

7. *See infra* Section III.B.

8. *See infra* Section III.C.

9. Pub. L. No. 108-173, 117 Stat. 2066 (2003).

10. *See* Colleen Kelly, *The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond*, 66 FOOD & DRUG L.J. 417, 432–36 (2011); Matthew Avery, *Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments*, 60 HASTINGS L.J. 171, 184–87 (2008).

11. Abbreviated New Drug Applications and 505(b)(2) Applications, 81 Fed. Reg. 69580 (Oct. 6, 2016) (to be codified at 21 C.F.R. pts. 314, 320).

Such agency obduracy precludes opportunities for valuable reforms. Lax FDA practices regarding drug patents have sown industry confusion,[12] allowed for abusive and strategic behavior,[13] and foisted responsibilities upon members of the public and the Federal Trade Commission ("FTC").[14] Partnership with the USPTO provides a promising pathway for resolving these persistent issues. For its part, the USPTO could do a far better job of ensuring that the patents it issues fit coherently with the dispute resolution procedures administered by the FDA.

This Article assesses current FDA–USPTO collaboration efforts and provides specific avenues that would better align the work of these two agencies. Part I of this Article frames this exercise as one involving institutional choice. The question before the "whole of government" is not what the correct rule ought to be, but rather who should make the decision—and consequently, when that decision is going to be made. Part II of this Article next discusses the details of the FDA–USPTO interface as it currently stands. Part III then describes recent FDA–USPTO cooperative programs, concluding that they fall short of the stated agency aspirations of encouraging the development of new cures while also providing financial relief to American families at the pharmacy.[15]

The remainder of this Article proposes impactful reforms that the FDA and USPTO could undertake within their areas of interaction. In Part IV, this Article initially calls for the two agencies to develop consistent, accurate terminology to describe Hatch–Waxman concepts. It then considers the award of patent term adjustment ("PTA") and patent term extension ("PTE") to compensate patent holders for regulatory delays. PTA compensates patent holders on a day-for-day basis should the USPTO fail to meet statutory deadlines during acquisition procedures,[16] while PTE augments the terms of FDA-regulated products that cannot be sold until marketing approval is obtained.[17] Under current rules, if USPTO and FDA regulatory delays that lead to PTA and PTE occur on the same business day, then the brand-name drug company receives a double benefit—as many as two days of effective patent term augmentation in exchange for one day of government

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12. *See* Emma Murray, *Skinny Labels and Skinnier Prospects: How a Recent Federal Circuit Court Decision on Patent Infringement Places a Well-Established Generic Drug Practice in Jeopardy*, 71 WASH. U. J.L. & POL'Y 131, 149 (2023) (observing that coordination between the FDA and USPTO could have prevented confusion over the propriety of listing a patent in the Orange Book).

13. *See, e.g.*, Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 IDEA: J.L. & TECH. 389, 415 (1998).

14. *See* Press Release, FTC, FTC Challenges More Than 100 Patents as Improperly Listed in the FDA's Orange Book (Nov. 7, 2023) [hereinafter FTC Orange Book Listing Challenges] (available at https://www.ftc.gov/news-events/news/press-releases/2023/11/ftc-challenges-more-100-patents-improperly-listed-fdas-orange-book [https://perma.cc/EK5X-PMEH])].

15. For an example of agency rhetoric concerning its public health policy goals, see Kathi Vidal & Robert M. Califf, *The Biden Administration is Acting to Promote Competition and Lower Drug Prices for All Americans*, USPTO: DIRECTOR'S BLOG (Jul. 6, 2022), https://www.uspto.gov/blog/the-biden-administration-is-acting [https://perma.cc/ED4U-D9GU].

16. 35 U.S.C. § 154(b).

17. *Id.* § 156.

delay.[18] This double counting should be eliminated. In addition, the FDA and USPTO should assess what costs their administrative delays impose upon U.S. citizens in terms of their accessibility to health care and, if appropriate, take steps to ameliorate any deficiencies.

This Article also calls for greater oversight of the FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, more commonly known as the Orange Book.[19] The Orange Book serves in part as a patent clearinghouse; FDA identification of patents within it holds profound consequences for the availability of generic drugs.[20] The FDA nonetheless views its role in administering the Orange Book as purely ministerial.[21] This posture has led to evident abuses,[22] and it creates uncertainty regarding the eligibility of medical devices[23] and Risk Evaluation and Mitigation Strategies ("REMS")[24] patents to be listed in the Orange Book. Permissive FDA Orange Book practice should be replaced with USPTO oversight of initial patent listings and adjudication of listing disputes. Alternatively, the agencies should establish a joint authority with the ability to resolve these issues.

This Article next turns to USPTO restriction practice. Under current law, the USPTO may require an applicant claiming two or more "independent and distinct inventions" in a single filing to select one for continued prosecution.[25] The applicant may pursue patents on the other inventions by filing a divisional application.[26] The USPTO currently implements its restriction practice without regard to the needs of the FDA, resulting in complexities and ambiguities concerning

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18. *Id.* § 156(a) (noting that the term of the patent to be extended "shall include any patent term adjustment granted under section 154(b)").

19. The Orange Book may be located at www.accessdata.fda.gov/scripts/cder/ob/index.cfm.

20. *See, e.g.*, Janet Freilich, *Government Misinformation Platforms*, 172 U. PA. L. REV. 1537, 1557–59 (2024).

21. *See, e.g.*, *In re* Merck Mumps Vaccine Antitrust Litig., 685 F. Supp. 3d 280, 300 (E.D. Pa. 2023) (noting ministerial role of FDA in listing a patent for publication in the Orange Book); Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed, 68 Fed. Reg. 36676, 36683 (June 18, 2003) (to be codified at 21 C.F.R. pt. 314) ("Indeed, the requirement of prompt publication ('upon submission'), combined with the 30-day time frame for updating the Orange Book, are strong evidence that Congress did not intend us to undertake anything other than a ministerial action.").

22. *See, e.g.*, Jane F. Djung, *Insufficient Mechanisms for Orange Book Corrections and the FDA's Ministerial Role: A Need for Reform*, 47 CONN. L. REV. 229, 229 (2014).

23. *See* Jacob S. Sherkow & Patricia J. Zettler, *EpiPen, Patents, and Life and Death*, 96 NYU L. REV. ONLINE 164, 176 (2021).

24. REMS refers to a safety strategy to manage risks associated with a medicine. *See infra* notes 204–09 and accompanying text.

25. 35 U.S.C. § 121.

26. *See generally, e.g.*, Heather Hildreth, *Rampant Restrictions and Improper Divisionals: The Gap Between "Independent or Distinct" at the USPTO and "Patentably Distinct" in the Federal Circuit and Why We Should Encourage Examiners to Keep Similar Claim Sets Together*, 102 J. PAT. & TRADEMARK OFF. SOC'Y 364 (2022).

"split certifications" and other quiddities of FDA practice.[27] The USPTO should alter its restriction practice to account for FDA administration of the Hatch–Waxman Act.

This Article also calls for the abandonment or modification of the FDA's incongruous "use code" practice.[28] The FDA does not assess the scope of patents claiming methods of using a drug based on the instrument the USPTO granted.[29] Rather, it relies upon patent proprietors to describe, using 250 characters or fewer, the scope of their patents.[30] This dubious approach to complex legal texts approved by a peer agency should be modified or abolished. The FDA should read patents as the USPTO grants them and, if needed, could turn to the USPTO for support in this effort.

This Article finally calls for an assessment of pharmaceutical patent enforcement. The USPTO issues patents incorporating dozens or hundreds of claims on a routine basis. It also issues multiple patents covering the same drug. This prolix USPTO work product has resulted in coping strategies by courts, which must encourage or require patent proprietors to choose a fraction of these claims to be subject to litigation.[31] That so many pharmaceutical patent claims remain unadjudicated breeds uncertainty, particularly regarding the 180-day generic exclusivity,[32] which should be addressed through changes to agency practice or to the wording of the Hatch–Waxman Act.

In addition, Hatch–Waxman litigation, which for the most part occurs in just 2 of the 94 federal districts in the United States,[33] follows idiosyncratic and possibly unbalanced practices. Local patent rules and scheduling orders often require generic drug companies to explain at the outset why they don't infringe[34]—even though the patent proprietor bears the burden of proving infringement.[35] Congress also afforded brand-name drug companies the ability to sue a dozen or more generic manufacturers in one courtroom at one time for no other reason than

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27. *See* U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY, 180-DAY EXCLUSIVITY: QUESTIONS AND ANSWERS 7 (2017) (observing that a single patent may incorporate drug product, drug substance, and method-of-use claims, leading to the potential need for a paragraph IV certification and a section viii statement with respect to a single patent).

28. *See* Michael Vincent Ruocco, *Brand Name or Generic? A Case Note on* Caraco Pharmaceutical Laboratories v. Novo Nordisk, 33 J. NAT'L ASS'N ADMIN. L. JUDICIARY 341, 349–50 (2013).

29. *See, e.g.*, Julie Dohm, *Expanding the Scope of the Hatch-Waxman Act's Carve-Out Exception to the Identical Drug Labeling Requirement: Closing the Patent Litigation Loophole*, 156 U. PA. L. REV. 151, 162–65 (2007).

30. 21 C.F.R. § 314.53(c)(2)(i)(O) (2024).

31. *See, e.g.*, PETER S. MENELL ET AL., PATENT CASE MANAGEMENT JUDICIAL GUIDE § 5.1.2.1.3, at 5–8 (2d ed. 2012) ("Cases commonly involve multiple patents, dozens or even hundreds of claims, and multitudes of claim terms that may need construction.").

32. 21 U.S.C. § 355(j)(5)(B)(iv).

33. *See* John R. Thomas, *Hatch-Waxman's Renegades*, 2023 U. ILL. L. REV. 831, 833 (2023).

34. *See, e.g.*, D. Md. L. Pat. R. 804(3).

35. *See, e.g.*, Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1565 (Fed. Cir. 1997).

that they allegedly infringe the same patent.[36] Finally, the Hatch–Waxman Act is out of step with modern understandings of injunctions in patent cases and bears reassessment.[37] A conclusion follows.

I. THE WHOLE OF GOVERNMENT AND INSTITUTIONAL CHOICE

The Biden Administration's whole-of-government approach has advanced an all-hands-on-deck multiagency effort. In part, it aims to ensure that the patent system, while incentivizing innovation, does not unjustifiably delay generic competition.[38] By engaging different agencies in conversations about achieving a common goal, it incorporates concepts of institutional choice—a methodology that evaluates alternative authorities to identify the best decision-makers.[39] Rational institutional choice assessments involve comparisons of the relative competence, timeliness, scale, and legitimacy of different actors.[40]

The choice of government institutions for implementing pharmaceutical innovation policy arose from a string of heady congressional initiatives from the early 1980s that in hindsight, seem rushed. The Bayh–Dole Act of 1980 was most famous for allowing private enterprise to patent inventions resulting from research funded by the federal government.[41] But this legislation also introduced the reexamination process to the USPTO, paving the way for *inter partes* review and other administrative revocation proceedings.[42] The Federal Courts Improvement Act of 1982 established the Court of Appeals for the Federal Circuit ("Federal Circuit"), which holds exclusive jurisdiction over patent cases.[43] The Orphan Drug Act of 1983, for the first time, established the FDA as an agency that administered formalized intellectual property rights.[44] Finally, in 1984, the Hatch–Waxman Act

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36. 35 U.S.C. § 299 (limiting permissive joinder in patent infringement cases, except those arising under Section 271(e)(2) of the Patent Act).

37. *Compare* eBay, Inc. v. MercExchange, L.L.C., 547 U.S. 388, 394 (2006), *with* 35 U.S.C. § 271(e)(4).

38. *See* Exec. Order No. 14,036, 3 C.F.R. § 5(p)(vi) (July 9, 2021).

39. *See* HENRY M. HART, JR. & ALBERT M. SACKS, THE LEGAL PROCESS: BASIC PROBLEMS IN THE MAKING AND APPLICATION OF LAW 9 (William N. Eskridge, Jr. & Philip P. Frickey eds., 1994); *see also* Ernest A. Young, *Institutional Settlement in a Globalizing Judicial System*, 54 DUKE L.J. 1143, 1149–50 (2005) (appreciating the paradigm advanced by Professors Hart and Sacks that "law should allocate decisionmaking to the institutions best suited to decide particular questions, and that the decisions arrived at by those institutions must then be respected by other actors in the system, even if those actors would have reached a different conclusion").

40. *See, e.g.*, Jonathan C. Lipson, *Against Regulatory Displacement: An Institutional Analysis of Financial Crises*, 17 U. PA. J. BUS. L. 673, 701 (2015).

41. Pub. L. No. 96-517, 94 Stat. 3015 (1980); *see, e.g.*, Brittany N. Day, Note, *A Modest Proposal: Leveraging Private Enforcement Mechanisms and the Bayh-Dole Act to Reduce Drug Prices in the U.S. Healthcare Industry*, 17 DUKE J. CONST. L. & PUB. POL'Y 185, 202 (2022); Jennifer Penman & Fran Quigley, *Better Late Than Never: How the U.S. Government Can and Should Use Bayh-Dole March-In Rights to Respond to the Medicines Access Crisis*, 54 WILLAMETTE L. REV. 171, 173–74 (2017).

42. *See* Gregory Dolin, *Dubious Patent Reform*, 56 B.C. L. REV. 881, 890–94 (2015).

43. Pub. L. No. 97-164, 96 Stat. 25 (1982).

44. Pub. L. No. 97-414, 96 Stat. 2049 (1983).

implemented the concept of linkage, under which the FDA could not ultimately approve a drug for marketing if it infringed another's patent.[45] Each of these four bills was enacted rapidly on the heels of the other, allowing little time for assessment of their interinstitutional implications.

With this legislation setting the stage, our system of pharmaceutical innovation incentives features a distinctive institutional structure that involves the USPTO, FDA, FTC, and the courts. The USPTO receives patent applications and decides whether to approve them or not.[46] It also features an internal Patent and Trial Appeal Board ("PTAB") that resolves disputes over patentability.[47] However, the agency lacks substantive rulemaking authority over patentability standards.[48] USPTO interactions with the FDA are also minimal. Once the USPTO issues a patent, or reviews an administrative challenge to its validity, the role of the agency is all but over.[49]

The FDA endeavors to protect the public from fraudulent or dangerous products.[50] Over the past four decades, Congress has expanded its functions to include the administration of more sorts of intellectual property rights—"regulatory exclusivities"—than the USPTO.[51] Because the FDA also administers the system of linkage between the award of marketing approval and the enforcement of patent rights, the agency stands in a strong position to reach timely decisions.[52] However, the FDA famously disclaims expertise in the patent law, insisting that its role is limited to ministerial matters.[53]

The FTC has also emerged as an actor willing to close regulatory gaps between the FDA and USPTO. It has issued policy statements,[54] submitted amicus

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45. *See* Daniel Gervais, *The Patent Option*, 20 N.C. J.L. & TECH. 357, 373–74 (2019).

46. *See* 35 U.S.C. § 2(a)(1). *See generally* John M. Golden, *Patentable Subject Matter and Institutional Choice*, 89 TEX. L. REV. 1041, 1044–46 (2011).

47. *See* 35 U.S.C. § 6.

48. *See* Merck & Co. v. Kessler, 80 F.3d 1543, 1550 (Fed. Cir. 1996) ("Congress has not vested the [Director of the USPTO] with any general substantive rulemaking power . . . ."); *see also* Brendan Costello, *Rulemaking § 101*, 129 YALE L.J. 2178, 2180–81 (2020); Sarah Tran, *Patent Powers*, 25 HARV. J.L. & TECH. 609, 611–12 (2012).

49. USPTO interactions with the FDA are ordinarily limited to the award of Patent Term Extension, or PTE, under 35 U.S.C. § 156. *See infra* notes 62–72 and accompanying text.

50. *See, e.g.*, Daniel G. Aaron, *The Fall of FDA Review*, 22 YALE J. HEALTH POL'Y, L., & ETHICS 95, 105–06 (2023).

51. *See* ROGER E. SCHECHTER & JOHN R. THOMAS, PRINCIPLES OF PATENT LAW 439 (3d. ed. 2019) (noting FDA administration of 16 different regulatory exclusivities).

52. *See* Eisenberg & Crane, *supra* note 2, at 204.

53. *See, e.g.*, Adam P. Hustad, *Competing with Patent Thickets: Antitrust Law's Role in Promoting Biosimilars*, 102 B.U. L. REV. 675, 718 (2022); Jordan Paradise, *Information Opacity in Biopharmaceutical Innovation Through the Lens of COVID-19*, 47 AM. J.L. & MED. 157, 170–71 (2021); Jacob S. Sherkow, *Administrating Patent Litigation*, 90 WASH. L. REV. 205, 215–16 (2015).

54. *See, e.g.*, FED. TRADE COMM'N, *Federal Trade Commission Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book*

briefs,[55] issued warning letters,[56] and pursued litigation[57] concerning pharmaceutical intellectual property. The FTC is a compact agency with limited resources, however, and its enforcement efforts are necessarily sporadic.

Further, as with lawsuits brought by private parties, FTC enforcement actions will be adjudicated in the federal court system. However, the courts possess institutional limitations as well.[58] Rules of standing limit access to the bench.[59] Courts may lack expertise in the specialized areas of patent law and food and drug law—although many have adopted local rules and scheduling orders specific to disputes arising under the Hatch–Waxman Act.[60] Courts also strongly favor the settlement of litigation,[61] sometimes delaying the resolution of pressing issues, and sometimes with little regard for their antitrust implications.

The whole-of-government approach recognizes that these different institutions, with diverse capabilities, collectively manage the complex pharmaceutical intellectual property system. It also recognizes that the executive branch agencies might achieve improved innovation and public health outcomes through policy coordination, the pooling of resources, and even consolidated administrative action. But thus far, this initiative has been met with established FDA and USPTO positions that appear difficult to change. Before considering the combined response of the FDA and USPTO to the whole-of-government approach, this Article first takes stock of existing areas of FDA–USPTO interaction.

II. THE FDA–USPTO INTERFACE

For most of their histories, the patent law, on one hand, and the food and drug law, on the other hand, operated as formally separate regimes. The two disciplines are, after all, based upon different federal statutes, implemented by distinct administrative agencies, and ordinarily pursued by attorneys practicing in different bars.[62] Congress altered this landscape with the enactment of the Hatch–

(Sept. 14, 2023) https://www.ftc.gov/system/files/ftc_gov/pdf/p239900orangebook policystatement092023.pdf [https://perma.cc/U8QY-L5SY].

55. *See, e.g.*, Brief for Federal Trade Commission's Brief as Amicus Curiae Supporting Defendant, Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC, 641 F. Supp. 3d 85 (D. Del. 2022) (No. 21-691) (available at www.ftc.gov).

56. *See, e.g.*, FTC Orange Book Listing Challenges, *supra* note 14.

57. *See, e.g.*, FTC v. Actavis, Inc., 570 U.S. 136 (2013).

58. *See* Timothy A. Cook, *Pharmaceutical Patent Litigation Settlements: Balancing Patent & Antitrust Policy Through Institutional Choice*, 17 MICH. TELECOMMS. & TECH. L. REV. 417, 423–24 (2011).

59. *See* TransUnion LLC v. Ramirez, 594 U.S. 141, 423 (2021).

60. *See, e.g.*, D.N.J. Civ. R. 9.3 L. Pat. R. 3.6.

61. *See, e.g.*, Schlegel Mfg. Co. v. U.S.M. Corp., 525 F.2d 775, 783 (6th Cir. 1975) ("The importance of encouraging settlement of patent-infringement litigation, which all too frequently is complex, long-drawn-out, carried on through all the Courts, and even in different jurisdictions, cannot be overstated. If every patent-infringement case filed had to be tried the Courts would be clogged.").

62. *See generally* Garreth W. McCrudden, *Drugs, Deception, and Disclosure*, 38 BERKELEY TECH. L.J. 1131 (2023) (observing the distinct nature of the FDA and USPTO procedures and practice).

Waxman Act in 1984.[63] This legislation incorporated a host of complex provisions that fused patent law with food and drug law, establishing the current landscape of pharmaceutical innovation policy.[64]

The close connection between the FDA and USPTO is belied by their lack of formal engagement in the everyday administration of pharmaceutical intellectual property law. At present time, the only direct interaction between the FDA and USPTO occurs when they calculate the period of PTE.[65] As with patents on other sorts of inventions, pharmaceutical patents ordinarily endure 20 years from the date an application was filed.[66] This 20-year term cannot be tolled, even though the patented invention may not yet be sold to the public because the FDA has not approved it for marketing.[67] Congressional recognition that the FDA approval process could substantially curtail the effective terms of pharmaceutical patents led to the concept of PTE, which may increase the term of patents to account for FDA regulatory delays for a period of up to five years.[68]

The FDA and USPTO share responsibility for determining whether a patent is eligible for PTE, and what the length of the extension ought to be. Brand-name companies initially file an application for PTE at the USPTO, which determines whether that patent is eligible for extension.[69] After consulting with the FDA to determine whether the patented product was approved for marketing and is otherwise eligible for PTE, the USPTO then requests the FDA to calculate the applicable "regulatory review period."[70] The FDA then completes the calculation, notifies the USPTO, and publishes its conclusions in the Federal Register.[71] The

63. Pub. L. No. 98-417, 98 Stat. 1585 (1984).

64. *See* Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMMS. & TECH. L. REV. 345, 348 (2007).

65. 35 U.S.C. § 156. The term "extension" reflects USPTO terminology. As noted previously, the FDA refers to the identical concept as the "restoration" of a patent term. *See supra* notes 3–4 and accompanying text.

66. 35 U.S.C. § 154. Enjoyment of the full 20-year term is subject to the payment of maintenance fees. 35 U.S.C. § 41(b).

67. *See, e.g.*, Cathryn Campbell & R.V. Lupo, *Exemption to Patent Infringement Under 35 U.S.C. Section 271(e)(1): Safe Harbor or Storm A-Brewing?*, 5 SEDONA CONF. J. 29, 30 (2004).

68. *E.g.*, Maria A. DeCicco RePass, *Will Current Obviousness-Type Double Patenting Jurisprudence Discourage Use of the Patent System?*, 51 AM. INTELL. PROP. L. ASS'N Q.J. 413, 418 (2023); Nicholas G. Vincent, *Patent Term Extension and the Active Ingredient Problem*, 9 NYU J. INTELL. PROP. & ENT. L. 279, 281 (2020); Natalie Pous, *Shifting the Balance Between Branded and Generic Pharmaceutical Companies: Amendments to Hatch-Waxman Past, Present, and Future*, 19 FED. CIR. BAR. J. 301, 303 (2009). In addition, PTE may not afford a period of more than 14 years that the FDA-approved product remains subject to patent protection. 35 U.S.C. § 156(c)(3).

69. The USPTO also determines whether the application meets formality requirements. *See* 37 C.F.R. § 1.750 (2022).

70. *See* 21 C.F.R. § 60.10 (2023); U.S. PATENT & TRADEMARK OFF., MPEP § 2756 (9th ed. Rev. 7, 2023). The Manual of Patent Examining Procedure ("MPEP") provides a compendium of USPTO practices.

71. 21 C.F.R. § 60.20 (2023).

length of PTE becomes final after any requests for revision, petitions, or hearings have been resolved.[72]

Beyond these limited exchanges concerning PTE, the FDA and USPTO have no other routine engagements. Since at least 1962, the two agencies have enjoyed the authority to seek information from each other.[73] The USPTO may request the FDA "to furnish full and complete information with respect to such questions relating to drugs as the Director may submit concerning any patent application."[74] Conversely, the FDA enjoys the broad authority to inspect USPTO records.[75] The FDA and USPTO appear to have taken advantage of this opportunity rarely, if ever. Notably, the USPTO's Manual of Patent Examining Procedure makes no mention of this possibility.[76]

The FDA and USPTO nonetheless share an intense de facto relationship in administering the nation's intellectual property rights that pertain to pharmaceuticals. FDA practices profoundly impact topics that are usually deemed matters of patent law, while USPTO decisions hold far-reaching consequences for matters nominally under the exclusive jurisdiction of the FDA. A brief review of some of the mechanisms of pharmaceutical patent law reveals their overlapping roles in promoting pharmaceutical innovation.

Under the Hatch–Waxman Act and related legislation, the FDA administers a host of intellectual property rights. This legislation establishes 16 "regulatory exclusivities" that protect the holder of FDA approval against competitor drugs.[77] For example, if a medicine serves a small patient population, it may qualify for seven years of exclusivity as an orphan drug.[78] A drug that qualifies as a new chemical entity ("NCE")—meaning that the FDA has not previously approved the same active moiety—ordinarily receives protection from generic competition for five years.[79] These and other regulatory exclusivities act in parallel with patents, often providing more effective proprietary rights but for shorter periods.[80]

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72. The USPTO has recently adopted one reform with respect to PTE. For nearly four decades, the USPTO required applications to file physical copies of PTE applications—which often extend to hundreds of pages—in triplicate. Establishing Permanent Electronic Filing for Patent Term Extension Applications, 88 Fed. Reg. 13028, 13028 (Mar. 2, 2023) (to be codified at 37 C.F.R. pt. 1). Following a waiver of that requirement during the COVID-19 pandemic in favor or electronic filing, the agency has now adopted that measure on a permanent basis. *Id.* at 13028–29.

73. S. Sean Tu, *FDA Reexamination: Increased Communication Between the FDA and USPTO to Improve Patent Quality*, 60 HOUS. L. REV. 403, 424–25 (2022) (discussing the legislative history of this FDA–USPTO information sharing provision).

74. 21 U.S.C. § 372(d).

75. *Id.* § 372(c).

76. U.S. PAT. & TRADEMARK OFF., MPEP (9th ed. Rev. 7, 2023).

77. *See* SCHECHTER & THOMAS, *supra* note 51, at 439.

78. 21 U.S.C. § 360cc.

79. *Id.* § 355(j)(5)(F)(ii).

80. *See* John R. Thomas, *The End of "Patent Medicines"? Thoughts on the Rise of Regulatory Exclusivities*, 70 FOOD & DRUG L.J. 39, 44 (2015).

Regulatory exclusivities are broadly viewed as falling within the domain of the FDA.[81] But many of them depend on USPTO decision-making. For example, brand-name firms may obtain a six-month pediatric exclusivity upon completion of clinical studies involving children.[82] Congress intended pediatric exclusivity to improve labeling on drug products.[83] Pediatric exclusivity is not a freestanding exclusivity, but rather extends the brand-name firm's existing patent and exclusivity protection for an additional six months.[84] For example, a drug that qualifies as an NCE and has been the subject of pediatric testing would obtain a regulatory exclusivity of five years and six months.[85] Any pertinent patent would also be subject to a six-month period of pediatric exclusivity that extends beyond the patent's nominal date of expiration.[86]

Pediatric exclusivity is ordinarily deemed an FDA program.[87] But as a practical matter, the decision of the USPTO of whether to grant a patent or not—and whether the courts will sustain that patent against generic competitors—establishes whether pediatric exclusivity will preclude generic competition. Not only do regulatory exclusivities ordinarily expire long before any relevant patents; but, for the most part, they conclude during the pendency of parallel pharmaceutical patent litigation.[88] Practically speaking, the quality of the patents granted by the USPTO determines whether pediatric exclusivity does any work in the marketplace.

Another regulatory exclusivity, awarded to generic manufacturers, is also seen as an FDA matter while largely falling within the control of the USPTO. The Hatch–Waxman Act encourages generic manufacturers to challenge pharmaceutical

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81. *See, e.g.*, Yaniv Heled, *Regulatory Competitive Shelters*, 76 OHIO ST. L.J. 299, 336–42 (2015).

82. 21 U.S.C. § 355(a); *see* U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: QUALIFYING FOR PEDIATRIC EXCLUSIVITY UNDER SECTION 505A OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT (1999). Much like PTE, pediatric exclusivity precludes FDA approvals rather than delaying the date of patent expiration, but it nonetheless effectively precludes generic competition. *Id.*

83. Allan M. Joseph, *Kid Tested, FDA Approved: Examining Pediatric Drug Testing*, 72 FOOD & DRUG. L.J. 543, 547 (2017); Lauren Hammer Breslow, *The Best Pharmaceuticals for Children Act of 2002: The Rise of the Voluntary Incentive Structure and Congressional Refusal to Require Pediatric Testing*, 40 HARV. J. ON LEGIS. 133, 134 (2003).

84. Karena J. Cooper, *Pediatric Marketing Exclusivity—As Altered by the Best Pharmaceuticals for Children Act of 2002*, 57 FOOD & DRUG L.J. 519, 524 (2002).

85. *See* Robin Feldman, *Regulatory Property: The New IP*, 40 COLUM. J.L. & ARTS 53, 87 (2016).

86. Barbara A. Noah, *Just a Spoonful of Sugar: Drug Safety for Pediatric Populations*, 37 J.L. MED. & ETHICS 280, 282 (2009) ("The testing incentive provided by the 180-day pediatric exclusivity mechanism has, for purposes of generic approvals, the same effect as a patent term extension.").

87. *See, e.g.*, Kurt R. Karst, *Pediatric Testing of Prescription Drugs: The Food and Drug Administration's Carrot and Stick for the Pharmaceutical Industry*, 49 AM. U.L. REV. 739, 739–40 (2000).

88. *See* Jonathan J. Darrow & Daniel T.C. Mai, *An Orange Book Landscape: Drugs, Patents, and Generic Competition*, 77 FOOD & DRUG L.J. 51, 54 (2022) (observing that regulatory exclusivities, except for the pediatric exclusivity, tend to expire before patent expiration).

patents by awarding them 180 days of protection from other generics.[89] Under this provision, the first generic applicant to challenge a patent listed in the Orange Book has the exclusive right to market a generic product for 180 days.[90]

The award of the 180-day exclusivity depends upon a favorable judgment on behalf of a generic firm.[91] If the brand-name pharmaceutical firm successfully enforces its patents against generic manufacturers, then this exclusivity never arises.[92] Although nominally administered by the FDA, the quality of USPTO decision-making determines whether generic firms may earn the 180-day exclusivity or not. In an ideal world of perfect patent quality, no generic manufacturer would ever defeat or avoid a patent, and generic exclusivity would not arise at all.

Beyond regulatory exclusivities, perhaps the most famous feature of the Hatch–Waxman Act is its adoption of an industry-specific, limited safe harbor from patent infringement.[93] The "*Bolar* exemption"[94] permits generic firms to engage in acts pursuant to obtaining FDA approval, free of the risk of patent infringement.[95] Congress adopted this safe harbor to encourage prompt entry of generic drugs, for otherwise generic manufacturers would not be able to commence the process of obtaining FDA marketing approval until patent expiration.[96]

In establishing the *Bolar* exemption, Congress also provided the FDA with some ability to control the scope of patent rights. The greater the demands that the FDA imposes upon applicants for marketing approval, the more cabined the scope of patent rights that may be enforced against them. In short, pharmaceutical patent

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89. 21 U.S.C. § 355(j)(5)(B)(iv); *see* David E. Korn et al., *A New History and Discussion of 180-Day Exclusivity*, 64 FOOD & DRUG L.J. 335, 335 (2009).

90. *See* U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: 180-DAY EXCLUSIVITY WHEN MULTIPLE ANDAS ARE SUBMITTED ON THE SAME DAY 5 (2003).

91. *See, e.g.*, Avery, *supra* note 10, at 178 (noting that the 180-day exclusivity is awarded to successful patent challengers).

92. *See* U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY, 180-DAY EXCLUSIVITIES: QUESTIONS AND ANSWERS 10 (2017) (observing that the first generic manufacturer to challenge a patent enjoys the 180-day exclusivity if it wins its patent litigation, is not sued by the patent proprietor, or settles with the patent proprietor).

93. 35 U.S.C. § 271(e)(1).

94. *See* Robert D. Cooter & Uri Y. Hacohen, *Progress in the Useful Arts: Foundations of Patent Law in Growth Economics*, 22 YALE J.L. & TECH. 191, 232 n.121 (2020). The name of the exemption references *Roche Prods, Inc. v. Bolar Pharm. Co.*, 733 F.2d 858 (Fed. Cir. 1984), which held that generic activities preparatory to FDA approval do not qualify as an experimental use under common law. The 98th Congress overturned that ruling when it enacted the Hatch–Waxman Act. *See* Mylan Inc. & Subsidiaries v. Comm'r, 76 F.4th 230, 234 (3d Cir. 2023) ("The Hatch-Waxman Act also effectively overturned the ruling in *Roche Products* by providing a legal safe harbor for the development of generic drugs prior to the expiration of a branded drug manufacturer's patents.").

95. *See, e.g.*, Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193, 202–04 (2005); Momenta Pharms., Inc. v. Amphastar Pharms., Inc., 686 F.3d 1348, 1354 (Fed. Cir. 2012); Proveris Sci. Corp. v. Innovasystems, Inc., 536 F.3d 1256, 1263–64 (Fed. Cir. 2008).

96. *See* Stacey B. Lee, *Is a Cure on the Way?—The Bad Medicine of Generics, Citizen Petitions, and Noerr-Pennington Immunity*, 20 KAN. J.L. & PUB. POL'Y 98, 104–05 (2010).

rights depend upon the precise wording of the claims that the USPTO grants, but they also depend upon the scope of regulation that the FDA imposes.[97]

The Orange Book, more formally titled *Approved Drug Products with Therapeutic Equivalence Evaluations*, provides another point of interaction between the FDA and USPTO.[98] The FDA initially published the Orange Book after being besieged by individual requests from state public health officials to determine what generic drugs might be appropriately substituted for brand-name drugs.[99] The Orange Book provides a list of all FDA-approved prescription drugs, along with a determination of whether a generic product is therapeutically equivalent to a brand-name drug.[100]

Congress took advantage of the Orange Book when it enacted the Drug Price Competition and Patent Term Restoration Act of 1984, better known as the Hatch–Waxman Act.[101] The Hatch–Waxman Act requires brand-name drug companies to identify relevant patents to the FDA as part of the regulatory review process. If the FDA approves the drug for marketing, the agency identifies these patents within the Orange Book—a process commonly termed "listing."[102]

FDA listing of a patent in the Orange Book holds weighty consequences for the availability of generic drugs. When seeking FDA approval, generic manufacturers must engage in a specialized certification procedure concerning Orange Book-listed patents. A generic manufacturer that submits an Abbreviated New Drug Application ("ANDA") to the FDA must file either a "section viii" statement or a patent certification.[103] Section viii statements are appropriate when the listed patent claims a method of use that the proposed generic product would not infringe.[104]

The generic applicant must otherwise provide one of four certifications.[105] Three of them are nonconfrontational, as they allow generic manufacturers to state that no patents have been listed in the Orange Book for that drug, or that any listed

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97. *See, e.g.*, Momenta Pharms., Inc. v. Amphastar Pharms., Inc., 686 F.3d 1348 (Fed. Cir. 2012) (use of a patented method of molecular analysis in order to test batches of drugs in keeping with FDA requirements fell within the *Bolar* exemption and was non-infringing).

98. U.S. FOOD AND DRUG ADMINISTRATION, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS iv (44th ed. 2024) [hereinafter ORANGE BOOK].

99. *Id.* at iv–v (noting that the FDA published the first edition of the Orange Book in October 1980).

100. *See, e.g.*, Darrow & Mai, *supra* note 88, at 55–56.

101. Pub. L. No. 98-417, 98 Stat. 1585 (1984).

102. 21 U.S.C. § 355(c)(2); *see In re* Lantus Direct Purchaser Antitrust Litig., 950 F.3d 1, 3 (1st Cir. 2020).

103. This Article omits discussion of Section 505(b)(2) applications for purposes of brevity. The FDA treats a § 505(b)(2) application as it if were a New Drug Application. U.S. FOOD AND DRUG ADMINISTRATION, APPLICATIONS COVERED BY SECTION 505(b)(2) (1999).

104. 21 U.S.C. § 355(j)(2)(A)(viii).

105. Jacob S. Wharton, *"Orange Book" Listing of Patents Under the Hatch-Waxman Act*, 47 ST. LOUIS U. L.J. 1027, 1033 (2003).

patents have already expired.[106] Once applicable regulatory requirements are met, the FDA may immediately approve these generic drugs for marketing.[107] Alternatively, the generic manufacturer may stipulate that it will not market its product until the Orange Book-listed patent expires.[108] In response, the FDA may issue a tentative approval that may be finalized once relevant patents have expired.[109]

The final option for generic firms is to file a "paragraph IV" certification. A paragraph IV certification asserts that the Orange Book-listed patent is invalid or would not be infringed by the proposed generic product.[110] This certification often leads to patent enforcement litigation.[111] At this point, the generic manufacturer has done nothing more than request FDA approval to market a drug. That approval may never come.[112] The Hatch–Waxman Act nonetheless established an "artificial" cause of action for infringement. Once a generic manufacturer has petitioned the government for approval to market its products, then the brand-name firm may assert its patents against the generic manufacturer immediately.[113]

If the patent proprietor seasonably commences an infringement suit against the paragraph IV ANDA applicant, the Hatch–Waxman Act ordinarily prohibits the FDA from approving the ANDA for 30 months.[114] The 30-month stay effectively acts as a preliminary injunction against the generic firm, without requiring the patent proprietor to address the usual equitable factors or post a bond.[115] If the patent proprietor's charge of infringement succeeds, then the Hatch–Waxman Act requires courts to order the effective date of FDA approval to be no earlier than the date the patents expire.[116] The mandatory award of a permanent injunction operationalizes

106. 21 U.S.C. § 355(j)(2)(A)(vii)(I)–(II).

107. *See* U.S. FOOD AND DRUG ADMINISTRATION, ANDA SUBMISSIONS—AMENDMENTS AND REQUESTS FOR FINAL APPROVAL TO TENTATIVELY APPROVED ANDAS, GUIDANCE FOR INDUSTRY 3 (2024).

108. 21 U.S.C. § 355(j)(2)(A)(vii)(III).

109. *See* Ernst R. Berndt, Rena M. Conti, & Stephen J. Murphy, *The Generic Drug User Fee Amendments: An Economic Perspective*, 5 J.L. & BIOSCIENCES 103, 108 n.23 (2018).

110. 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

111. *See, e.g.*, Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 566 U.S. 399 (2012).

112. For this reason, whether a brand-name firm may successfully establish standing to pursue a cause of action for artificial infringement under Article III of the Constitution remains an open question. *See* Transunion LLC v. Ramirez, 594 U.S. 413, 423 (2021) (requiring that plaintiffs show, in part, that they have "suffered an injury . . . that is concrete, particularized, and actual or imminent").

113. *See* Eli Lilly & Co. v. Medtronic Inc., 496 U.S. 661, 678 (1990).

114. 21 U.S.C. § 355(j)(5)(B)(iii).

115. *See* Takeda Pharms. U.S.A., Inc. v. Mylan Pharms. Inc., 967 F.3d 1339, 1345 (Fed. Cir. 2020). If one of the litigants fails to reasonably cooperate in expending the action, the district court may reduce or extend the 30-month period. 21 U.S.C. § 355(j)(5)(B)(iii).

116. 35 U.S.C. § 271(e)(4)(A).

the concept of "linkage," under which the FDA may not approve a drug for marketing if it would infringe the brand-name drug company's patent.[117]

These examples demonstrate that the FDA and USPTO share many areas of interaction but few of coordination.[118] The USPTO examines and issues pharmaceutical patents with no sense of what use the Hatch–Waxman Act regime will make of them. For its part, the FDA disclaims knowledge of the patents presented to it, resulting in interface issues, industry confusion, and, at times, outright abuse. A whole-of-government approach encourages solutions to these problems; but, as will be seen, current FDA–USPTO interactions have been decidedly modest.

III. CURRENT AGENCY EFFORTS

Although the Hatch–Waxman Act connected the patent laws and food and drug laws, the FDA and USPTO have resisted cooperation. Only recently have the two agencies engaged in discussions regarding administrative rationalization of what is already a deeply interlocked, de facto functional relationship.[119] The short-term consequences of this conversation should not inspire confidence. FDA and USPTO efforts undertaken thus far will have, at best, scant impact. They seem particularly pallid given more effective options that the agencies could pursue. Before considering more fruitful ways that the agencies could interact, this Article takes a quick look at their current efforts.

A. Duty of Disclosure

As an ex parte procedure, patent acquisition depends a great deal upon the observance of a duty of candor towards the USPTO. To this end, the USPTO has promulgated a notice concerning the duties of disclosure owed to the agency.[120] The USPTO Disclosure Notice primarily calls for consistent representation between the FDA and USPTO.[121] The tension between the two sorts of advocacy is clear—patent attorneys commonly assert a product is novel and nonobvious, while food and drug lawyers assure the government that a product is safe and effective because it has

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117. *See, e.g.*, Molly F.M. Chen, *Reconsidering the U.S. Patent System: Lessons from Generics*, 45 VAND. J. TRANSNAT'L L. 1249, 1263 (2012); Ron Bouchard et al., *Structure-Function Analysis of Global Pharmaceutical Linkage Regulations*, 12 MINN. J.L. SCI. & TECH. 391 (2011).

118. Other areas of interaction include the truncation of the five-year NCE exclusivity to as little as four years in the event of a patent challenge. 21 U.S.C. § 355(j)(5)(F)(ii).

119. *See* USPTO, *What are the USPTO-FDA collaboration initiatives?*, https://www.uspto.gov/initiatives/fda-collaboration/what-are-uspto-fda-collaboration-initiatives [https://perma.cc/FWR9-UHKN] (last visited Dec. 1, 2024).

120. Duties of Disclosure and Reasonable Inquiry During Examination, Reexamination, and Reissue, and for Proceedings Before the Patent Trial and Appeal Board, 87 Fed. Reg. 45764 (July 29, 2022) [hereinafter USPTO Disclosure Notice].

121. *Id.* at 45765 ("If a party to a USPTO proceeding discovers that an earlier position taken in a submission to the USPTO or another Government agency was incorrect or inconsistent with other statements made by the party, the party must promptly correct the record.").

been done before.[122] Adding to the difficulty of keeping a story straight is that pharmaceutical firms ordinarily employ different counsel before the two agencies.[123]

The substance of the USPTO Disclosure Notice is to remind patent owners and applicants of their existing duty of candor before the USPTO under an existing regulation, Rule 56.[124] Rule 56 in part requires individuals associated with the preparation or prosecution of a patent application to disclose all information they know to be material to patentability.[125] That information may well consist of information submitted to the FDA, including test results and comparisons of an unapproved product to others that the FDA has allowed into the marketplace.[126] According to Rule 56, "no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct."[127]

The USPTO's approach presents shortcomings. Years ago, the agency operated a "Fraud Squad" that investigated possible instances of "inequitable conduct."[128] The agency ultimately abandoned this effort and now no longer investigate applications under Rule 56.[129] Absent this capability, the USPTO seems extremely unlikely to learn of the contents of statements a patent applicant or proprietor made to the FDA.

Furthermore, the Federal Circuit has dealt a serious blow to Rule 56. The Federal Circuit issued its en banc decision in *Therasense, Inc. v. Becton, Dickinson & Co.* more than a decade ago, holding that the courts should not follow Rule 56 when determining whether inequitable conduct occurred or not.[130] The USPTO has

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122. *Belcher Pharms., LLC v. Hospira, Inc.*, 11 F.4th 1345 (Fed. Cir. 2021), illustrates this tension. In that case, a brand-name drug company informed the FDA that a certain pharmaceutical formulation was "old," while contemporaneously asserting to the USPTO that the same formulation was a "critical" advance with unexpected results. *Id.* at 1351–52. The Federal Circuit held that the patent was unenforceable due to inequitable conduct. *Id.* at 1354.

123. *See* Tu, *supra* note 73, at 422 ("[T]he attorney who prosecutes the patent will likely not be the same attorney who helps submit the FDA approval documents.").

124. 37 C.F.R. § 1.56 (2012).

125. *Id.*

126. *See, e.g.*, Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd., 394 F.3d 1348, 1354 (Fed. Cir. 2005).

127. 37 C.F.R. § 1.56(a) (2012).

128. *See* Lisa Dolak, *America Invents the Supplemental Examination, But Retains the Duty of Candor: Questions and Implications*, 6 AKRON INTELL. PROP. J. 147, 170 n.111 (2012).

129. *Compare* U.S. PATENT & TRADEMARK OFF., MPEP § 2021 (5th ed. Aug. 1983) (explaining that the Office of Assistant Commissioner for Patents will consider violations of the duty of disclosure), *with* U.S. PATENT & TRADEMARK OFF., MPEP § 2010 (6th ed. 1995) (explaining that the USPTO no longer investigates or comments upon allegations of inequitable conduct).

130. 649 F.3d 1276, 1294 (Fed. Cir. 2011) (en banc); *see, e.g.*, Kerri M. Patterson, *Inequitable Conduct Post-*Therasense, 27 GEO. J. LEGAL ETHICS 825, 830 (2014); Brandee N. Woolard, *The Resurrection of the Duty to Inquire After* Therasense, Inc. v. Becton, Dickinson & Co., 12 DUKE L. & TECH. REV. 41, 43 (2014); Sam S. Han, Therasense *Nonsense*, 37 U. DAYTON L. REV. 185, 186 (2012).

lent serious consideration towards modifying Rule 56 to account for the *Therasense* decision; such an amendment presents complex questions, and the agency may have good reasons for not yet doing so.[131]

The USPTO Disclosure Notice nonetheless fails to demonstrate a commitment to enforcing the Rule 56 requirements it articulates. Further, should allegations of inconsistent advocacy between the USPTO and FDA arise, courts will adjudicate the issue without regard to Rule 56. Although emphasizing that individuals should comply with longstanding obligations may serve a salutary purpose, the USPTO Disclosure Notice, by itself, has no practical implications for agency operations.

B. Cross-Training

In another collaborative initiative, the FDA has provided USPTO examiners with training on publicly available FDA resources that could be used in prior art searches.[132] As with the USPTO Disclosure Notice, this proposal will likely have little impact. The FDA maintains the applications filed before it—whether it be an Investigational New Drug Application ("IND"),[133] New Drug Application ("NDA"),[134] or ANDA[135]—in confidence. The FDA does not even disclose that one of these applications has been filed unless the applicant has previously released that information to the public.[136] In those circumstances, the entirety of the contents of the application remains publicly unavailable.[137] As a result, this information fails to qualify as prior art under established patent law principles[138] and lacks pertinence to patentability determinations.[139]

Even when the FDA approves an ANDA or NDA, the agency discloses only very limited information to the public.[140] Indeed, the FDA explicitly states that

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131. In particular, whether patent quality is best served by *Therasense*'s "but for" standard of materiality remains questionable. *See Therasense*, 649 F.3d at 1293–95 (stating that a reference is deemed material for purposes of inequitable conduct if "but for" its nondisclosure, the USPTO's patentability determination would have differed); *see also* James Toupin, *Comments of James Toupin in Response to the US Patent and Trademark Office's Notice of Proposed Rulemaking, Revision of the Duty to Disclose Information in Patent Applications and Reexamination Proceedings*, USPTO 5–6 (Dec. 27, 2016) https://www.uspto.gov/sites/default/files/documents/rule56_f_toupin_27dec2016.pdf [https://perma.cc/G6Z3-GHDT].

132. *See USPTO-FDA Cross Training—March 16, 2023*, USPTO (Mar. 16, 2023), https://www.uspto.gov/about-us/events/uspto-fda-cross-training-0 [https://perma.cc/V6AP-FT8M]; Joint USPTO-FDA Collaboration Initiatives; Notice of Public Listening Session and Request for Comments, 87 Fed. Reg. 67019, 67021 (Nov. 7, 2022).

133. 21 C.F.R. § 312.130(a) (2004).

134. *Id.* § 314.3(b) (2024).

135. *Id.*

136. *Id.* § 314.430(c) (2016).

137. *Id.* § 314.430(d)(1).

138. *See, e.g.*, Del Mar Eng'g Labs. v. United States, 524 F.2d 1178, 1182–83 (Ct. Cl. 1975) (classified government documents and tests do not qualify as prior art).

139. The information could have relevance in terms of the enforceability of the patent. *See supra* notes 124–27 and accompanying text.

140. 21 C.F.R. § 314.430(e) (2016).

it will not disclose the information in the portions of the application that are most pertinent to patentability, including manufacturing processes and quantitative formulae.[141] The notion that this sort of USPTO examiner training will unearth a rich trove of FDA data that may be used to assess the state of the art seems misguided.

Not to be outdone by FDA training, the USPTO has taught classes to FDA employees concerning the patenting process, including patentability standards, patent examination process, and public-facing patent databases.[142] Such off-the-shelf seminars might prove interesting for FDA employees considering a different career path. However, given the FDA's persistent unwillingness to address issues pertaining to patent law, they hold little practical impact by themselves. These courses have provided FDA employees with information they are unlikely ever to use and, therefore, fail to contribute meaningfully to agency rhetoric regarding the nation's public health.

C. Proposed Legislation

The intransigent reaction of the FDA and USPTO to the Interagency Patent Coordination and Improvement Act ("IPCIA") provides another indication of the deep entrenchment of our current, siloed approach to pharmaceutical intellectual property.[143] That proposed legislation would establish an Interagency Task Force on Patents ("Task Force") composed of FDA and USPTO employees.[144] The Task Force has modest aspirations. It would provide a vehicle for the agencies to share general information about their procedures.[145] It would also allow USPTO examiners to request specific, nonconfidential information from the FDA, such as label updates or newly approved indications.[146]

The proposed Task Force would play a limited role, as it appears merely to institutionalize abilities that the two agencies have possessed for the last six decades.[147] Yet the FDA provided an outlandish estimate for the costs of implementing it. As reported by the Congressional Budget Office, the FDA asserts that putting the Task Force into operation would require 50 employees for $325,000 each.[148] Over the 2023–2028 timeframe, those costs would amount to $90 million.

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141. *Id.* § 314.430(g).

142. *See USPTO-FDA Cross Training—July 31, 2023*, USPTO (July 31, 2023), https://www.uspto.gov/about-us/events/uspto-fda-cross-training-july-31-2023 [https://perma.cc/9UWS-RXW4].

143. The Interagency Patent Coordination and Improvement Act of 2023, S. 79, 118th Cong. (2023). The Bill was previously introduced as S. 4430 in the 117th Congress. S. 4430, 117th Cong. (2022). Each bill would introduce a new Section 15 into the Patent Act.

144. The Interagency Patent Coordination and Improvement Act of 2023, S. 79, 118th Cong. (2023).

145. 35 U.S.C. § 15(d)(1), (2) (proposed).

146. 35 U.S.C. § 15(d)(3), (4) (proposed).

147. *See supra* notes 73–76 and accompanying text.

148. CONGRESSIONAL BUDGET OFFICE, COST ESTIMATE, S. 79, AS REPORTED BY THE SENATE COMMITTEE ON THE JUDICIARY (July 6, 2023) https://www.cbo.gov/system/files/2023-07/s79.pdf [https://perma.cc/32SH-K7PQ].

Meanwhile, the USPTO side estimated that it would require eight employees for $200,000 each, for a total of $7 million from 2023 to 2028.[149]

As a basis for assessing the FDA's $90 million estimate, between 2015 and 2023, the agency's Center for Drug Evaluation and Research ("CDER") has approved an average of 46 new drugs, including both small molecule drugs and therapeutic biologics, each year.[150] The FDA's estimate effectively calls for more than one full-time employee to field inquiries from USPTO examiners for each new drug the CDER approves. To be sure, the FDA also approves other sorts of potentially patentable products, such as vaccines, plasma derivatives, and gene therapies, which are assigned to the FDA's Center for Biologics Evaluation and Research.[151] However, given the limited public availability of information submitted to the FDA in this context,[152] as well as the fact that the USPTO often grants patents more quickly than the FDA approves new drugs,[153] the FDA would most likely not receive any specific inquiries from the USPTO regarding most of its approved products.

Perhaps the best way to advance the IPCIA would be to amend it in two respects. First, the legislation could stipulate the number of employees that each agency could assign to the Task Force. Second, the legislation could set an annual limit on the number of requests that the USPTO could send and that the FDA could receive.[154] This trial period would then allow for assessment of the collaborative concept and the actual level of staffing and budget to support it. Absent this sort of reality check, the IPCIA seems unlikely to move forward as enacted legislation due to agency intransigence.

IV. REFORM PROPOSALS

Despite the obdurate posture of the FDA and USPTO, fruitful pathways for collaboration exist between the two agencies. They collectively possess the capability to build knowledge of Hatch–Waxman's operations through suggested

149. *Id.*

150. Information on the number of drugs approved each year since 2015 may be found on the FDA website. *Novel Drug Approvals at FDA*, U.S. FOOD & DRUG ADMIN. (Apr. 8, 2023), https://www.fda.gov/drugs/development-approval-process-drugs/novel-drug-approvals-fda [https://perma.cc/96FV-MF7Z].

151. *See Center for Biologics Evaluation and Research (CBER)*, U.S. FOOD & DRUG ADMIN. (Sept. 18, 2024), https://www.fda.gov/about-fda/fda-organization/center-biologics-evaluation-and-research-cber [https://perma.cc/BLE7-HBKU].

152. *See supra* notes 140–41 and accompanying text.

153. As of August 2024, the USPTO measured the average pendency of patent applications as 26.2 months. *See Patents Pendency August 2024*, U.S. FOOD & DRUG ADMIN. (Aug. 2024), https://www.uspto.gov/dashboard/patents/pendency.html [https://perma.cc/2KBB-M5YG]. In contrast, new drug approvals in the United States average 12 years. *See* Gail A. Van Norman, *Drugs, Devices, and the FDA: Part I: An Overview of the Approval Processes for Drugs*, 1 JACC: BASIC TO TRANSLATIONAL SCI. 170, 178 (2016).

154. The 112th Congress took this approach with respect to the newly introduced *inter partes* review ("IPR") proceedings. The America Invents Act allowed the USPTO to place a limit on the number of IPRs that it would institute for the first four years that proceeding came into effect. Leahy–Smith America Invents Act, Pub. L. No. 112-29, § 319(c)(2)(B) (2011), 125 Stat. 284, 304 (2011).

studies. They would also benefit from regulatory reforms and, ultimately, congressional intervention. The remainder of this Article offers opportunities for meaningful changes to Hatch–Waxman practice by reducing departmentalism, taking advantage of comparative agency expertise, and increasing the interoperability of patents with Hatch–Waxman's dispute resolution framework.

A. Reconciling Terminology

As a readily achievable starting point, the FDA and USPTO could improve their efforts to use consistent and accurate terminology when conveying information about the complex discipline of pharmaceutical patents. First, as noted above,[155] the FDA refers to increases in patent terms to compensate for regulatory delays as "restoration,"[156] while the USPTO prefers the term "extension."[157] The agencies should choose one of the terms and employ it consistently.

Second, the FDA distinguishes between method and process patents, with the former term concerning methods of use and the latter generally pertaining to processes of manufacture.[158] This usage is inconsistent with the Patent Act. Because the terms "process" and "method" are synonyms,[159] the FDA should refer more specifically to "method of making" or a similar phrase to describe patents claiming chemical manufacturing techniques.

Finally, although the FDA refers to certifications made under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) as falling under "paragraph IV," as the preceding citation indicates, the relevant provision is housed within a "subclause IV" of the Federal Food Drug and Cosmetic Act. Similarly, the "section viii statement," sitting in 21 U.S.C. § 355(j)(2)(A)(viii), should be identified as a "clause viii statement." The FDA should improve the accuracy of its terminology to comply with legislative drafting norms and to promote comprehension of the legislation.

B. Adjusting and Extending Patent Term

The patent terms of pharmaceuticals, biologics, medical devices, and other FDA-regulated products deserve reconsideration. Patents claiming pharmaceuticals, as with other sorts of inventions, ordinarily endure for 20 years from the date of filing.[160] As noted previously, the Hatch–Waxman Act may afford them a period of PTE of up to five years due to administrative delays at the FDA.[161]

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155. *See supra* notes 3–4 and accompanying text.

156. 21 C.F.R. § 60.2 (2023) ("The purpose of this part is to establish a thorough yet efficient process for the Food and Drug Administration review of patent term restoration applications.").

157. 37 C.F.R. § 1.710 (2022) ("Patents subject to extension of the patent term.").

158. *See* 21 C.F.R. § 314.53(b) (2024).

159. *See* 35 U.S.C. § 100(b) (2015).

160. 35 U.S.C. § 154. Enjoyment of the full 20-year term is subject to the payment of maintenance fees. 35 U.S.C. § 41(b).

161. *See supra* note 68 and accompanying text. In addition to the five-year extension cap, the remaining term of the extended patent following FDA approval of an NDA may not exceed 14 years. 35 U.S.C. § 156(c)(3).

A few of the details of PTE are worth reviewing here. The period of PTE consists of the "regulatory review period,"[162] which generally comprises one-half of the "testing phase" of the product,[163] plus the entirety of the "approval phase" before the FDA.[164] Suppose, for example, that clinical trials for a drug consumed three years, while the FDA required six months to approve a drug. In that case, the term of PTE would equal two years. The PTE period is subject to certain caps. It may not exceed five years; further, the remaining term of the extended patent following FDA approval of the NDA may not exceed 14 years.[165] The period of extension may be reduced by the failure of the applicant to act with due diligence.[166] In the event multiple patents cover the approved product, their proprietor must choose one for PTE.[167]

Another possibility for an increase in patent term exists under a different statute, the Patent Term Guarantee Act.[168] This legislation may increase patent terms due to delays in patent prosecution at the USPTO through PTA.[169] PTA recognizes that the 20-year patent term may, as a practical matter, be truncated by USPTO inaction, for the patent proprietor obtains no enforceable rights until the USPTO grants an application.[170] Stated differently, each day a patent application sits at the USPTO effectively amounts to a lost day concerning the exercise of patent rights. The USPTO calculates PTA by compensating patent holders if the agency should fail to meet statutory deadlines during patent prosecution.[171] For example, if the USPTO does not initially respond to a patent application within 14 months of the filing date, or the entire pendency of that application exceeds three years, then the patent obtains a day-for-day increase in patent term.[172] This potential term of adjustment is offset by any applicant delay.[173]

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162. 35 U.S.C. § 156(c).

163. More formally, with respect to the FDA, the testing phase consists of the period time between the filing of an IND and an NDA. *See Step 3: Clinical Research*, U.S. Food & Drug Admin. (Jan. 4, 2018), https://www.fda.gov/patients/drug-development-process/step-3-clinical-research [https://perma.cc/62AP-WAZX].

164. More formally, with respect to the FDA, the approval phase consists of the time between the filing of an NDA and the approval of that NDA. *See Step 4: FDA Drug Review*, U.S. FOOD & DRUG ADMIN. (Jan. 4, 2018), https://www.fda.gov/patients/drug-development-process/step-4-fda-drug-review [https://perma.cc/E9E2-MEJ4].

165. 35 U.S.C. § 156(c)(3).

166. *Id.* § 156(c)(1).

167. *Id.* § 156(c)(4).

168. Congress enacted this statute as Subtitle D of the American Inventors Protection Act of 1999. Pub. L. No. 106-113, 113 Stat. 1501 (1999).

169. *See generally* Stephanie Plamondon Bair, *Adjustment, Extensions, Disclaimers, and Continuations: When Do Patent Term Adjustments Make Sense?*, 41 CAP. U.L. REV. 445 (2013); Emily M. Hinkens, *Patent Term Adjustment and Terminal Disclaimers: Are the Terms of Patents Being Decided Ad Hoc?*, 94 MARQ. L. REV. 375 (2010).

170. *See, e.g.*, Idorsia Pharms. Ltd. v. Iancu, 393 F. Supp. 3d 445, 450 (E.D. Va. 2019), *aff'd*, 811 Fed. Appx. 650 (Fed. Cir. 2020).

171. *See, e.g.*, Bair, *supra* note 169, at 455.

172. 35 U.S.C. § 154(b)(1).

173. *Id.* § 154(b)(2).

Most patents receive some PTA,[174] and the increase in patent term is sometimes quite substantial. For example, U.S. Patent No. 10,024,588 received 4,855 days (or over 13 years) of PTA,[175] although the average award is 411 days.[176] In addition, PTA and PTE are cumulative.[177] U.S. Patent No. 7,399,865, which pertains to NERLYNX (neratinib), provides one example, having obtained 475 days of PTA and five years of PTE.[178]

PTA and PTE operate differently as a formal matter. Unlike PTA, PTE does not provide a traditional increase in the patent term. Rather than providing a temporal extension of the original right to exclude from practicing the patented invention, the scope of rights afforded by PTE is generally limited to an FDA-approved use.[179] If, for example, a patented hypertension medication also had an unregulated use—say, as a solution for cleaning eyeglasses—then opticians would be free to sell that solution during the period of PTE. As a practical matter, however, both PTA and PTE preclude competition from generic drug companies for their entire cumulative period.

The difficulty with our current framework leads to the possibility of double counting—namely, a brand-name company receiving more than one day of effective term augmentation in exchange for a single day of government delay. Firms commonly prosecute pharmaceutical patents at the USPTO at the same time they are pursuing FDA marketing approval. If a USPTO delay occurs during the FDA's "testing phase,"[180] then every two days of government delay results in three additional days of patent term—namely, two days of PTA and one day of PTE. Further, if the USPTO delay occurs during the FDA's "approval phase,"[181] then a single day of government delay would result in the award of both one day of PTA and one day of PTE. Whether brand-name drug companies deserve two additional days of effective patent term in exchange for a single day of delay caused by the "whole of government" bears reconsideration.

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174. Mark A. Lemley & Jason Reinecke, *Our More-than-Twenty-Year Patent Term* 1 (Stanford L. & Econ. Olin Working Paper No. 586), https://ssrn.com/abstract=4529670 [https://perma.cc/NW9M-FJBP] (noting that 63.6% of patents receive PTA).

175. U.S. Patent No. 10,024,588 (issued Jul. 17, 2018).

176. *Id.*

177. 35 U.S.C. § 156(a) ("[O]riginal expiration date of the patent . . . shall include any patent term adjustment under section 154(b) . . . .").

178. U.S. Patent No. 7,399,865 (issued Jul. 15, 2008) identifies an award of PTA of 475 days. *See also* PTE certificates issued (updated through August 2024), USPTO (Sept. 2024), https://www.uspto.gov/patents/laws/patent-term-extension/patent-terms-extended-under-35-usc-156 [https://perma.cc/37UW-G3F5] (spreadsheet file noting five years of PTE for U.S Patent No. 7,399,865).

179. 35 U.S.C. § 156(b)(1).

180. The "testing phase" consists of the period between the filing of the IND and NDA. *See* Jaime F. Cárdenas-Navia, *Thirty Years of Flawed Incentives: An Empirical and Economic Analysis of Hatch-Waxman Patent-Term Restoration*, 29 BERKELEY TECH. L.J. 1301, 1310–11 (2014).

181. The "approval phase" consists of the period between the filing of an NDA and FDA approval of that NDA. *Id.*

In addition, our understanding of the costs that PTA and PTE impose upon the public is poor. Particularly in the case of the USPTO, prompt turnaround of applications claiming pharmaceuticals could potentially lead to enormous savings in costs of healthcare. The FDA and USPTO would do well to quantify the costs that their regulatory delays impose upon U.S. citizens in terms of their accessibility to healthcare and, if appropriate, take steps to ameliorate any deficiencies.

C. Administering the Orange Book

In 2023 and 2024, the FTC unexpectedly sent succinct letters to 14 leading healthcare firms.[182] In its correspondence, the agency asserted that these firms had improperly identified, in total, over 400 patents for listing in the Orange Book.[183] Although the FTC declined to offer any substantive explanation for its position, the agency appears to be focusing on patents claiming drug-device combinations. That the FTC felt the need to take this step might strike many as an odd institutional choice. The FDA bears responsibility for maintaining the Orange Book;[184] the USPTO issues the patents identified within it;[185] and the two agencies had engaged in discussions regarding collaboration initiatives for more than two years before the FTC acted.[186] An understanding of the dysfunctions that led us to this situation suggests future pathways for the FDA and USPTO.

Orange Book patent listings hold considerable consequences for brand-name and generic pharmaceutical companies alike. Generic manufacturers must provide their views and intentions concerning listed patents, in general stating that they will wait until the patents expire,[187] draft labels to avoid them,[188] or state their willingness to challenge their validity of scope.[189] The latter option, the paragraph

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182. *See* FTC Orange Book Listing Challenges, *supra* note 14; Press Release, FTC, FTC Expands Patent Listing Challenges, Targeting More Than 300 Junk Listings for Diabetes, Weight Loss, Asthma and COPD Drugs (Apr. 30, 2024) (available at https://www.ftc.gov/news-events/news/press-releases/2024/04/ftc-expands-patent-listing-challenges-targeting-more-300-junk-listings-diabetes-weight-loss-asthma [https://perma.cc/9T4Q-HJ6X]).

183. To read the letters, see *Warning Letters by Press Release: FTC Challenges More Than 100 Patents as Improperly Listed in the FDA's Orange Book*, FTC, https://www.ftc.gov/legal-library/browse/warning-letters/81927 [https://perma.cc/2Q5X-28JF] (last visited Dec. 1, 2024).

184. 21 U.S.C. § 355(j)(7).

185. 35 U.S.C. § 131.

186. *See* Letter from Janet Woodcock, Acting Comm'r of Food & Drugs, to Andrew Hirshfeld, Performing the Functions & Duties of the Under Sec'y of Com. for Intell. Prop. & Dir. of the USPTO (Sept. 10, 2021) (available at https://optimalcancercare.org/wp-content/uploads/2021/09/EO-14036-FDA-Letter-to-PTO.pdf [https://perma.cc/4B7E-KP3L]).

187. The industry refers to this option as a "paragraph III certification." 21 U.S.C. § 355(j)(2)(A)(vii)(III).

188. This option is termed a "section viii statement." *Id.* § 355(j)(2)(A)(viii).

189. This option is termed a "paragraph IV certification." *Id.* § 355(j)(2)(A)(vii)(IV).

IV certification, may result in immediate patent enforcement litigation brought by the brand-name firm.[190]

Given these significant ramifications, the question naturally arises about what sorts of patents brand-name companies should identify to the FDA. According to the Hatch–Waxman Act, a patent may be identified for listing if it claims: (1) the active ingredient of the drug, which the FDA terms a "drug substance"; (2) a formulation or composition of the drug, known as a "drug product"; or (3) a method of using the drug.[191] In 2003, the FDA issued regulations elaborating upon the sorts of patents that should be identified for listing in the Orange Book in keeping with the statutory definition.[192] The agency reasoned that patents claiming manufacturing methods, packaging, metabolites, and chemical intermediates were among those that should not be identified for listing.[193]

Disputes often arise as to whether the patents listed in the Orange Book appropriately follow these guidelines.[194] The MMA authorized generic firms that were sued for patent infringement to bring a counterclaim requesting the delisting of the patent.[195] As the MMA expressly stipulated that it did not authorize any other cause of action for delisting, and further provided that a generic firm is ineligible for damages in the event of an improper listing, it has not proven an effective mechanism for policing the Orange Book.[196]

In 2016, following its nearly 13-year delay in implementing the MMA,[197] the FDA established an administrative procedure that allows for generic manufacturers and other interested parties to challenge the propriety of patent listings.[198] Consistent with its longstanding practices, the FDA merely plays a ministerial role in this procedure. The agency allows petitioners to dispute the accuracy or relevancy of patent information in the Orange Book—or the lack of information in the Orange Book—by communicating a statement of dispute to the FDA. Unless the brand-name drug company voluntarily withdraws or amends its patent information, the FDA will not change the information in the Orange Book.

Orange Book listing disputes often involve the facts of individual cases. However, persistent issues have arisen over patents falling into one of two broad

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190. 35 U.S.C. § 271(e)(2).

191. 21 U.S.C. § 355(b)(1)(A)(viii).

192. *See* Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed, 68 Fed. Reg. 36676, 36678 (June 18, 2003) (to be codified at 21 C.F.R. pt. 314) [hereinafter FDA 2003 Notice].

193. *Id.* at 36679; *see also* 21 C.F.R. § 314.53(b) (2024).

194. The FDA maintains a chart identifying Orange Book listing dispute petitions that the agency has received. *See Patent Listing Disputes*, U.S. FOOD & DRUG ADMIN. (Dec. 8, 2023), https://www.fda.gov/media/105080/download [https://perma.cc/YMU4-PBGQ].

195. 21 U.S.C. § 355(j)(5)(C)(ii)(I).

196. *See* Eisenberg & Crane, *supra* note 2, at 222; Ge Lei, *Counterclaim? Not a Real Fix to Prevent Patent Use Code Abuse*, 6 N.C. CENT. U. SCI. & INTELL. PROP. L. REV. 25, 26 (2013).

197. *See supra* notes 9–11 and accompanying text.

198. 21 C.F.R. § 314.53(f)(1) (2024).

categories.[199] The first relates to drug-device combination products, the sort that the FTC identified in its late 2023 letters.[200] These consist of two or more FDA-regulated components—ranging from pre-filled syringes, insulin injector pens, drug-eluding stents, patches, and inhalers—that are joined or packaged together for drug delivery. Brand-name drug companies commonly procure patents on both the drug and the components of the device.[201]

The extent to which patents on the device components of these combination products may be listed in the Orange Book remains unclear. Sometimes the claims of the device component patents recite the drug's active ingredient or formulation, but other times they do not.[202] Sometimes the devices are individually tailored for a particular drug; other times they are of more general use, but may be asserted against generic manufacturers nonetheless.[203] But whether these patents claim a drug product, drug substance, or method of use in keeping with the statutory standard for Orange Book listing seems doubtful. The FTC likely has the right of the matter, but its approach seems ham-fisted given the lack of written guidance from the FDA regarding a role for drug-device combinations within the Orange Book.

The eligibility of REMS patents for listing in the Orange Book has also been subject to a lively debate. REMS patents pertain to FDA programs intended to ensure that the benefits of using a drug outweigh its disadvantages.[204] As such, they are typically directed to systems and methods, including restricted distribution provisions and the provision of risk information to prescribers, for mitigating the potentially negative outcomes of using particular drugs.[205] More specifically, pursuant to the Food and Drug Amendments Act of 2007, REMS programs may include: (1) a medication guide or package insert distributed with a drug;[206] (2) a communication plan for healthcare providers;[207] (3) packaging and disposal

199. *See* Michael S. Sinha, *Costly Gadgets: Barriers to Market Entry and Price Competition for Generic Drug-Device Combinations in the United States*, 23 MINN. J.L. SCI. & TECH. 293, 293 (2022); Taylor Stemler, *Minor Advances, Major Consequences: Hatch-Waxman Administers Exclusivity for Drug Delivery Devices*, 46 MITCHELL HAMLINE L. REV. 655, 686 (2020); Sherkow & Zettler, *supra* note 23, at 176.

200. *See supra* notes 182–86 and accompanying text.

201. *See* Rigel Menard, *A Survey of the Legal Landscape Facing Entities with Patents Reciting a Method of Using a Medical Device*, 4 CYBARIS AN INTELL. PROP. L. REV. 129, 131 (2013).

202. *See* U.S. GOV'T ACCOUNTABILITY OFF., GAO-23-105477, GENERIC DRUGS: STAKEHOLDER VIEWS ON IMPROVING FDA'S INFORMATION ON PATENTS 12–14, 17 (2023).

203. *Id.*

204. *See* Michael A. Carrier & Brenna Sooy, *Five Solutions to the REMS Patent Problem*, 97 B.U. L. REV. 1661, 1665–68 (2017).

205. The FDA maintains a list of approved REMS on its website. *See Approved Risk Evaluation and Mitigation Strategies (REMS)*, U.S. FOOD & DRUG ADMIN. (May 16, 2023), https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems [https://perma.cc/49ZN-TNDJ].

206. 21 U.S.C. § 355-1(e)(2).

207. *Id.* § 355-1(e)(3).

requirements, such as a safe disposal system;[208] and (4) elements to assure safe use ("ETASU"), such as a specific monitoring program.[209]

Recent litigation concerning the narcolepsy drug XYREM has focused attention on the listing of REMS patents in the Orange Book. The active ingredient of XYREM, sodium oxybate, has been misused as a date-rape drug. As a result, the FDA conditioned approval of XYREM upon the development of REMS protocols that restricted its distribution to a single pharmacy, thereby allowing the tracking of prescriptions, patients, and prescribers.[210] Jazz Pharmaceuticals ("Jazz") successfully obtained FDA approval for XYREM and also obtained U.S. Patent No. 8,731,963 ("the '963 Patent").[211] The '963 Patent, which Jazz listed in the Orange Book, claims a computer-implemented single pharmacy system for controlling access to abuse-prone drugs.

When Avadel CNS Pharmaceuticals ("Avadel") filed an NDA seeking to sell a generic XYREM product, Jazz reacted by bringing suit for infringement of the '963 Patent.[212] Avadel then brought a counterclaim seeking the delisting of the '963 Patent from the Orange Book. The Federal Circuit responded with a narrow ruling. It concluded that the claims of the '963 Patent were directed to systems and did not meet the "method of use" requirement for Orange Book listing.[213] However, the Federal Circuit avoided offering broader observations about whether REMS patents reciting methods may qualify for listing in the Orange Book.[214]

Given the narrow holding in *Jazz Pharmaceuticals, Inc. v. Avadel CNS Pharmaceuticals, LLC*, whether other sorts of REMS patents may be listed in the Orange Book remains a live issue. Some REMS programs should prove more difficult to patent going forward, as single-pharmacy systems and other FDA programs have now taken their place in the prior art. However, patents claiming ETASU inventions seem more sustainable going forward. Because they typically address adverse events that may result from the use of a specific drug, they seem more likely both to be patentable and to qualify as a "method of using" a drug suitable for Orange Book listing.[215]

Consider, for example, U.S. Patent No. 10,452,815 ("the '815 Patent"),[216] currently listed in the Orange Book for FINTEPLA (fenfluramine).[217] The '815 Patent is titled "Control System for Control of Distribution of Medication."[218] Each

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208. *Id.* § 355-1(e)(4).

209. *Id.* § 355-1(f).

210. *See* Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC, 60 F.4th 1373, 1376 (Fed. Cir. 2023).

211. U.S. Patent No. 8,731,963 (issued May 20, 2014).

212. *Jazz Pharms.*, 60 F.4th at 1378.

213. *Id.* at 1379–81.

214. *Id.* at 1381.

215. *See* 21 U.S.C. § 355(b)(1)(A)(viii) (requiring the NDA applicant to identify patents that claim "a method of using such drug for which approval is sought or has been granted in the application").

216. U.S. Patent No. 10,452,815 (issued Oct. 22, 2019).

217. *See* ORANGE BOOK, *supra* note 98, at 226. For Patent and Exclusivity N212102 "Fenfluramine Hydrochloride (FINTEPLA) Solution EQ 2.2 mg base/ml," see id.

218. *Id.*

of the claims of the ’815 Patent calls for methods of treating epilepsy patients with fenfluramine only after they have obtained satisfactory results from echocardiogram testing. Such claims resemble traditional methods of medical treatment claims, even though they mirror an ETASU for FINTEPLA’s REMS program.[219] In view of the more comfortable fit of ETASU and other REMS patents in the Orange Book than the one addressed in *Jazz Pharmaceuticals*, controversies appear likely to linger absent regulatory or legislative changes.[220]

Despite these disputes, the FDA remains steadfast in its belief that its role regarding patent listings is solely ministerial.[221] Conversely, USPTO officials have stated that Orange Book patent listings are a matter for the FDA to administer.[222] This sort of parochialism is, of course, precisely the problem that the whole-of-government approach attempts to ameliorate.

Four decades of experience suggests the need for greater oversight of the Orange Book. Further, the FDA and USPTO cannot plausibly assert that they cannot perform functions that Hatch–Waxman practitioners complete on an everyday basis. The agencies should also appreciate the operations of the South Korean Ministry of Food and Drug Safety. The South Korean Ministry actively supervises an equivalent of the Orange Book termed the “Green List,” and in so doing ensures that the patents identified there comport with statutory listing standards.[223] International best practices have long informed U.S. patent law reforms and, with respect to the Orange Book, should continue to do so in the future. Through productive collaboration, the FDA and USPTO could bring greater order to the Orange Book in the service of public health.

D. Aligning Patents with Hatch–Waxman Practice

Only some types of patents may be listed in the Orange Book. As we have seen,[224] a patent may be identified for listing if it claims a drug’s active ingredient or its formulation, or a method of using the drug.[225] Methods of manufacturing

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219. *See Highlights of Prescribing Information*, UCB GROUP OF COMPANIES (Dec. 2023) https://www.ucb-usa.com/fintepla-prescribing-information.pdf [https://perma.cc/4DZK-4AE5].

220. In the 118th Congress, the proposed, but unenacted Increasing Prescription Drug Competition Act would eliminate any FDA approval delay associated with Orange Book-listed REMS patents. S. 574, 118th Cong. (2023).

221. U.S. FOOD & DRUG ADMIN., THE LISTING OF PATENT INFORMATION IN THE ORANGE BOOK 5 (2022), https://www.fda.gov/media/155200/download [https://perma.cc/5RMG-7Z9Y].

222. *See* Brenda Sandburg, *FDA-USPTO Collaboration: Stakeholders Want More Clarity on Orange Book Patent Listings*, PINK SHEET (Oct. 23, 2003) (noting statement of USPTO official that the agency was not considering a possible role for the agency’s Patent Trial and Appeal Board to resolve Orange Book patent listing disputes).

223. *See* Jerry I-H Hsiao, *An Analysis of the Patent Linkage System and Development of the Biosimilar Industry in Taiwan*, 46 BROOK. J. INT’L L. 479, 505–07 (2021); Kimberlee Thompson Raley, *The South Korean Patent Linkage System: A Model for Reforming the United States*, 33 EMORY INT’L L. REV. 459, 468 (2019); Keum Nang Park et al., *South Korea’s Patent-Approval Linkage System*, IP LIFE SCI. INDUS. 121, 122 (2014).

224. *See supra* note 192 and accompanying text.

225. 21 U.S.C. § 355(b)(1)(A)(viii).

drugs, among other types of patents, may not be listed in the Orange Book. This statutory framing interfaces poorly with USPTO practice. Issued patents often claim inventions that fall within multiple categories, creating needless disconnects with the Hatch–Waxman Act.

Consider, for example, U.S. Patent No. 11,254,652 ("the '652 Patent").[226] The Orange Book identifies the '652 Patent in connection with PYRUKYND (mitapivat), a drug indicated for hereditary homolytic anemias. Claims 1–5 of the '652 Patent recite an active ingredient; claims 6 and 7 pertain to a formulation; and claim 8 sets out a process of manufacturing the active ingredient.[227] By itself, claim 8 should not be identified for listing in the Orange Book.

U.S. Patent No. 9,732,075 ("the '075 Patent") provides another example.[228] The Orange Book lists the '075 Patent with respect to the insomnia drug QUVIVIQ (daridorexant). Claim 1 of the '075 Patent recites an active ingredient; claim 2 pertains to a formulation (the active ingredient along with an excipient); and claim 3 sets forth a method of medical treatment.[229]

The USPTO's indifference to Orange Book listing standards creates two fundamental problems. First, claims reciting manufacturing methods that should not be listed in the Orange Book may nonetheless reside there, so long as they are incorporated within a patent that also contains claims directed towards active ingredients, formulations, or methods of use. Second, the FDA has been left to develop a complex "split certification" process to deal with patents incorporating claims across different inventive categories.[230] Under this approach, generic manufacturers submit, with respect to a single patent, a section viii statement concerning claims reciting methods of medical treatment for which they are not seeking FDA approval—alongside a paragraph IV certification for any remaining active ingredient, formulation, or method use for which they are seeking approval.[231] FDA procedures, while necessary given the patents the USPTO grants, create needless complexities and sow confusion about the award of generic exclusivity to paragraph IV ANDA applicants.

Two solutions to this problem present themselves. First, the FDA could require brand-name drug companies to identify patents for Orange Book listing on

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226. U.S. Patent No. 11,254,652 (issued Feb. 22, 2022).

227. *Id.* col. 68.

228. U.S. Patent No. 9,732,075 (issued Aug. 15, 2017).

229. *Id.* col. 168-70.

230. *See* Erika Lietzan & Julia Post, *The Law of 180-Day Exclusivity*, 71 FOOD & DRUG L.J. 327, 389–90 (2016).

231. *See* U.S. FOOD & DRUG ADMIN. GUIDANCE FOR INDUSTRY, 180-DAY EXCLUSIVITY: QUESTIONS AND ANSWERS 7 (2017) (observing that a single patent may incorporate drug product, drug substance, and method-of-use claims, leading to the potential need for a paragraph IV certification and a section viii statements with respect to a single patent).

a claim-by-claim basis.[232] While superior to current practice, this approach would dramatically expand the length and complexity of Orange Book patent listings.

USPTO alignment of the pharmaceutical patents it issues with the Hatch–Waxman practice provides another better alternative. The Patent Act has long allowed the USPTO to require an applicant claiming two or more "independent and distinct inventions" in a single filing to select one for continued prosecution.[233] The applicant may pursue patents on the other inventions by filing "divisional" applications.[234] The USPTO could readily put this well-established practice to use to approve pharmaceutical patents consistent with the Hatch–Waxman framework.[235]

E. Assessing Use Code Practice

Another target for reform at the intersection of patent and food and drug law concerns patent "use codes."[236] This anomalous FDA practice for paraphrasing patents results in broader intellectual property protection for brand-name drug companies than Congress has allowed. The FDA should seek the advice of the USPTO to modify or terminate its use code procedures.

The circumstances leading to the FDA's adoption of use codes reflect the often-complex patent landscape concerning pharmaceuticals. Brand-name drug companies typically file patent applications early in the drug development process,[237] often claiming such inventions as the drug's active ingredient, the pharmaceutical formulation including that active ingredient, and the drug's therapeutic uses.[238] But they may also seek patent protection later in time, and even long after the FDA has approved the drug for marketing. These later patents often deal with secondary indications of the medicine—namely, new therapeutic uses for a drug that is already known.[239]

Suppose, for example, that a brand-name drug company developed a pharmaceutical as an antidepressant. It obtains patents covering that product and its

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232. The Ministry of Food and Pharmaceutical Safety (MFDS) of South Korea maintains this practice for its Green List, the analog of the U.S. Orange Book. *See* Raley, *supra* note 223, at 476.

233. 35 U.S.C. § 121.

234. *See generally* Hildreth, *supra* note 26; Jeannette M. Braun, *The Safe Harbor of 35 U.S.C. § 121: Judicial Deviation from Congressional Intent Necessary to Uphold 35 U.S.C. § 101*, 18 J. MARSHALL REV. INTELL. PROP. L. 205, 207–08 (2018); Kevin Rizzuto, *Fixing Continuing Application Practice at the USPTO*, 13 MARQ. INTELL. PROP. L. REV. 411, 414–15 (2009).

235. As a possible downside of this approach, the USPTO's use of a restriction requirement would allow the applicant to claim the safe harbor against obvious-type double patenting found in 35 U.S.C. § 121.

236. *See* U.S. GOV'T ACCOUNTABILITY OFF., GAO-23-105477, GENERIC DRUGS: STAKEHOLDER VIEWS ON IMPROVING FDA'S INFORMATION ON PATENTS (2023).

237. *See* Hedwig A. Murphy, *Limiting Continuations: A Pharmaceutical Based Perspective*, 6 RUTGERS J. L. & PUB. POL'Y 856, 873 (2009).

238. *See* JOHN R. THOMAS, PHARMACEUTICAL PATENT LAW 46–48 (3d. ed. 2015).

239. *See* Julian W. Marrs, *Forever Green? An Examination of Pharmaceutical Patent Extensions*, 18 OR. REV. INT'L L. 81, 83 (2016) (noting later-stage patents including those on additional medical uses).

known use. Some years later, the brand-name company determines that the pharmaceutical may also be used to help people stop smoking. The brand-name company may not again patent that product, or its original use, which is already publicly available. However, it could obtain a patent on the new use of the drug for smoking cessation. Because the brand-name company filed the application that led to the smoking cessation patent long after it obtained its initial patents, the smoking cessation patent would expire later.[240]

In these circumstances, the Hatch–Waxman Act allows generic manufacturers to sell their products provided that their labeling speaks only to uses that are no longer patented. The generic label simply does not mention uses that remain subject to patent protection, which from the perspective of a physician may constitute only a fraction of the drug's medical indications.[241] The industry refers to this sort of label as a "skinny label."[242]

The FDA currently calls for brand-name firms to draft a narrative termed a "use code" concerning patents claiming methods of medical treatment. [243] The FDA assigns a number to each use code and lists them in the Orange Book, which currently houses nearly 3,800 of them.[244] Each use code may contain no more than 250 characters. Exemplary use codes include "treatment of type 2 diabetes mellitus,"[245] "for the treatment of patients with follicular lymphoma,"[246] and "treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy."[247]

Use codes hold significant consequences. If the use code indicates that the patent claims a method of use for which approval is sought, then the generic manufacturers must submit an ANDA with either a paragraph III or paragraph IV

240. Critics of this practice deem it as "evergreening." *See* McKenzie E. List, *The Hollow Rhetoric of Evergreening*, 61 JURIMETRICS J. 495, 495 (2021); Malissa S. Magiera, *Leaving the Evergreening Problem to the Patent Experts - The USPTO, the PTAB, and the Federal Circuit*., 54 IND. L. REV. 195, 197 (2021); Erika Lietzan, *The "Evergreening" Metaphor in Intellectual Property Scholarship*, 53 AKRON L. REV. 805, 828–29 (2019).

241. The FDA does not regulate off-label uses by physicians. *See* David A. Simon, *Off-Label Innovation*, 56 GA. L. REV. 701, 719–720 (2022).

242. *See, e.g.*, Maya Lorey, *Insurance Coverage and Induced Infringement: A Threat to Hatch-Waxman's Skinny Labeling Pathway*, 90 U. CHI. L. REV. 1517, 1521 (2023); Kayla MacCallum, *Hacking or Hatching the Skinny Label: How the Federal Circuit's Decision in* GSK v. Teva *Threatens Generics and Induced Infringement*, 9 TEX. A&M J. PROP. L. 197, 208 (2023); Garrett T. Potter, *Beefing Up Skinny Labels: Induced Infringement as a Question of Law*, 97 NOTRE DAME L. REV. 1707, 1714 (2002).

243. 21 C.F.R. § 314.53(c)(2)(i)(O) (2024).

244. *See* ORANGE BOOK, *supra* note 98.

245. *Id.* at 1856. The FDA identifies this narrative as U-493. It is associated with U.S. Patent No. 6,515,117, and the NDA approval of FARXIGA (dapagliflozin). *Id.* at 1427.

246. *Id.* at 1921. The FDA identifies this narrative as U-2413. It is associated with U.S. Patent No. 9,840,505, and the NDA approval of COPIKTRA (duvelisib). *Id.* at 1454.

247. *Id.* at 1964. The FDA identifies this narrative as U-3434. It is associated with U.S. Patent No. 11,021,475, and the NDA approval of SOTYKTU (deucravacitinib). *Id.* at 1437.

certification.[248] A paragraph III certification reveals the generic manufacturer's intention to wait to market its product until the patent expires. In contrast, a paragraph IV certification is confrontational. It states the generic manufacturer's view that the patent is invalid, unenforceable, or not infringed, and it often leads to litigation.[249]

Otherwise, the generic applicant may submit a section viii statement asserting that the Orange Book-listed patent "does not claim a use for which the applicant is seeking approval."[250] Such a skinny label might provide that the drug is indicated for a public domain use as an anti-depressant, for example, while remaining silent about the patented use as a smoking cessation medication. Absent any other relevant regulatory or intellectual property issue, the FDA will approve an ANDA with a section viii statement without delay.

Given the significance of use codes, one might suppose that they accurately portray the patents they describe. However, actual comparisons of FDA use code narratives with USPTO-issued patent claims reveal surprising outcomes. Consider the Orange Book listing for MYDAYIS (amphetamine or dextroamphetamine), which includes U.S. Patent No. 9,173,857 ("the '857 Patent").[251] The FDA associates the '857 Patent with use code U-2025, which reads in its entirety as follows: "Treatment of attention deficit hyperactivity disorder."[252]

In comparison, claim 1 of the '857 Patent recites:

> A method for treating attention deficit hyperactivity disorder (ADHD) which comprises:
>
> administering to a patient in need thereof, a pharmaceutical composition comprising:
>
> (a) an immediate release bead comprising at least one amphetamine salt;
>
> (b) a first delayed release bead comprising at least one amphetamine salt; and
>
> (c) a second delayed release bead comprising at least one amphetamine salt; wherein the first delayed release bead provides pulsed release of the at least one amphetamine salt and the second delayed release bead provides sustained release of the at least one amphetamine salt;
>
> wherein the second delayed release bead comprises at least one amphetamine salt layered onto or incorporated into a core; a

248. 21 U.S.C. § 355(j)(2)(A)(vii)(III), (IV). Although commonly termed "paragraphs" by Hatch–Waxman practitioners, each provision appears in a subclause of 21 U.S.C. § 355.

249. *See supra* notes 110–14 and accompanying text.

250. 21 U.S.C. § 355(j)(2)(A)(vii). The "section viii" statement in fact appears in a clause of 21 U.S.C. § 355.

251. U.S. Patent No. 9,173,857 (issued Nov. 3, 2015) [hereinafter '857 Patent].

252. *See* ORANGE BOOK, *supra* note 98, at 60, 1346. NDA 022063, MYDAYIS (amphetamine aspartate; amphetamine sulfate; dextroamphetamine saccharate; dextroamphetamine saccharate (MYDAYIS) capsule; extended release 3.125 mg each). *Id.*

> delayed release coating layered onto the amphetamine core; and a sustained release coating layered onto the delayed release coating, wherein the sustained release coating is pH-independent; and
>
> wherein the first delayed release bead and the second delayed release bead comprise an enteric coating.[253]

Comparisons such as these are quite revealing. Claim 1 of the ’857 Patent, as with others in the field of pharmaceutical patent law, includes numerous limitations detailed at a high level of specificity. A modest summary of 250 characters cannot possibly capture them all. And like many use codes, U-2025 simply recites the introductory words of the claim, commonly known as the preamble.[254] However, long-established principles of patent claim construction measure claim scope with primary reference to the body of the claim. Courts sometimes assign the preamble no patentable weight whatsoever.[255] By ignoring the body of patent claims and elevating their preambles to serve as the sole measure of proprietary rights, use codes turn bedrock principles of patent claim construction on their head.

The FDA’s practice of allowing a single use code to represent numerous patent claims exacerbates this problem. Consider, for example, the Orange Book listing for RHOPRESSA (netarsudil mesylate).[256] The FDA associates U-1524, which recites “Reduction of Elevated Intraocular Pressure,” with 13 patents including a total of 347 claims, of which 221 recite methods.[257] No person with even a rudimentary knowledge of patent law would possibly attempt to summarize that volume of claims in 250 characters or less.[258]

The way the FDA chose a 250-character limit on patent use codes appears particularly troubling. The agency did not reach this limit based upon its understanding of patent claim construction—of which it disclaims any expertise—or following a discussion of the matter with the USPTO. Rather, the agency reckoned that 250 characters were the most that a cell with the agency’s antiquated database could house.[259]

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253. ’857 Patent at cols. 31–32.

254. *See* Mark A. Lemley, *Without Preamble*, 100 B.U. L. REV. 357, 365 (2020); Kyle D. Petaja, *Claim Preambles and the Unassailable Patent Claim*, 5 J. MARSHALL REV. INTELL. PROP. L. 121, 123 (2005); Li-Hua Weng, *Preamble Interpretation: Clarifying the “Giving Life, Meaning and Vitality” Language*, 11 B.U. J. SCI. & TECH. L. 77, 79 (2005).

255. *See*, *e.g.*, Shoes by Firebug LLC v. Stride Rite Child.’s. Group, LLC, 962 F.3d 1362, 1367 (Fed. Cir. 2020); *In re* Fought, 941 F.3d 1175, 1178 (Fed. Cir. 2019); Bicon, Inc. v. Straumann Co., 441 F.3d 945, 952 (Fed. Cir. 2006) (each observing that preambles do not arise to the level of claim limitations when they state only the purpose or intended use for inventions).

256. *See* ORANGE BOOK, *supra* note 98, at 369. For NDA 208254, RHOPRESSA ((netarsudil mesylate), solution/drops EQ 0.02% base), see id.

257. *Id.*

258. *See* SCHECHTER & THOMAS, *supra* note 51, at 207 (“The claims form the most significant part of the patent instrument, for it is the claims themselves that set forth the proprietary technological rights possessed by the patentee.”).

259. *See* Abbreviated New Drug Applications and 505(b)(2) Applications, 81 Fed. Reg. 69580, 69598 (Oct. 6, 2016) (to be codified at 21 C.F.R. pts. 314, 320).

The litigation in *Caraco Pharmaceutical Laboratories, Ltd. v. Novo Nordisk A/S* suggests the possibilities for the strategic drafting of use codes given FDA policies.[260] In that case, Novo Nordisk's patent claimed the active ingredient of the drug PRANDIN (repaglinide) had expired.[261] The USPTO had granted Novo Nordisk an additional patent claiming a method of using repaglinide in combination with metformin,[262] while the FDA granted Novo Nordisk marketing approval for three uses of repaglinide to treat diabetes: repaglinide by itself; repaglinide in combination with thiazolidinediones ("TZDs"); and repaglinide in combination with metformin.[263]

As a result of these FDA and USPTO decisions, Novo Nordisk held marketing approval for three methods of using repaglinide, but only one of them, the combination therapy of repaglinide and metformin, remained patented. Novo Nordisk nonetheless presented to the FDA a use code narrative reciting a "method for improving glycemic control in adults with type 2 diabetes."[264] This expansive use code covered each of the three approved methods for using repaglinide—which, in effect, amounted to Novo Nordisk awarding itself proprietary rights beyond what the USPTO had authorized. Supreme Court intervention ultimately brought some resolution to this matter,[265] but only at great time and expense to generic firms and ultimately to the public.

Given the potential mischief surrounding use code narratives, one might suppose that the FDA provides some supervision over them. This is not the case. The FDA merely accepts use code narratives from brand-name drug companies and reprints them in the Orange Book. The agency accepts challenges from third parties regarding the propriety of a patent use but limits them to the submission of a statement of no more than 250 words directed towards the "person's interpretation of the scope of the patent."[266] The FDA then forwards the information to the brand-name drug company. Unless the brand-name drug company withdraws or amends the use code, the FDA will take no further action.[267]

The FDA possesses at least three paths forward to address this aberrant practice. First, the agency may simply terminate its use code procedures. When an agency receives a section viii statement from a generic firm, it could take the generic firm at its word that its proposed labeling does not cover a patented indication. Generic firms would, of course, remain susceptible to a garden-variety claim of

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260. 566 U.S. 399, 406–08 (2012).
261. *Id.* at 409.
262. *Id.*
263. *Id.*
264. *Id.* at 410.
265. *Id.* at 417–19 (concluding that use codes qualify as "patent information" that a generic manufacturer may challenge by bringing a counterclaim against a brand-name drug company in a patent infringement suit).
266. 21 C.F.R. § 314.53(f) (2019) ("For a dispute regarding the accuracy or relevance of patent information regarding an approved method of using the drug product, this statement of dispute must be only a narrative description (no more than 250 words) of the person's interpretation of the scope of the patent.").
267. *Id.* § 314.53(i).

patent infringement if its sales infringe.[268] Second, the FDA could substitute use codes with the broadest claim of the method-of-use patents with which they are associated.[269] As with the abandonment of use codes altogether, this approach avoids the problems of misdescriptive, overly terse summaries of patent claims. Finally, the FDA could develop an improved dispute resolution system for challenging use codes. The FDA and USPTO could partner to address petitions asserting that a use code is inappropriately drafted. In doing so, the FDA could enlist the PTAB, or take advantage of employees detailed from the USPTO, to adjudicate these disputes.[270]

F. Forfeiting Generic Exclusivity

To promote challenges to pharmaceutical patents, the Hatch–Waxman Act established 180 days of regulatory exclusivity for generic firms.[271] In broad brush, once a court issues a favorable judgment concerning a brand-name drug company's patents,[272] the FDA shields a first paragraph IV ANDA applicant from competition with other generic firms for 180 days. The 180-day period begins on the date the first paragraph IV ANDA applicant commercially markets its generic product.[273]

Initial experience with Hatch–Waxman suggested possibilities for abuse of this exclusivity by generic manufacturers. Possibly with the encouragement of brand-name drug companies, first paragraph IV ANDA applicants were seen as "parking" their exclusivity to forestall generic competition, rather than actively pursuing the sale of their products.[274] Put differently, if the 180-day period never began, it would never end, resulting in a bottleneck in the availability of generic drugs.

Congress reacted to these allegations of parking when it enacted the MMA in 2003.[275] That legislation established seven so-called "forfeiture events," which if

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268. Such a lawsuit would proceed under subsections § 271(a), (b), or (c) of the Patent Act, rather than subsection § 271(e)(2). *See* 35 U.S.C. § 271.

269. *See* Frederick (Rick) R. Ball & Elese Hanson, *Patent Use Codes, The Orange Book and Section viii Statements: A Response to Terry Mahn's Is it Time for FDA to Revise its Orange Book Rules to Deal with "Skinny-Labeled" Generic Drugs?*, 1 FDLI'S FOOD & DRUG POL'Y F. 5 (2011).

270. *See* John R. Thomas, *Noticing Patents*, 24 COLUM. SCI. & TECH L. REV. 299, 342–44 (2023).

271. 21 U.S.C. § 355(j)(5)(B)(iv); *see supra* notes 89–92 and accompanying text.

272. The first paragraph IV ANDA applicant enjoys the generic exclusivity even it was not the one to obtain a ruling of invalidity or non-enforceability. *See* C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 ANTITRUST L.J. 947, 947–80 (2011) (criticizing this approach).

273. This "marketing trigger" remains in force today. As originally enacted, the Hatch–Waxman Act also incorporated a "court decision" trigger, which Congress eliminated in 2003 along with enactment of the MMA. *See* THOMAS, *supra* note 238, at 474, 485.

274. *See, e.g.*, Ankur N. Patel, *Delayed Access to Generic Medicine: A Comment on the Hatch-Waxman Act and the "Approval Bottleneck"*, 78 FORDHAM L. REV. 1075, 1088 (2009); C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1560 (2006); Elizabeth Stanley, *An Ounce of Prevention: Analysis of Drug Patent Settlements Under the Hatch-Waxman Act*, 10 GEO. MASON L. REV. 345, 348 (2002).

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

triggered, cause a paragraph IV ANDA applicant to lose entitlement to the 180-day exclusivity.[276] One of the forfeiture events, and the one most likely to occur, involves a generic company's failure to market promptly. Stated generally, the first paragraph IV ANDA applicant forfeits its generic exclusivity if it has not begun selling its product at such time that one of the dates (1)–(2) and one of the dates (3)–(5) comes to pass:

1. 75 days after the FDA approves the ANDA;

2. 30 months after the generic submits the ANDA;

3. 75 days after a court judgment that the challenged patent is invalid or not infringed;

4. 75 days after a suit over the challenged patent is settled favorably to the ANDA filer; and

5. 75 days after the challenged patent is delisted from the Orange Book.[277]

An apparent difficulty with the forfeiture statute is that it speaks towards judgments concerning "the patent" rather than the claims the brand-name pharmaceutical firm asserts. In particular, the relevant statute defines one of the forfeiture events as a final court ruling that "the patent is invalid or not infringed."[278]

By speaking to a decision regarding "the patent" rather than the asserted claims of a patent, this legislation fails to reflect the realities of modern litigation. The USPTO regularly issues patents incorporating far more claims than can be handled in a single contentious proceeding.[279] It also commonly issues multiple patents covering the same thing.[280] Such prolix USPTO work product has resulted in troubling coping strategies by the tribunals that adjudicate patent disputes. The courts encourage, or cajole, patent proprietors into choosing just a few of these claims to be subject to adjudication.[281]

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276. *See, e.g.*, Jennifer E. Sturiale, *Hatch-Waxman Patent Litigation and Inter Partes Review: A New Sort of Competition*, 69 ALA. L. REV. 59 (2017).

277. *See* Teva Pharm. USA Inc. v. Sebelius, 595 F.3d 1303, 1306–07 (D.C. Cir. 2010).

278. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA) (emphasis added).

279. *See, e.g.*, MENELL ET AL., *supra* note 31, at § 5.1.2.1.3.

280. Multiple claims of the same patent may cover the same product or process. In addition, applicants may obtain multiple patents with highly similar claim sets, provided they file a so-called "terminal disclaimer." *See* 37 C.F.R. § 1.321 (2013).

281. The PTAB acts similarly. It has opined, without substantive explanation, that a single IPR petition should ordinarily suffice to challenge the claims of a patent. U.S. PAT. & TRADEMARK OFF., PATENT TRIAL AND APPEAL BOARD CONSOLIDATED TRIAL PRACTICE GUIDE 59 (2019). Because the PTAB places a limit of 14,000 words with respect to petitions, as a practical matter, no more than 20 to 25 claims may be challenged at one time. *See Reforming the Patent Trial and Appeal Board—The PREVAIL Act and Proposals to Promote U.S. Innovation Leadership: Hearing Before the Subcomm. on Intell. Prop.*, 118th Cong. 8 (2023) (statement of Joseph Matal). Many patents feature so many thornily worded claims that a single petition cannot possibly address them all.

Most notably, the Advisory Council of the Federal Circuit[282] issued a Model Order that endeavored to limit the assertion of "excess patent claims."[283] According to the Advisory Council, no more than 16 claims should be asserted during patent enforcement litigation, a number that increases to 24 if all of them are found in the same patent.[284] Across the nation, local rules and standing orders that do not strictly follow the Model Order operate similarly.[285]

Under the Patent Act, each claim of a patent stands on its own concerning validity and infringement.[286] A judicial determination that a subset of a patent's claims are invalid or not infringed may therefore not rise to a conclusion that the patent in its entirety is invalid or not infringed.[287] This statutory wording would seemingly encourage brand-name companies to hold claims in reserve when they bring charges of patent infringement against paragraph IV ANDA applicants. Indeed, the practices of the federal judiciary might require them to do so. By keeping their powder fresh with some unasserted claims, brand-name companies might potentially preclude the forfeiture of the 180-day generic exclusivity and defeat the congressional purposes in enacting the MMA. Congress would do well to address this issue at the interface of FDA and USPTO practice as it advances its "whole of government" initiative.

G. Appraising Pharmaceutical Patent Litigation

Few trials involve such high stakes, technical complexity, and idiosyncratic practices as those involving pharmaceutical patent enforcement. Brand-name firms face high risks because of the devastating impact of generic competition when their drugs fall off the "patent cliff" through a holding of invalidity, noninfringement, or unenforceability.[288] In addition, Hatch–Waxman litigation stands among the most idiosyncratic and complex to be found in federal courts.[289] Many attorneys and

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282. For information about the Federal Circuit's Advisory Council, see *Advisory Council*, U.S. CT. OF APPEALS FOR THE FED. CIR., cafc.uscourts.gov/home/the-court/advisory-council/ [https://perma.cc/BJ7M-BRGN] (last visited Dec. 1, 2024).

283. FEDERAL CIRCUIT ADVISORY COUNCIL, A MODEL ORDER LIMITING EXCESS PATENT CLAIMS AND PRIOR ART 1 (2013), https://patentlyo.com/media/docs/2013/07/model-order-excess-claims.pdf [https://perma.cc/4RHZ-9HJL].

284. *Id.* at 6.

285. *See, e.g.*, U.S. DISTRICT COURT FOR THE NORTHERN DISTRICT OF TEXAS, DALLAS DIVISION, [MODEL] ORDER FOCUSING PATENT CLAIMS AND PRIOR ART TO REDUCE COSTS (n.d.), https://patentlyo.com/media/docs/2013/07/model-order-excess-claims.pdf [https://perma.cc/2ZCW-LR3J].

286. 35 U.S.C. § 282 (providing that each claim presumably valid independently of the validity of other claims); Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc., 424 F.3d 1293, 1310 (Fed. Cir. 2005) ("To prove direct infringement, the plaintiff must establish by a preponderance of the evidence that one or more claims of the patent read on the accused device literally or under the doctrine of equivalents.").

287. *See* Jaimin Shah & Steve Auten, *Must Whole Patent Be Nixed to Forfeit 180-Day Exclusivity?*, LAW360 (July 25, 2018), https://www.law360.com/articles/1064298 [https://perma.cc/YS3H-AHJE].

288. *See* Dmitry Karshtedt, *The More Things Change: Improvement Patents, Drug Modifications, and the FDA*, 104 IOWA L. REV. 1129, 1150 (2019).

289. *See* Melanie R. Rupert, *Managing the Complexities of Hatch-Waxman Pharmaceutical Litigation*, ASPATORE, 2014 WL 788285 (2014).

academics who specialize in intellectual property or in food and drug law know little about this intersectional discipline,[290] which is marked by local rules and practices distinct from those of garden-variety patent cases.[291] In addition, each Hatch–Waxman case involves complex fields such as biochemistry, cellular biology, drug formulation, engineering, medicine, pharmacometrics, pharmacokinetics, and translational sciences beyond the reach of those without specialized training.[292]

Given its significance to public health, pharmaceutical patent enforcement deserves far greater scrutiny than it has yet received. Although neither the FDA nor USPTO directly participates in Hatch–Waxman trials, the two agencies stand in the best position to do so given their collective expertise. The USPTO issues the litigated patents, of course, and the FDA partners with patent proprietors to enforce those patents under the linkage concepts introduced by the Hatch–Waxman Act.[293] As the organs of government that set the stage for pharmaceutical patent litigation, the FDA and USPTO are well-suited to assess whether that litigation proceeds in a manner conducive to public health and intellectual property policy goals. This Article next addresses the unique traits of pharmaceutical patent litigation that deserve further consideration.

1. Venue

Considerable attention has been paid to the rise of "magnet" jurisdictions for patent cases.[294] A broad range of commentators has questioned why the Eastern District of Texas—located a considerable distance from Silicon Valley, Automation Alley, the Route 128 corridor, and other hubs of innovative industry—attracts an outsized share of patent cases.[295] Many have criticized the east Texas court for its perceived friendliness to patent proprietors generally and patent trolls more

290. *See, e.g.*, THOMAS, *supra* note 238, at 9 (observing that patent law, on one hand, and food and drug law, on the other, are "ordinarily pursued by attorneys practicing in different bars").

291. *Id.*

292. *See* Janet Freilich, *Patent Infringement in the Context of Follow-On Biologics*, 16 STAN. TECH. L. REV. 9, 19–20 (2012).

293. *See* Raley, *supra* note 223, at 466 ("'[P]atent linkage' . . . requires the FDA to delay generic drug marketing approval until (a) after expiration of a branded equivalent's patent term, (b) after a court determines that the branded drug's patent would not be infringed or was invalid, or (c) after the patent owner otherwise consents."). More specifically, the FDA maintains a patent registry in the Orange Book to which generics are held to account. 21 U.S.C. § 355(b)(1)(A)(viii). The legislation further mandates that the FDA be enjoined from approving a generic drug, both when the litigation begins, 21 U.S.C. § 355(j)(5)(B)(iii), and when it ends if a court upholds the patent. 35 U.S.C. § 271(e)(4)(A) (stipulating that when a court finds that a proposed generic product infringes, "the court shall order the effective date of approval . . . to be a date which is not earlier than the date of the patent which has been infringed . . . .").

294. *See generally, e.g.*, J. Jonas Anderson, *Reining in a "Renegade" Court:* TC Heartland *and the Eastern District of Texas*, 39 CARDOZO L. REV. 1569 (2018); Paul R. Gugliuzza & Megan M. LaBelle, *The Patently Unexceptional Venue Statute*, 66 AM. UNIV. L. REV. 1027 (2017); Jonas Anderson, *Judge Shopping in the Eastern District of Texas*, 48 LOY. U. CHI. L.J. 539 (2016).

295. *See, e.g.*, Brian J. Love & James Yoon, *Predictably Expensive: A Critical Look at Patent Litigation in the Eastern District of Texas*, 20 STAN. TECH. L. REV. 1, 7 (2017).

specifically, although other observers have viewed these courts more favorably.[296] More recently, the Western District of Texas has also fallen under scrutiny for perceived "forum selling,"[297] resulting in a congressional inquiry,[298] Supreme Court oversight,[299] and a change to the court's judicial assignment practices.[300]

Given this broad-ranging debate over the appropriate location for patent trials, a puzzling question is why the districts of Delaware and New Jersey, which collectively hear on the order of 90% of Hatch–Waxman cases each year,[301] have received far less attention. This astonishing concentration is vastly greater than that achieved by the Texas courts, and it may be for entirely salutary reasons. The Mid-Atlantic courts have developed a reputation for their considerable expertise in pharmaceutical patents and efforts to issue their rulings in a timely fashion. They offer familiar fora to patent litigators and their clients, and generic drug companies have voiced few objections to being called into the courthouses there.[302]

Serious questions should nonetheless arise over the dominance of Delaware and New Jersey courts in pharmaceutical patent cases. As a de facto matter, a limited number of judges in the Mid-Atlantic play a leading role in setting public health policy for the entire nation. In addition, given the choice of law rules of the Federal Circuit, the procedural and non-patent substantive law of the Court of Appeals for the Third Circuit rules the roost.[303] We should remain aware of the continuing specter of anticompetitive pharmaceutical patent settlements,[304] many that have

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296. *See* Andrei Iancu & Jay Chung, *Real Reasons the Eastern District of Texas Draws Patent Cases—Beyond Lore and Anecdote*, 14 SMU SCI. & TECH. L. REV. 299, 319 (2011).

297. *See, e.g.*, J. Jonas Anderson & Paul R. Gugliuzza, *Federal Judge Seeks Patent Cases*, 71 DUKE L.J. 419 (2021); J. Jonas Anderson, *Court Competition for Patent Cases*, 163 U. PA. L. REV. 631 (2015).

298. Letter from Thom Tillis & Patrick Leahy, U.S. Senators, to the Honorable Chief Justice John Roberts, Presiding Officer of the Jud. Conf. of the U.S. (Nov. 2, 2021) (available at https://patentlyo.com/media/2021/11/Letter-to-the-Chief-Justice-about-Judge-Albright.pdf [https://perma.cc/958K-UMSW]) ("In the last two years our nation has seen a consolidation of a large portion of patent litigation before a single district court judge in Texas.").

299. *See* CHIEF JUSTICE JOHN ROBERTS, 2021 YEAR-END REPORT ON THE FEDERAL JUDICIARY 5 (2021).

300. *See* Michael Shapiro, *West Texas Patent Case Assignment Order Stays in Place, for Now*, BLOOMBERG L. (Dec. 22, 2022), https://news.bloomberglaw.com/ip-law/west-texas-patent-case-assignment-order-stays-in-place-for-now [https://perma.cc/RQ8L-FKFS].

301. *See* Ryan Davis, *As ANDA Suit Venue Options Shrink, Del., NJ Rule for Now*, LAW360 (Nov. 24, 2021), https://www.law360.com/articles/1441251/as-anda-suit-venue-options-shrink-del-nj-rule-for-now [https://perma.cc/KVB4-9Q53]; *see also* Mengke Xing, *Looking for Venue in the Patently Right Places: A Parallel Study of the Venue Act and Venue in ANDA Litigation*, 55 SAN DIEGO L. REV. 183, 204 (2018).

302. *See* Karen L. Pascale, *Delaware in the Vanguard*, 40 DEL. LAW. 22, 23–24 (2022).

303. *See, e.g.*, Jennifer E. Sturiale, *A Balanced Consideration of the Federal Circuit's Choice-of-Law Rule*, 2020 UTAH L. REV. 475 (2020).

304. *See, e.g.*, Michael A. Carrier, *After* Actavis: *Seven Ways Forward*, 67 RUTGERS U. L. REV. 543 (2015).

been approved by Mid-Atlantic jurists in keeping with a policy of promoting the private settlements of disputes. Long experience has nonetheless taught us that in the context of Hatch–Waxman, we can rely neither upon brand-name nor generic firms to represent the public interest.

Moreover, venue in Hatch–Waxman cases has become a moving target. A recent Federal Circuit opinion, *Valeant Pharmaceuticals North America LLC v. Mylan Pharmaceuticals Inc.*,[305] restricted venue options for Hatch–Waxman cases. No longer may brand-name drug companies bring suit in Delaware and New Jersey merely because firms hope to sell generic products there. Rather, venue for Hatch–Waxman cases resides only in a generic firm's state of incorporation, or where the generic firm has a regular and established place of business and where actions related to the submission of ANDA occur.[306] The full impact of the *Valeant* ruling remains to be seen, but it will likely place greater emphasis upon where the ANDA was prepared or submitted—namely, the location of the generic firm's law department or outside counsel or possibly the District of Maryland, where the FDA sits.[307] The result may be multiple parallel patent trials involving the same patented pharmaceutical proceeding in courts across the nation. Given the significance of pharmaceutical patent trials, the FDA and USPTO collectively possess the expertise and ability to gather stakeholders to assess venue in pharmaceutical patent litigation.

2. Joinder

Section 299 stands as one of the Patent Act's more curious provisions. At once, Section 299 modifies Rule 20 of the Federal Rules of Civil Procedure for garden-variety patent cases, while retaining it for Hatch–Waxman cases.[308] The impact of the carve-out for pharmaceutical patents, which generally weighs in favor of brand-name firms, deserves evaluation.

Under Rule 20(a)(2) of the Federal Rules of Civil Procedure, multiple accused infringers may be joined in one lawsuit as defendants if: (1) "any right to relief is asserted against them jointly, severally, or in the alternative with respect to or arising out of the same transaction, occurrence, or series of transactions or occurrences" and (2) "any question of law or fact common to all defendants will arise in the action."[309] Before the enactment of the America Invents Act in 2011,[310] little controversy arose about whether the second prong was met in patent cases brought against multiple accused infringers. Such shared issues as the asserted patent's claim construction or validity provided the necessary common issue of fact or law.

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305. 978 F.3d 1374 (Fed. Cir. 2020).

306. *Id.* at 1375.

307. *See* Matthew Makowski, *Toward a Centralized Hatch-Waxman Venue*, 89 U. CHI. L. REV. 1838, 1849–51 (2022).

308. *See generally* David O. Taylor, *Patent Misjoinder*, 88 N.Y.U. L. REV. 652 (2013).

309. FED. R. CIV. P. 20(a)(2). Rule 42(a) of the Federal Rules of Civil Procedure provides another mechanism for consolidation of trial, so long as venue is proper, and the cases share "a common question of law or fact." FED. R. CIV. P. 42(a).

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

The first prong of Rule 20(a) proved more controversial. Some courts attached a broad meaning to the phrase "same transactions or occurrences," ruling that infringement by multiple unrelated defendants qualified so long as "there is some connection or logical relationship between the various transactions or occurrences."[311] Under the *MyMail* rule, a "logical relationship" existed if "there is some nucleus of operative facts or law"—which is to say, if the second prong of Rule 20(a) was satisfied, then so was the first.[312]

Congress responded to the concerns over the *MyMail* rule by introducing Section 299 to the Patent Act. That statute provides that "accused infringers may not be joined in one action as defendants or counterclaim defendants, or have their actions consolidated for trial, based solely on allegations that they each have infringed the patent or patents in suit."[313] Section 299 further stipulates that accused infringers may be joined in a single trial only if the infringement relates to the same transaction or has common issues of fact.[314] Section 299 overturned the *MyMail* rule, making voluntary joinder in patent cases more difficult than the standard developed under Rule 20(a)(2).[315]

Section 299 does incorporate one exception: it expressly carves out Hatch–Waxman cases from these amendments.[316] On one hand, this exemption tends to favor brand-name drug companies, which may enjoy considerable efficiencies in enforcing their patents against multiple generic manufacturers in a single lawsuit.[317] On the other hand, generic firms may sell different products, cite different prior art references, propose different claim constructions, and offer different theories of invalidity and noninfringement.[318] They may compete directly against one another

311. FED. R. CIV. P. 20(a)(2)(A); *see, e.g.*, MyMail Ltd. v. America Online, Inc., 223 F.R.D. 455 (E.D. Tex. 2004).

312. FED. R. CIV. P. 20(a)(2). The *MyMail* opinion left open the possibility of severing defendants if their accused products or processes differed dramatically. As a practical matter, however, this determination can ordinarily not be made until at least the close of discovery, which timing—a common reason for severance—including inefficiencies and prejudice from joinder, might no longer apply. *See MyMail*, 223 F.R.D. at 456.

313. 35 U.S.C. § 299(b).

314. *Id.* § 299(a).

315. Shortly after the congressional enactment of Section 299, the Federal Circuit issued *In re EMC Corp.*, 677 F.3d 1351 (Fed. Cir. 2012). *EMC Corp*. announced more stringent joinder standards for Rule 20 than those of *MyMail*. However, the Federal Circuit stressed that its "decision will only govern a number of cases that were filed before the passage of the new joinder provision," *id.* at 1356, and therefore apparently did not address Hatch–Waxman cases.

316. *See, e.g.*, Dongbiao Shen, *Misjoinder or Mishap? The Consequences of the AIA Joinder Provision*, 29 BERKELEY TECH. L.J. 545, 556 (2014); Tracie L. Bryant, *The America Invents Act: Slaying Trolls, Limiting Joinder*, 25 HARV. J.L. & TECH. 687, 700 n.94 (2012).

317. Taylor, *supra* note 308, at 672.

318. Given that the active ingredient of a generic product must be identical to that of the brand-name firm, 21 U.S.C. § 355(j)(2)(A)(ii), noninfringement arguments are often difficult to mount with respect to patents on active pharmaceutical ingredients. But brand-name drug companies also obtain patents on such inventions on formulations, isomers,

and, as such, understandably wish to avoid sharing confidential information to coordinate a common defense.[319] An analysis of these apparent concerns—along with an assessment of other factors, including Section 299's impact on the workload of the federal judiciary, remains a topic well-suited for the FDA and USPTO to pursue.

3. Local Rules

Another area of focus should be local patent rules and scheduling orders governing Hatch–Waxman cases. These rules, at times, appear to defy fundamental patent law principles. For example, the New Jersey local Hatch–Waxman rules require an early exchange of invalidity and noninfringement contentions, with the generic manufacturers going first.[320] As a result, even though the brand-name drug companies bear the burden of proving infringement,[321] the generic manufacturers must be the first to state their noninfringement position.

Other rules seem to unnecessarily favor brand-name firms over generic manufacturers. Under the New Jersey local rules, generic manufacturers must notify the FDA of all motions for injunctive relief within three days of when a motion is filed—even though brand-name firms will likely be the ones filing the motions.[322] In addition, generic manufacturers must provide copies of all correspondence they have with the FDA to each party asserting infringement within seven days of receipt.[323] The New Jersey local rules impose no such requirement upon brand-name firms. The FDA and USPTO also stand in a strong position to assess the propriety of these local rules in view of public health and intellectual property policy.

4. Injunctions

A final area of focus should be the availability of injunctions to patent proprietors in Hatch–Waxman cases. For garden-variety patent cases, Section 283 of the Patent Act allows courts to issue injunctions "in accordance with the principles of equity."[324] This provision should be contrasted with Section 271(e)(4)(A), a provision directed towards Hatch–Waxman litigation. Under the Hatch–Waxman Act, if a brand-name drug company prevails against a generic manufacturer in patent litigation, then the court "shall order" the effective date of FDA approval to be the expiration date of the infringed patent.[325] As enacted in 1984, Section 271(e)(4)(A) reflected the shared view of the intellectual property

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crystals, polymorphs, chemical intermediates, enantiomers, and combination therapies. In those circumstances in particular, generic products may differ in relevant ways, and noninfringement arguments are far more viable.

319. *See* Taylor, *supra* note 308, at 673–75.

320. L. Pat. R. 3.6(e) [hereinafter New Jersey Local Rules].

321. Eli Lilly & Co. v. Teva Parenteral Medicines, Inc., 845 F.3d 1357, 1364 (Fed. Cir. 2017).

322. New Jersey Local Rules, *supra* note 320, at R. 3.6(j).

323. *Id.*

324. 35 U.S.C. § 283.

325. *Id.* § 271(e)(4)(A).

community that absent exceptional circumstances,[326] courts should award a prevailing patent proprietor a permanent injunction against an adjudicated infringer.[327] As a result, courts effectively employed the same injunction rules for mainstream and Hatch–Waxman patent litigation alike.

The 2006 Supreme Court decision in *eBay, Inc. v. MercExchange, L.L.C.*,[328] significantly altered the remedial landscape in patent cases. There, the Court characterized the Federal Circuit's "categorical grant" of permanent injunctions as "unique to patent disputes,"[329] unauthorized by the express wording of the Patent Act, and a departure from long-standing principles of equity practice. Henceforth, the Supreme Court announced that the successful patent plaintiff must satisfy a four-factor test to be awarded a permanent injunction: (1) irreparable harm, (2) inadequate remedies at law, (3) the balance of hardships between the litigants, and (4) the public interest.[330] In practice, courts now generally deny injunctive relief to non-practicing entities, firms that do not directly compete with the adjudicated infringer, and in circumstances where the patented invention forms only a minor component of the adjudicated infringement.[331]

Another provision, this time found in the Federal Food, Drug, and Cosmetic Act, also governs injunctions in Hatch–Waxman cases. Upon commencing suit against a generic drug company that has challenged its patents, brand-name firms obtain a 30-month stay that technically enjoins the FDA from approving a paragraph IV ANDA.[332] In practice, however, the 30-month stay amounts to a preliminary injunction against generic manufacturers that the brand-name drug company obtains automatically upon bringing charges of artificial infringement.[333] This approach contrasts with garden-variety patent cases, where the

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326. *See* Vitamin Technologists, Inc. v. Wis. Alumni Rsch. Found., 146 F.2d 941, 946 (9th Cir. 1944) (denying permanent injunction due to the public interest in irradiation of oleomargarine); City of Milwaukee v. Activated Sludge, 69 F.2d 577, 593 (7th Cir. 1934) (denying permanent injunction where its grant would have led to the introduction of raw sewage into Lake Michigan).

327. *See, e.g.*, Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1247 (Fed. Cir. 1989) ("It is the general rule that an injunction will issue when infringement has been adjudged, absent a sound reason for denying it."); *see also* Joseph R. Sozzani, *Patent Law: Redefining Equitable Injunctions*, 11 J. TECH. L. & POL'Y 341, 344 (2006).

328. 547 U.S. 388 (2006).

329. *Id.* at 393.

330. More particularly, in order to obtain a permanent injunction, the prevailing patent proprietor must demonstrate: "(1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction." *Id.* at 391.

331. See Eric Maughan, *Protecting the Rights of Inventors: How Natural Rights Theory Should Influence the Injunction Analysis in Patent Infringement Cases*, 10 GEO. J.L. & PUB. POL'Y 215, 226–27 (2012).

332. 21 U.S.C. § 355(j)(5)(B)(iii).

333. From the perspective of generic manufacturers, FDA-administered regulatory exclusivities effectively add to the term of the statute's stay of approval. In particular, the

award of the preliminary injunction depends upon the demonstration of a slightly different set of four equitable factors[334] and requires the posting of a bond.[335]

Commentators widely regard *eBay* as a watershed moment that marked an extraordinary shift in the balance of power between patent proprietors and technology implementers.[336] But *eBay* simply did not speak to injunctions in Hatch–Waxman cases, for they arise under different statutes and remain subject to a "categorical rule" that the Supreme Court rejected.[337] Remedies in Hatch–Waxman cases are now misaligned with our modern approach to injunctions not just in patent cases, but across the entire breadth of U.S. law. Given these changed circumstances, the FDA and USPTO are collectively well-positioned to consider the role of remedies as part of a broader review of the Hatch–Waxman Act.

CONCLUSION

If a project enhancing collaboration between the FDA and USPTO moves forward, it should anticipate two related criticisms. First, some observers have pointed to the Brazilian experience.[338] In the recent past, the Brazilian equivalent of the FDA, Agência Nacional de Vigilância Sanitária ("ANVISA"), played a role in determining whether patents should be granted in the first instance.[339] One of the factors that ANVISA considered was whether the public interest favored the grant of a patent.[340] In addition, ANVISA would at times reach substantive patentability determinations that differed from those of the Brazilian patent authority, the Instituto

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combination of the five-year NCE exclusivity and the 30-month stay effectively provides each eligible pharmaceutical patent with 7.5 years of protection, even if they are plainly invalid, were procured through fraud, or do not cover the proposed generic product. *See* Claire K. Comfort, *Will the Federal Circuit's* Eli Lilly v. Teva *Decision Lead to Efforts to Abuse the Modification Provision of the Hatch-Waxman Act?*, 16 RICH. J.L. & TECH. 1, 9 ("During the statutory stay period, a pioneer manufacturer remains in complete control of the product market regardless of the strength of its patents.").

334. "To obtain a preliminary injunction, a court examines four factors: (1) a reasonable likelihood of success on the merits; (2) irreparable harm if an injunction is not granted; (3) a balance of hardships tipping in its favor; and (4) the injunction's favorable impact on the public interest." Altana Pharma AG v. Teva Pharms. USA, Inc., 566 F.3d 999, 1005 (Fed. Cir. 2009).

335. FED. R. CIV. P. 65(c).

336. *See, e.g.*, Mark P. Gergen et al., *The Supreme Court's Accidental Revolution? The Test for Permanent Injunctions*, 112 COLUM. L. REV. 203, 205 (2012).

337. eBay Inc. v. MercExchange L.L.C., 547 U.S. 388, 393 (2006).

338. *See, e.g.*, Letter to the Honorable Kathi Vidal, Under Sec'y of Com. & Dir. Of U.S. Pat. Trademark Off., from Karen Cochran, President, Intell. Prop. Owners Ass'n 6 (Feb. 6, 2023).

339. ANVISA is an acronym standing for Agência Nacional de Vigilância Sanitária, commonly presented in English as the Brazilian Health Advisory Agency or similar phrases. *See* Katherine Cortesy, *Maized and Confused: How Pesticide Regulations in the United States and Brazil Are Failing to Protect Maize Crops in the Face of Climate Change*, 40 WIS. INT'L L.J. 113, 122 (2022).

340. *See* Edson Beas Rodrigues Jr. & Bryan Murphy, *Brazil's Prior Consent Law: A Dialogue Between Brazil and the United States Over Where the TRIPS Agreement Currently Sets the Balance Between the Protection of Pharmaceutical Patents and Access to Medicines*, 16 ALB. J.L. SCI. & TECH. 423, 424 (2006).

Nacional da Propriedade Industrial ("INPI"), causing friction between the two agencies.[341] The Brazilian National Congress ultimately removed ANVISA's authority to examine patent applications.[342] For some, this experiment strongly suggests that the FDA should stay away from the patent system.

Second, the whole-of-government approach has been criticized for distracting agencies from their core duties and requiring them to perform tasks for which they are ill-suited.[343] Patent law, on the one hand, and food and drug law, on the other hand, are each technically complex disciplines that may take half a lifetime to master. Surely the FDA and USPTO have enough work to do already.

The response to these two criticisms is the same. When Congress enacted and built upon the Hatch–Waxman Act, it established a far more elaborate system of enforcement than applies to other sorts of patents, or those commonly found in other jurisdictions.[344] No serious proposal envisages a substantive role for the FDA during the everyday task of examining patent applications, as was the case in Brazil. However, the FDA does maintain a registry of pharmaceutical patents that it should more actively supervise, and its burden would be substantially eased if it harnessed the expertise of the USPTO. The FTC—an agency that neither issues patents nor administers the Orange Book—intervened to maintain the integrity of the publication, revealing the institutional dysfunction of our current way of doing business.

Enhanced coordination between the FDA and USPTO would have much to contribute to the health and well-being of U.S. citizens. It would increase clarity and comprehension between the patent and food and drug systems. It would contribute to greater coherence between issued patents and the Hatch–Waxman Act's dispute resolution system. It would shed much-needed light upon the implications of the distinct practices of pharmaceutical patent law. And it would join two agencies with the shared expertise to administer a system of laws that is fundamentally interdisciplinary. Ultimately, the interests of the FDA and USPTO align in achieving the goals of the Hatch–Waxman Act—promoting pharmaceutical innovation, while also ensuring affordable access to medicines for the American public.

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341. The Brazilian Patent Office is more formally the Instituto Nacional da Propriedade Industrial, referenced as INPI or the National Institute for Intellectual Property. *See* Luiz Miranda, *Brazil's New Path to Meaningful Intellectual Property Protection*, 48 U. MIAMI INTER-AM. L. REV. 122, 125 (2016).

342. *See* Giovanna Chinait, *Brazilian Pharmaceutical Patents: The End of ANVISA's Controversial Prior Consent*, BOS. PAT. L. ASS'N NEWSL. (2022), https://newsletter.bipla.org/brazilian-pharmaceutical-patents-the-end-of-anvisas-controversial-prio [https://perma.cc/F733-3ANX].

343. *See* Clyde Wayne Crews Jr. & Ryan Young, *Biden's 'Whole of Government' Overhaul of Federal Agencies Undermines Their Purpose*, THE HILL (Oct. 26, 2022), https://thehill.com/opinion/congress-blog/3705521-bidens-whole-of-government-overhaul-of-federal-agencies-undermines-their-purpose/ [https://perma.cc/9CUR-YRA8].

344. *See, e.g.*, Fed. Trade Comm'n v. Actavis, Inc., 570 U.S. 136, 155–56 (2013) (appreciating "Hatch-Waxman's unique regulatory framework").