2023

Hatch-Waxman's Renegades

John R. Thomas

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No intellectual property rights impact society more forcefully than patents on pharmaceuticals. But as a practical matter, only a handful of jurists resolve disputes involving them. Two neighboring federal districts, Delaware and New Jersey, adjudicate the vast majority of patent contests between brand-name drug companies and generic manufacturers. And in contrast to Eastern Texas, which has been persistently derided as a renegade jurisdiction, the authority of the mid-Atlantic courts has seldom been questioned. The complex workings of the Hatch-Waxman Act, the compromise legislation that governs pharmaceutical patent litigation, go a long way to explaining such distinct shareholder reactions to highly similar judicial behaviors.

Yet the dominance of Delaware and New Jersey in pharmaceutical patent litigation may have come to an end. A recent decision of the U.S. Court of Appeals for the Federal Circuit, Valeant v. Mylan, *has narrowed the rules for venue in Hatch-Waxman cases. We are now poised to see multiple, parallel trials involving the same patented pharmaceutical proceeding in courts across the country.*

The new order of pharmaceutical patent litigation affords an opportunity to reconsider an intellectual property environment that aims to promote pharmaceutical innovation but also increase public access to medications. Venue determinations are puzzling in pharmaceutical patent cases due to a concept originating within the Hatch-Waxman Act, the tort of "artificial" infringement. Artificial infringement occurs when a manufacturer petitions the federal government to obtain permission to market a generic drug. But the federal government both issues patents, and awards regulatory approval to sell a drug, with effect across the entire nation. Congress gave no thought towards situating artificial infringement at a certain place, and judicial efforts to do so have amounted to a facile and strained exercise.

Venue is not artificial infringement's only problem. Artificial infringement also creates disconnects with personal jurisdiction principles, incorporates obsolete remedial provisions, and fails to comply with the

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international commitments of the United States. Courts should instead recognize their authority to accept declaratory judgment actions to resolve pharmaceutical patent infringement cases, with legislative abolition of artificial infringement presenting another, preferred possibility.

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I. INTRODUCTION

The location of patent trials matters. The rise of the Eastern District of Texas as the leading U.S. forum for patent trials drew the attention of practitioners,[1] academics,[2] the national media,[3] and even late-night television comedians.[4] No less an authority than the late Justice Scalia, who spoke of a "renegade jurisdiction," joined the fray.[5] Commentators criticized the East Texas court as a forlorn judicial outpost that openly promoted itself as plaintiff-friendly; encouraged

1. *See, e.g.*, G. Warren Bleeker, *Heart of the Matter: Despite Its New Ruling in* TC Heartland, *the High Court Leaves "Wiggle Room" Regarding What Constitutes a "Regular and Established Place of Business,"* L.A. LAW., Oct. 2017, at 20.

2. *See, e.g.*, J. Jonas Anderson, *Reining in a "Renegade" Court:* TC Heartland *and the Eastern District of Texas*, 39 CARDOZO L. REV. 1569, 1601 (2018); 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, 13 (2017).

3. Adam Liptak, *Supreme Court Considers Why Patent Trolls Love Texas*, N.Y. TIMES (Mar. 27, 2017), https://www.nytimes.com/2017/03/27/business/supreme-court-patent-trolls-tc-heartland-kraft.html [https://perma.cc/8PGA-LS2L].

4. LastWeekTonight, *Patents: Last Week Tonight with John Oliver (HBO)*, YOUTUBE, at 7:23 (Apr. 19, 2015), https://www.youtube.com/watch?v=3bxcc3SM_KA [https://perma.cc/D5T2-G6A9].

5. *See* Transcript of Oral Argument at 7, eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388 (2006) (No. 05-130).

the rise of patent trolls;[6] and brazenly supported the local bar and businesses.[7] Others were more supportive. A leading practitioner, later the Director of the U.S. Patent and Trademark Office ("USPTO"), was perhaps the most notable defender of East Texas, viewing that tribunal as providing efficient, effective, and predictable administration of patent cases.[8]

The Supreme Court reacted by issuing the 2017 decision in *TC Heartland L.L.C. v. Kraft Foods Group Brands L.L.C.*[9] There the Court held that an enterprise could ordinarily not be sued for patent infringement in a particular judicial district—in that case, Delaware—merely because it shipped allegedly infringing products there. A roundly cheered decision, at least outside of East Texas, *TC Heartland* tightened the venue requirement for patent litigants. In the wake of *TC Heartland*, East Texas remains an active, but diminished site for patent litigation.[10]

Barely noticed in the debate over the role of East Texas in patent litigation has been the location of lawsuits brought pursuant to the Hatch-Waxman Act. More formally known as the Drug Price Competition and Patent Term Restoration Act of 1984,[11] this compromise legislation between brand-name drug companies and generic manufacturers establishes complex rules governing patents pertaining to prescription drugs.[12] Among the most valuable of intellectual properties, pharmaceutical patents dictate the availability of generics, drug pricing, and ultimately the access of U.S. citizens to healthcare.[13]

With respect to patent dispute resolution under Hatch-Waxman, two neighboring jurisdictions have stood above the rest. The District of Delaware and the District of New Jersey ordinarily hear 90% of these cases each year[14]—an astonishing concentration that would likely make the jurists of East Texas blush, even during that court's pre-*TC Heartland* heyday. The numbers are even more impressive when one recognizes the degree of consolidation that occurs within a particular lawsuit. Because numerous Hatch-Waxman cases most often arise at

6. Peter Lattman, *Patent Trolls: Grazing the Piney Woods?*, WALL ST. J. L. BLOG (Mar. 27, 2006), https://www.wsj.com/articles/BL-LB-933 [https://perma.cc/Z4U9-NDJZ].

7. Melissa Repko, *How Patent Suits Shaped a Small East Texas Town Before Supreme Court's Ruling*, DALLAS MORNING NEWS (May 23, 2017, 6:25 PM), https://www.dallasnews.com/business/technology/2017/05/23/how-patent-suits-shaped-a-small-east-texas-town-before-supreme-court-s-ruling/ [https://perma.cc/2LJY-77M4].

8. 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).

9. 581 U.S. 258, 267 (2017).

10. Michael C. Smith, *The Effect of* TC Heartland *on Patent Litigation in Texas*, 86 ADVOC. (TEX.) 45, 45 (2019); *see* Colleen V. Chien & Michael Risch, *Recalibrating Patent Venue*, 77 MD. L. REV. 47, 75 (2017).

11. Drug Price Competition and Patent Term Restoration Act of 1981, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

12. *See id.*

13. *See, e.g.*, Alexander Walsdorf, *I Get by with a Little Help from My 750-Dollar-Per-Tablet Friends: A Model Act for States to Prevent Dramatic Pharmaceutical Price Increases*, 102 MINN. L. REV. 2497, 2502 (2018).

14. *See* Ryan Davis, *As ANDA Suit Venue Options Shrink, Del., NJ Rule for Now*, LAW360 (Nov. 24, 2021, 6:09 PM), https://www.law360.com/articles/1441251/as-anda-suit-venue-options-shrink-del-nj-rule-for-now [https://perma.cc/Z8RP-8ZAU]; *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).

the same time,[15] and because Congress has permitted them to be tried together based upon more liberal joinder rules than those that apply to other sorts of patent cases,[16] the Delaware and New Jersey courts often summon ten or more generic firms into their courtrooms to conduct a single patent infringement case.[17]

But *TC Heartland* has come home to roost. In *Valeant Pharmaceuticals v. Mylan Pharmaceuticals*,[18] the Court of Appeals for the Federal Circuit ("Federal Circuit") similarly restricted venue for Hatch-Waxman cases as well.[19] The hegemony of Delaware and New Jersey in Hatch-Waxman cases may well be over, for we are poised to see multiple, parallel patent trials involving the same patented pharmaceutical proceeding in venues across the United States.[20] This incident again demonstrates that the legal environment surrounding pharmaceutical innovation, although subject to complex and specialized legislation, is surprisingly sensitive to general developments in the patent field that advanced without regard for Hatch-Waxman.[21]

The recent displacement of Hatch-Waxman's renegade jurisdictions, Delaware and New Jersey, provides an opportunity to revisit that legislation's "Grand Bargain" between brand-name firms and generic manufacturers.[22] In Part II, this Article tries to solve the puzzle of why so little concern is expressed about the consistent dominance of just two courts for Hatch-Waxman litigation, while East Texas has been subject to withering criticism for engaging in many of the same practices found in the mid-Atlantic.[23] It concludes that Hatch-Waxman litigation exhibits distinctive traits—including a unique infringement definition, timeframe, remedial provisions, and joinder rules—that favor concentration in Delaware and New Jersey. While not an unalloyed good, this arrangement has led to widespread approval by relevant stakeholders and, to a degree, by Congress itself.

Part III of this Article considers the recent, abrupt restriction of suitable venue in Hatch-Waxman cases. *Valeant v. Mylan* may scatter Hatch-Waxman lawsuits across the land, potentially sowing discord, draining judicial resources, and leading to a push for more cumbersome litigation consolidation efforts.

15. *See infra* notes 38–41.

16. 35 U.S.C. § 299; *see infra* notes 127–28.

17. *See* Novartis Pharms. Corp. v. Accord Healthcare Inc., No. 18-1043-LPS, 2019 WL 2502535, at *1 (D. Del. June 17, 2019).

18. Valeant Pharms. N. Am. LLC v. Mylan Pharms. Inc., 978 F.3d 1374, 1375 (Fed. Cir. 2020).

19. *See id.*

20. *See infra* notes 236–41.

21. *See* John R. Thomas, *The End of "Patent Medicines"? Thoughts on the Rise of Regulatory Exclusivities*, 70 FOOD & DRUG L.J. 39, 41 (2015).

22. *See* MARYLL TOUFANIAN & MARTIN SHIMER, HATCH-WAXMAN 101 2 (2015), https://medcitynews.com/uploads/2021/08/Hatch-Waxman-Patent-and-Certification-Process-101.pdf [https://perma.cc/AAT4-7RN5].

23. Other commentators have previously drawn parallels between patent litigation in Delaware and New Jersey. *See* Matthew Sag, *IP Litigation in U.S. District Courts: 1994–2014*, 101 IOWA L. REV. 1065, 1104 (2016) (observing that in patent cases, "the advantages that the Eastern District of Texas, and to a lesser extent the District of Delaware, bestows on plaintiffs are anything but slight").

Some have called upon Congress to amend the unique patent venue statute specifically to account for pharmaceutical patent litigation under Hatch-Waxman.[24]

In Part IV, this Article suggests a more fundamental target for legislative reform. Over the centuries, a number of curiosities have accumulated in the attic of the patent law, but none more impactful than the "artificial" act of infringement established by the Hatch-Waxman Act.[25] Artificial infringement occurs when a manufacturer petitions the government in order to obtain approval to market a generic drug.[26] A tort that appears out of thin air,[27] artificial infringement has several failings beyond its incompatibility with the patent venue statute. It also creates a disconnect with personal jurisdiction principles, incorporates obsolete remedial provisions, and fails to comply with the international commitments of the United States.

Not only has artificial infringement not aged well over the past four decades, but, as Part V of this Article asserts, it appears wholly unnecessary. Increasingly permissive standards for declaratory judgment jurisdiction in Hatch-Waxman cases provide a sufficient vehicle for brand-name drug companies to assert their patent rights against proposed generic products. Courts have all the tools on hand needed to solve the numerous problems associated with artificial infringement, with legislative reform presenting another, preferred possibility.

Part VI of this Article closes with three succinct points. It first anticipates objections to the proposed abolition of artificial infringement by reinforcing that Hatch-Waxman's "Grand Bargain," far from being a fixed compromise, is one that has been subject to continuing refinement over the past four decades. Second, it encourages consideration of whether Hatch-Waxman's hybrid approach provides the best legal architecture for sustained pharmaceutical innovation. Finally, it observes that the recent entry of the latest renegade jurisdiction, the Western District of Texas, may test the thesis of this Article, and provide further insight into how the context of patent litigation influences perception of highly similar practices.

24. *See, e.g.*, Letter from Intellectual Property Owners Association to President-Elect Joe Biden and Vice-President-Elect Kamala Harris, INTELL. PROP. OWNERS ASS'N 4 (Dec. 18, 2020), https://patentdocs.typepad.com/files/ipo-letter-1.pdf [https://perma.cc/3UUA-6U56] [hereinafter Letter from Intellectual Property Owners Association].

25. Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 675 (1990).

26. 35 U.S.C. § 271(e)(2).

27. Michael Marusak, *Personal Jurisdiction in Hatch-Waxman Cases*, 66 CATH. U. L. REV. 189, 220 (2016).

II. PATENT LAW'S RENEGADE JURISDICTIONS

Suppose you learned of a federal district court that engages in active forum selling,[28] hears an outsized portion of cases,[29] and houses a compact bench quite capable of coordinating practices.[30] A federal district court that rarely grants motions for summary judgment[31] and that joins multiple defendants, strangers to each other, into a single infringement lawsuit based solely on the allegation that they infringe the same patent.[32] A federal district court that has issued capacious personal jurisdiction and venue rulings that have been rejected by other trial courts and ultimately overturned by the Federal Circuit.[33] Each of these criticisms has been levelled at East Texas, fairly or unfairly, but much the same could be said of the Delaware and New Jersey courts, most notably with respect to Hatch-Waxman cases.[34]

Resolving why these three courts, which indulge in highly similar behaviors, have met with such distinct responses proves quite a puzzle. Some reasons for this disparate treatment may be extrajudicial, including East Coast bias, the proximity of the mid-Atlantic courthouses to major cities, more convenient means of transportation, and perhaps even better hotels and restaurants in the vicinity.[35] But, the primary cause of these diverse reactions relates to the distinctive traits of Hatch-Waxman litigation. Hatch-Waxman lawsuits are simply unlike other sorts of patent cases, and these qualities have strongly encouraged the concentration of litigation into just two fora.[36] These traits include the timing, lenient joinder practices, superior remedies, and decision makers of this special kind of patent case.[37]

28. Daniel Klerman & Greg Reilly, *Forum Selling*, 89 S. CAL. L. REV. 241, 243 (2016).

29. J. Jonas Anderson, *Court Capture*, 59 B.C. L. REV. 1543, 1576 (2018); Michael C. Smith, *Rocket Docket: Marshall Court Leads Nation in Hearing Patent Cases*, 69 TEX. BAR J. 1045, 1045 (2006).

30. *See* Shawn P. Miller, *Venue One Year After* TC Heartland*: An Early Empirical Assessment of the Major Changes in Patent Filing*, 52 AKRON L. REV. 763, 810 (2018).

31. Love & Yoon, *supra* note 2, at 17; Katherine Rhoades, *Do Not Pass Go, Do Not Stop for Summary Judgment: The U.S. District Court for the District of Delaware's Seemingly Disjunctive yet Efficient Procedures in Hatch-Waxman Litigation*, 14 NW. J. TECH. & INTELL. PROP. 81, 95 (2016).

32. *See, e.g.*, Novartis Pharms. Corp. v. Accord Healthcare Inc., No. 18-1043-LPS, 2019 WL 2502535, at *1 (D. Del. June 17, 2019) (consolidating twenty-three groups of generic makers in a Hatch-Waxman proceeding); MyMail, Ltd. v. Am. Online, Inc., 223 F.R.D. 455, 458 (E.D. Tex. 2004) (articulating liberal joinder standards).

33. *See, e.g.*, Valeant Pharms. N. Am. LLC v. Zydus Pharms. (USA) Inc., No. 18-cv-13635, 2019 WL 4179832, at *1 (D.N.J. Aug. 14, 2019), *rev'd sub nom.*, Valeant Pharms. N. Am. LLC v. Mylan Pharms. Inc., 978 F.3d 1374, 1385 (Fed. Cir. 2020).

34. *See* Miller, *supra* note 30, at 809 ("Delaware and the Eastern District of Texas are similar in many ways that indicate that the incentives to adopt pro-plaintiff rules and practices are stronger than the counter-incentives towards balance.").

35. *See* Megan Woodhouse, *Shop 'til You Drop: Implementing Federal Rules of Patent Litigation Procedure to Wear Out Forum Shopping Patent Plaintiffs*, 99 GEO. L.J. 227, 228 (2010) (noting the remote location of East Texas).

36. *See* Amanda Walton Newton, *Tightening the Gilstrap: How TC Heartland Limited the Pharmaceutical Industry When It Reined in the Federal Circuit*, 25 J. INTELL. PROP. L. 255, 279 (2018).

37. *See infra* Sections II.A, II.B, II.C.

A. The Timing of Hatch-Waxman Trials

Hatch-Waxman cases almost always arise at the same time.[38] They do so because generic manufacturers commence litigation by engaging in the act of "artificial" infringement;[39] they are statutorily prohibited from doing that until four years have elapsed since the patented drug was approved;[40] and they are incented to commence litigation on the very day this four-year period ends.[41] Understanding why a dozen or more lawsuits involving the same patent may occur contemporaneously draws us into the complex vocabulary and workings of the Hatch-Waxman system.

Two centuries of U.S. patent law have led to many curiosities. The reverse doctrine of equivalents,[42] hypothetical patent claims,[43] and two-way obviousness-type double patenting[44] likely top the list, but the artificial act of infringement established by the Hatch-Waxman Act stands as the most practically consequential.[45] Here one enters a "strange, fictive realm,"[46] in which generic manufacturers are haled into a sometimes distant court, and made to engage in one of the most costly forms of litigation on the planet, merely by submitting an entirely accurate petition to the government.

More concretely, artificial infringement occurs when a generic manufacturer submits an application for marketing approval to the FDA for "a drug claimed in a patent or the use of which is claimed in a patent."[47] The generic manufacturer does so after reviewing an FDA publication known as the Orange Book, where the agency lists patents previously identified by the brand-name drug company.[48] To be clear, the generic manufacturer has not made, used, placed on sale, sold, or imported into the United States the patented invention.[49] Rather, it has merely filed an "Abbreviated New Drug Application" ("ANDA")

38. C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 ANTITRUST L.J. 947, 983 (2011).

39. 35 U.S.C. § 271(e)(2); Sandoz Inc. v. Amgen Inc., 137 S. Ct. 1664, 1670 (2017).

40. 21 U.S.C. § 355(j)(5)(F)(ii); *see infra* notes 59–62 and accompanying text. This Article will limit its statutory citations to those concerning ANDAs and avoid the often-parallel provisions pertaining to § 505(b)(2) applications, the so-called "paper NDAs."

41. *See* 21 U.S.C. § 355(j)(5)(F)(ii); *infra* notes 63–66 and accompanying text.

42. *See* Samuel F. Ernst, *The Lost Precedent of the Reverse Doctrine of Equivalents*, 18 VAND. J. ENT. & TECH. L. 467, 471–74 (2016).

43. *See* Henrik D. Parker, *Doctrine of Equivalents Analysis After* Wilson Sporting Goods*: The Hypothetical Claim Hydra*, 18 AM. INTELL. PROP. L. ASS'N Q.J. 262, 273–74 (1990).

44. *See* Daniel Kazhdan, *Obviousness-Type Double Patenting: Why It Exists and When It Applies*, 53 AKRON L. REV. 1017, 1019–23 (2019).

45. *See* Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 676–77 (1990).

46. Ben Venue Labs., Inc. v. Novartis Pharm. Corp., 146 F. Supp. 2d 572, 577 (D.N.J. 2001).

47. 35 U.S.C. § 271(e)(2)(A).

48. *See* U.S. Food & Drug Admin., Approved Drug Products with Therapeutic Equivalence Evaluations (42d ed. 2022).

49. *See* 35 U.S.C. § 271(a).

with the FDA at its headquarters in White Oak, Maryland, a suburb of Washington, DC.[50]

Artificial infringement generally occurs when, in conjunction with its ANDA, the generic manufacturer asserts that the brand-name firm's patents are invalid, unenforceable, or not infringed.[51] Although the statement is found in a "subclause IV" within the Hatch-Waxman Act,[52] the patent bar, perhaps not fully appreciative of the nuances of legislative drafting, has uniformly termed it to be a "Paragraph IV certification."[53] The generic firm must then provide notice of its paragraph IV certification to the brand-name firm and, if the ownership is distinct, the patent holder.[54]

Filing an ANDA with a paragraph IV certification "means provoking litigation."[55] Not every paragraph IV ANDA results in an assertion of patent infringement, but the brand-name usually responds in this manner.[56] Paragraph IV certifications stand apart from other, less confrontational statutory options, through which generic manufacturers may state that no patents have been listed in the Orange Book for that drug, that any listed patents have already expired, or that the generic manufacturer will not market its product until they do.[57]

When artificial infringement litigation occurs, it ordinarily takes place at least four years since the brand-name drug company obtained permission to market its product from the FDA.[58] Four years must pass because the drugs of most interest to generic manufacturers ordinarily qualify as "new chemical entit[ies],"[59] which is to say that that the FDA has not previously approved the drug's active moiety.[60] New chemical entities are subject to a so-called "regulatory exclusivity"[61]—an FDA-administered intellectual property right—that bars generic firms from filing ANDAs for five years from the date the brand-name drug was approved. But if the generic manufacturer files an ANDA with a

50. *See Abbreviated and New Drug Application (ANDA) Forms and Submission Requirements*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/abbreviated-new-drug-application-anda-forms-and-submission-requirements (Mar. 7, 2022) [https://perma.cc/8MRV-CWS3].

51. This situation represents the usual practice for the pharmaceutical industry. But because 35 U.S.C. § 271(e)(2) makes no mention of either the Orange Book or any intellectual property position taken by a generic drug manufacture, not every court requires an assertion of invalidity, unenforceability, or noninfringement of an Orange-Book-listed patent for artificial infringement to occur. *See, e.g.*, Allergan Sales, LLC v. Teva Pharms. USA, Inc., No. 2:15-CV-01471-JRG-RSP, 2017 WL 3446634, at *6 (E.D. Tex. July 25, 2017); Takeda Pharm. Co., Ltd. v. TWi Pharms., Inc., No. C-11-01609 JCS, 2013 WL 12164680, at *21 (N.D. Cal. May 20, 2013).

52. 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

53. *See, e.g.*, GlaxoSmithKline LLC v. Teva Pharms. USA, Inc., 976 F.3d 1347, 1349 (Fed. Cir. 2020).

54. 21 U.S.C. § 355(j)(2)(B)(iii).

55. Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 566 U.S. 399, 407 (2012).

56. *See In re* Nexium (Esomeprazole) Antitrust Litig., 842 F.3d 34, 40 (1st Cir. 2016).

57. 21 U.S.C. § 355(j)(2)(A)(vii)(I)–(III).

58. 21 U.S.C. § 355(j)(5)(F)(ii).

59. *See* Erika Lietzan, *The Myths of Data Exclusivity*, 20 LEWIS & CLARK L. REV. 91, 98 (2016).

60. 21 U.S.C. § 355(j)(5)(F)(ii).

61. *See generally* Yaniv Heled, *Regulatory Competitive Shelters in the Area of Personalized Medicine*, 21 B.U. J. SCI. & TECH. L. 287, 287 (2015).

paragraph IV certification, it may do so a year early, as soon as the date that is four years from the date the drug was approved.[62]

The new chemical entity exclusivity pushes generic manufacturers away from the FDA for at least four years; but another incentive, the 180-day generic exclusivity, draws them towards the agency.[63] Generic exclusivity resulted from congressional recognition that patents are valid or invalid as to all the world, a legal reality that results in a collective action problem.[64] Generic manufacturers may not be so keen to invalidate the patents of brand-name firms if their competitors could immediately capitalize upon the result of their costly litigation.[65] Hatch-Waxman therefore establishes a regulatory exclusivity that acts in favor of the first ANDA applicant to file a paragraph IV certification. During the 180-day period, the FDA may not issue marketing approval to a subsequently filed ANDA with a paragraph IV certification for the same drug.[66]

Congress apparently contemplated a duopoly marketplace for the nearly six-month generic exclusivity period, shared between the brand-name firm and generic manufacturer.[67] Once the 180 days expire, other generic manufacturers may enter the fold, driving prices down as the drug becomes a commodity.[68] Described as an "Edenic moment of freedom from the pressures of the marketplace,"[69] the 180-day bounty may provide the majority of profits that the generic manufacturer will obtain throughout the product cycle of the drug.[70]

But the FDA soon encountered situations where multiple generic manufacturers filed paragraph IV certifications on the same day—namely, four years after the brand-name drug company obtained marketing approval.[71] After some initial uncertainty, Congress settled the matter by stipulating that all first applicants may obtain the 180-day exclusivity.[72] As a result, generic manufacturers qualify as "first applicants" if, on the first day on which a paragraph IV ANDA is filed, they did themselves file a paragraph IV ANDA.[73] The generic "exclusivity" is

62. The Hatch-Waxman Act sets the term of the new chemical entity exclusivity to five years; however, if the generic manufacturer files a paragraph IV ANDA, then it may do so four years following the date the FDA granted marketing approval of the brand-name product. 21 U.S.C. § 355(j)(5)(F)(ii). This litigation is often said to occur on the "NCE-1" date. *See* D. Christopher Ohly & Sailesh K. Patel, *The Hatch-Waxman Act: Prescriptions for Innovative and Inexpensive Medicines*, 19 U. BALT. INTELL. PROP. L.J. 107, 116 (2011).

63. *See* Nora Xu, *AIA Proceedings: A Prescription for Accelerating the Availability of Generic Drugs*, 66 EMORY L.J. 1007, 1019 (2017).

64. Hemphill & Lemley, *supra* note 38, at 947–48.

65. *See id.* at 953.

66. *See* Erika Lietzan & Julia Post, *The Law of 180-Day Exclusivity*, 71 FOOD & DRUG L.J. 327, 327–29 (2016).

67. *See* Bruce H. Kobayashi, Joshua D. Wright, Douglas H. Ginsburg & Joanna Tsai, Actavis *and Multiple ANDA Entrants: Beyond the Temporary Duopoly*, 29 ANTITRUST L.J. 89, 89 (2015) (discussing the general assumption that a single generic manufacturer will enter the market during the 180-day exclusivity period).

68. *See id.*

69. Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1064 (D.C. Cir. 1998).

70. Fed. Trade Comm'n v. Actavis, Inc., 570 U.S. 136, 144 (2013).

71. *See id.* at 174–75 (Roberts, J., dissenting).

72. 21 U.S.C. § 355(j)(5)(B)(iv).

73. *Id.*

now one that may be shared, and any of its joint owners may trigger the 180-day period through sales of its generic product.[74]

The results of this confluence of factors—artificial infringement, the new chemical entity exclusivity, and shared generic exclusivity—strongly encourages generic manufacturers to file paragraph IV ANDAs as close as possible to the four-year mark, and preferably on that exact date. These cumulative incentives often lead to impressive results. Since 2016, at least twenty drugs have, at the four-year mark, been subject to ten or more separate patent lawsuits brought against generic manufacturers.[75] Four of those drugs generated paragraph IV ANDAs, and resulting artificial infringement claims, involving more than twenty generic manufacturers.[76] The surprising synchronicity of paragraph IV ANDA filings provides a partial explanation for the popularity and approval of Delaware and New Jersey as for Hatch-Waxman litigation, but as we shall see, other factors contribute as well.

B. Hatch-Waxman's Remedies

The Hatch-Waxman Act includes several provisions providing a sui generis system of damages and injunctions for paragraph IV ANDA cases.[77] Ironically, the primary consequences of these provisions have nothing at all to do with compensating the brand-name drug company for infringement, or for preserving the status quo. Rather, they essentially dictate who will decide the matter, when the trial will end, and whether summary judgment will be routinely granted or not.[78] Each of these factors contributes to the widespread approval of Delaware and New Jersey in Hatch-Waxman cases.

First, the Hatch-Waxman Act explicitly states that monetary damages are ordinarily unavailable against generic manufacturers held to be solely artificial infringers.[79] After all, the generic manufacturer has done nothing more than file paperwork at the FDA and has not yet sold its products in the marketplace. Because damages are generally not awarded in paragraph IV ANDA cases, the courts have now firmly established that juries are unavailable as well.[80] The uniform result is the bench trial, with the district judges deciding the many factual issues that arise in patent law, including anticipation and infringement; subsidiary issues of nonobviousness and enablement; and, possibly, aspects of claim interpretation and the statutory subject matter inquiry.[81]

74. Lietzan & Post, *supra* note 66, at 344–46.

75. Brief of *Amicus Curiae* Pharmaceutical Research & Manufacturers of America (PhRMA) in Support of Rehearing En Banc and Reversal at 9, Valeant Pharms. N. Am. LLC v. Mylan Pharms. Inc., 978 F.3d 1374 (Fed. Cir. 2020) (No. 2019-2402).

76. *Id.*

77. *See* 21 U.S.C. § 355(j)(5)(B)(iii)(III)–(IV).

78. *See id.*

79. 35 U.S.C. § 271(e)(4)(C).

80. *See In re* Apotex, Inc., 49 F. App'x 902, 903 (Fed. Cir. 2002); *see also* Minsuk Han, *A Two-Branched Attack on the Jury Right in Patent Litigation*, 99 CORNELL L. REV. 659, 669–72 (2014).

81. *See* Paul R. Gugliuzza, *Law, Fact, and Patent Validity*, 106 IOWA L. REV. 607, 609–10 (2020).

Many commentators have referred to patent litigation as the "sport of kings" given its complexity, high stakes, and otherworldly costs.[82] If this analogy is correct, then paragraph IV ANDA litigation often involves a greater contest over a vast pharmaceutical empire. Hatch-Waxman trials stand among the most particularized and complicated litigation to be found in federal courts; many attorneys and academics who specialize in intellectual property know little about this crucial subdiscipline.[83] Further, although many patent cases involve sophisticated technologies, each Hatch-Waxman case inevitably does so. They invoke such fields as biology, various branches of chemistry, medicine, pharmacokinetics, engineering, and informatics that are beyond the grasp of those without specialized training.[84]

In addition, pharmaceutical patents hew most closely to the traditional account that patents exclude others from practicing the claimed invention for twenty years. The conventional wisdom does not hold much water in many industries, where most patents expire prematurely due to the decision not to pay maintenance fees[85] and competitors routinely cross-license vast intellectual property portfolios.[86] These events are less common in the pharmaceutical field, however, explaining why paragraph IV ANDA litigation invariably holds commercially significant implications.[87]

Of comfort to the litigants, then, is that the judges in Delaware and New Jersey have developed expertise in Hatch-Waxman procedures.[88] They also develop familiarity with pharmaceutical technologies, as well as relevant legal precedent because, for the most part, it is all theirs.[89] In addition, New Jersey has promulgated local Hatch-Waxman rules.[90] In Delaware, three of the four judges have issued ANDA-specific patent scheduling orders that are akin to local Hatch-Waxman rules.[91] These factors establish familiarity and reasonable expectations amongst the stakeholders, in high relief to the juries of East Texas which, fairly or unfairly, have frequently been subject to criticism.[92]

82. *See, e.g.*, Bernard Chao, *Focusing Patent Litigation*, 18 CHI.-KENT J. INTELL. PROP. 497, 497 (2019).

83. *See, e.g.*, Jonathan Ball, *Adjusting Patent Strategies with Recent Key Decisions in Mind*, *in* THE IMPACT OF RECENT PATENT LAW CASES AND DEVELOPMENTS 1, 1 (2010).

84. *See* Melanie R. Rupert, *Managing the Complexities of Hatch-Waxman Pharmaceutical Litigation*, *in* RECENT TRENDS IN PATENT INFRINGEMENT LAWSUITS 1, 8 (2014).

85. Kimberly A. Moore, *Worthless Patents*, 20 BERKELEY TECH. L.J. 1521, 1525–26 (2005).

86. *See* W. Michael Schuster & Gregory Day, *Colluding Against a Patent*, 2021 WIS. L. REV. 537, 553–55 (2021).

87. *See* Uri Y. Hacohen, *Evergreening at Risk*, 33 HARV. J.L. & TECH. 479, 497–98 (2020).

88. *See* Rhoades, *supra* note 31, at 83–84.

89. *Id.*

90. D.N.J. Loc. Pat. R. 3.6. The New Jersey local Hatch-Waxman rules require an early exchange of invalidity and noninfringement contentions, with the generic manufacturers going first. *Id.* at R. 3.6(e). As a result, even though the brand-name drug companies bear the burden of proving infringement, *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 845 F.3d 1357, 1364 (Fed. Cir. 2017), the generic manufacturers are the first to state their infringement position.

91. The local rules may be found at *Local Rules*, U.S. DIST. CT. DIST. DEL., https://www.ded.uscourts.gov/local-rules (last visited Jan. 21, 2023) [https://perma.cc/5KLL-Q8PF].

92. *See generally* Anderson, *supra* note 2; Love & Yoon, *supra* note 2.

Second, the Hatch-Waxman Act also contains an analog to the traditional preliminary injunction. If the patent proprietor seasonably commences an infringement suit against paragraph IV ANDA applicant, the Hatch-Waxman Act ordinarily prohibits the FDA from approving the ANDA for thirty months.[93] This thirty-month stay will be extended should the paragraph IV ANDA be filed between the fourth- and fifth-year anniversary of the date of approval of the brand-name NCE drug.[94] Because generic manufacturers are most often constrained by the NCE exclusivity, generic competition is in practice constrained for seven and a half years after the date the FDA approved the brand-name drug for marketing.[95]

Getting the FDA involved was an was odd legislative drafting choice, for the agency is not a party to artificial infringement litigation.[96] Nonetheless, the thirty-month stay effectively acts as a preliminary injunction against the generic firm, without requiring the patent proprietor to demonstrate the presence of the usual equitable factors or posting a bond.[97] If one of the litigants fails reasonably to cooperate in expending the action, the district court may reduce or extend the thirty-month period.[98]

This peculiar entitlement leads to another anomaly of artificial infringement—the frequent filing of so-called "protective suits." Under the Hatch-Waxman Act, the brand-name firm obtains the thirty-month stay only if it files suit against the generic manufacturer within forty-five days of receiving notice of the paragraph IV ANDA.[99] Brand-names firms therefore often assert claims of artificial infringement in two fora—typically in one mid-Atlantic district; as well as in the district in which the generic firm is incorporated or, if the generic firm is based in the United States, where it is located.[100] The second lawsuit protects the brand-name firm's entitlement to the thirty-month stay if concerns over personal jurisdiction and venue arise.[101]

93. 21 U.S.C. § 355(j)(5)(B)(iii).

94. 21 U.S.C. § 355(j)(5)(F)(ii). Upon filing a paragraph IV ANDA, generic manufacturers must wait until the FDA issues an acknowledgement letter, usually about sixty to ninety days later. The generic manufacturer is then afforded twenty days to send to the brand-name drug company. 21 C.F.R. § 314.95(b) (2022). As a practical matter, most thirty-month stays in NCE-1 cases are extended by about nine or ten months due to the gap between the filing date of the ANDA and the FDA's issuance of an acknowledgement letter.

95. *See In re* Ciprofloxacin Hydrochloride Antitrust Litig., 261 F. Supp. 2d 188, 195 n.8 (E.D.N.Y. 2003). The seven and a half-year period may be increased to eight years if the brand-name drug company conducts pediatric studies and is awarded a six-month "pediatric exclusivity" by the FDA. 21 U.S.C. § 355a; *Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act: Frequently Asked Questions on Pediatric Exclusivity (505A)*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/development-resources/qualifying-pediatric-exclusivity-under-section-505a-federal-food-drug-and-cosmetic-act-frequently (Mar. 1, 2022) [https://perma.cc/2NPP-SMD2]; 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. LEGIS. 133, 154–55 (2003).

96. *See, e.g.*, AbbVie Inc. v. Alvotech hf., 582 F. Supp. 3d 584, 586 (N.D. Ill. 2022).

97. *See* Takeda Pharms. U.S.A., Inc. v. Mylan Pharms. Inc., 967 F.3d 1339, 1343 (Fed. Cir. 2020).

98. 21 U.S.C. § 355(j)(5)(B)(iii).

99. *Id.*

100. *Newton*, *supra* note 36, at 279–81.

101. *Id.*

At all events, at the close of the thirty-month stay, if litigation has not run its course, the patent proprietor may move for a preliminary injunction under the usual standards.[102] If it does not, or does so unsuccessfully, a generic drug may obtain FDA approval and commence sales of its product before patent litigation has fully run its course.[103] In industry parlance, such sales are termed an "at-risk" launch.[104] This choice of words yields little insight, for virtually every person in the United States could be sued for infringing multiple patents at any time. We are all at risk. The phrase nonetheless reflects the possibility that a patent may be held not invalid and infringed after the generic launches, and thus lead the generic manufacturer to withdraw its product and face the possibility of infringement damages.[105]

The legislative history of the Hatch-Waxman Act shows that the thirty-month period resulted from difficult negotiations among the stakeholders.[106] Originally the automatic stay provision was set to a period of eighteen months; it was, controversially, later increased to thirty months.[107] Congressman Waxman explained that this extension would improve the likelihood that such patent litigation would be concluded prior to generic market entry.[108]

To be sure, however as ultimately enacted, Hatch-Waxman placed no deadline upon the federal courts whatsoever. No court is required to reach a definitive conclusion about the validity, enforceability, and infringement of a pharmaceutical patent within any particular timeframe, at least because of this legislation.[109] Experience shows, however, that the judges of both Delaware and New Jersey strive to issue their judgments within the statutory stay period.[110] They do so out of recognition of the commercial importance of paragraph IV ANDA cases, the goal of obviating the need to entertain motions for a preliminary injunction or extension of the stay, as well as the desire to avoid untidy situations where generic drugs initially enter the marketplace and then must be withdrawn.[111] Such a circumstance could possibly lead to confusion in pharmacies and medicine cabinets, price erosion of the brand-name drug, and additional judicial labor over the long term.

102. *See, e.g.*, Tyco Healthcare Grp. LP v. Mut. Pharm. Co., Inc., No. 07-1299(SRC), 2009 WL 2422382, at *1 (D.N.J. Aug. 4, 2009).

103. *See id.*

104. Michael Barker, *Coloring Consideration: Defining Illegal Payments in Alleged "Reverse Payment" Settlements Between Brand and Generic Makers Post*-Actavis, 13 J. HEALTH & BIOMEDICAL L. 109, 117 (2017).

105. *See id.* at 116–17.

106. Eli Lilly & Co. v. Teva Pharms. USA, Inc., 557 F.3d 1346, 1354 n.3 (Fed. Cir. 2009) (Prost, J., dissenting).

107. *Id.*

108. 130 CONG. REC. 24,425 (daily ed. Sept. 6, 1984) (statement of Rep. Henry Waxman).

109. *See id.*

110. *See* Christine A. Gaddis, *COVID-19 and Hatch-Waxman Litigation in the District of New Jersey*, N.J. L.J, Sept. 14, 2020 ("In Hatch-Waxman cases, district courts and litigants generally endeavor to conclude the case before or by the termination of the date of any applicable 30-month stay."); Dana A. Elfin, *Know Your Judge: Jose Linares Handles Top-Selling Drug Cases*, BLOOMBERG L. (June 1, 2018, 1:23 PM), https://news.bloomberglaw.com/business-and-practice/know-your-judge-jose-linares-handles-top-selling-drug-cases [https://perma.cc/3476-L7PH] ("ANDA cases 'are judge trials that have to be done in 30 months . . . .'").

111. *See* Gaddis, *supra* note 110.

The result of all of this is that, in Delaware and New Jersey, stakeholders have a strong sense of when Hatch-Waxman trials will begin and when they are going to end.[112] To be sure, not every litigation meets the thirty-month deadline. Particularly during the COVID-19 pandemic, many courts have struggled to maintain this brisk pace.[113] Still, the aspirational thirty-month deadline provides brand-name drug companies and generic manufacturers alike with a good sense of the intellectual property landscape with respect to a particular pharmaceutical.

One further trait of paragraph IV ANDA trials results from Hatch-Waxman's remedial provisions. As with East Texas generally, the courts of Delaware and New Jersey rarely grant summary judgment motions in Hatch-Waxman cases.[114] Of course, nothing in the Hatch-Waxman Act explicitly prevents or discourages the grant of motions for summary judgment. But, particularly in Delaware, summary judgment in Hatch-Waxman cases is by far the exception.[115] The Scheduling Orders of both Chief Judge Leonard Stark[116] and Judge Maryellen Noreika[117] state that they will generally not hear dispositive motions in ANDA cases at all, and Judge Richard Andrews has placed fairly strict limitations upon them.[118] Chief Judge Colm Connolly has promulgated a delightfully written Standing Order stipulating that, in all patent cases, once he denies a motion for summary judgment, he will not entertain any further summary judgment motions from that party.[119]

Summary judgment provides another example where highly similar practices among different courts results in vastly different perceptions. In East Texas, the reluctance of courts to grant summary judgment has been viewed as

112. *See id.*; Elfin, *supra* note 110.

113. *See* Geoff Biegler, Megan Chacon & Madelyn McCormick, *How Pandemic-Related Delays Affect Hatch-Waxman Litigants*, LAW360 (May 21, 2020, 6:06 PM), https://www.law360.com/articles/1274140/how-pandemic-related-delays-affect-hatch-waxman-litigants [https://perma.cc/F4VV-88WY].

114. *See* Rhoades, *supra* note 31, at 81.

115. *See id.* at 96–97, 107.

116. *See Revised Patent Form Scheduling Order (ANDA)*, U.S. DIST. CT. DIST. DEL., https://www.ded.uscourts.gov/sites/ded/files/LPS-PatentSchedOrder-ANDA.pdf (July 1, 2014) [https://perma.cc/5UEE-SHWX]. Judge Stark has recently been elevated to the Court of Appeals for the Federal Circuit. Jacob Owens, *Del. Judge Stark Appointed to Federal Circuit*, DEL. BUS. TIMES (Feb. 10, 2022), https://delawarebusinesstimes.com/news/stark-appointed-to-fed-circuit/ [https://perma.cc/62JW-GM26].

117. *Patent Form Scheduling Order (ANDA)*, U.S. DIST. CT. DIST. DEL., https://www.ded.uscourts.gov/sites/ded/files/chambers/April%202021%20-%20MN%20Scheduling%20Order%20-%20Patent%20ANDA.pdf (Apr. 5, 2021) [https://perma.cc/78TN-4UGY]. Noreika was formerly a partner at Morris Nichols, a notable Wilmington, Delaware firm representing brand-name drug companies. *White House Announces District of Delaware Judicial Nominees*, MORRIS NICHOLS ARSHT & TUNNELL (Dec. 21, 2017), https://www.morrisnichols.com/insights-white-house-announces-district-of-delaware-judicial-nominees#:~:text=Ms.,consumer%20products%2C%20computers%20and%20telecommunications [https://perma.cc/74J7-8WJN].

118. *Scheduling Order*, U.S. DIST. CT. DIST. DEL., https://www.ded.uscourts.gov/sites/ded/files/chambers/Form%20Sch.%20Order.pdf (Dec. 2019) [https://perma.cc/B9MY-T655].

119. *Standing Order for Summary Judgment Practice in Patent Cases Assigned to Judge Connolly*, U.S. DIST. CT. DIST. DEL., https://www.ded.uscourts.gov/sites/ded/files/FINAL%20STANDING%20ORDER%20FOR%20SUMMARY%20JUDGMENT%20PRACTICE%20IN%20PATENT%20CASES.pdf (Apr. 13, 2021) [https://perma.cc/N8T8-TBZF].

prolonging trial and promoting patent trolling.[120] For the mid-Atlantic courts in Hatch-Waxman cases, however, summary judgment motions are viewed as distractions that impede the ability of the court to issue a final judgment before the 30-month stay expires.[121] And from the perspective of the bench, the Delaware and New Jersey courts appear to have little incentive to entertain summary judgment motions when they are poised to issue a final judgment anyway. The Federal Circuit reviews appeals from bench trials with greater deference to the district court than it would from a grant of summary judgment, particularly with respect to such findings of fact as anticipation and infringement, along with aspects of claim construction, patentable subject matter, and nonobviousness.[122]

The willingness of Delaware and New Jersey to strive to complete paragraph IV ANDA trials within thirty months provides a partial explanation for the favorable public sentiment towards these fabulously popular fora. But another factor is the ability and inclination of these courts to consolidate patent trials to an extent that is impossible in garden-variety patent cases.[123] This Article next reviews the distinctive history of voluntary joinder in patent trials and explores the consequences for artificial infringement trials.

C. Joinder

Over the past decade, Hatch-Waxman cases have been among the most heavily consolidated patent lawsuits in the nation.[124] Not infrequently, they bring together ten or more generic manufacturers, each of which competes vigorously against each other, to defend themselves in among the most technically complex, high-stakes litigation in the nation.[125] Brand-name firms most commonly achieve this outcome by suing each paragraph IV ANDA applicant in the same forum—usually either Delaware or New Jersey—and then asking the court to join them in a single lawsuit.[126]

120. *See* Grace Heinecke, *Pay the Troll Toll: The Patent Troll Model Is Fundamentally at Odds with the Patent System's Goal of Innovation and Competition*, 84 FORDHAM L. REV. 1153, 1179 (2015).

121. *See* Rhoades, *supra* note 31, at 104.

122. Under the law of the Third Circuit—which the Federal Circuit applies due to its distinctive choice-of-law principles—the grant of summary judgment is viewed de novo. ArcelorMittal Atlantique et Lorraine v. AK Steel Corp., 908 F.3d 1267, 1273 (Fed. Cir. 2018). On appeal from a full bench trial, however, findings of fact are reviewed for clear error. Galderma Laby's, L.P. v. Teva Pharms. USA, Inc., 799 F. App'x 838, 842 (Fed. Cir. 2020).

123. *See* discussion *infra* Section II.C; *see also* Alex Wolf, *Jazz's Xyrem Patent Cases Consolidated in NJ Fed Court*, LAW360 (Jan. 15, 2016, 3:28 PM), https://www.law360.com/articles/747012/jazz-s-xyrem-patent-cases-consolidated-in-nj-fed-court [https://perma.cc/T82K-KVKU]; David L. Finger, *Delaware Trial Handbook § 2:8. Motion for Consolidation of Civil Cases*, FINGER & SLANINA, LLC, https://www.delawgroup.com/delaware-trial-handbook-%C2%A7-28-motion-for-consolidation-of-civil-cases/ [https://perma.cc/8R97-HGTF].

124. Brian Goldberg & Robert Rhoad, *Finding MDL Ground in Venue for Hatch-Waxman Cases*, JD SUPRA (Aug. 23, 2022), https://www.jdsupra.com/legalnews/finding-mdl-ground-in-venue-for-hatch-2527563/ [https://perma.cc/8BBZ-PZU2].

125. *See, e.g.*, *In re* Omeprazole Patent Litigation, 84 F. App'x 76, 78 (Fed. Cir. 2003).

126. FED. R. CIV. P. 42(a).

Permissive joinder in patent cases has a somewhat convoluted history in both East Texas and the mid-Atlantic courts,[127] and the disparate congressional treatment of joinder practice in these courts could not be starker. Readers will recall that under Rule 20 of the Federal Rules of Civil Procedure, 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."[128] Prior to the enactment of the America Invests Act in 2011,[129] courts differed markedly in their approach to Rule 20(a) in patent cases. In particular, East Texas expressed a capacious view of permissive joinder, while other jurisdictions took a more cautious approach.[130]

The most famous of the East Texas joinder cases, *MyMail Ltd. v. America Online, Inc.*,[131] involved several unrelated enterprises that were accused of infringing the same patent. The defendants agreed that the second prong of Rule 20 was satisfied through such shared issues as the asserted patent's validity or claim construction.[132] But the defendants took the straightforward position that infringement by multiple, unrelated defendants did not satisfy the "same transaction" standard of Rule 20.[133]

Judge Leonard Davis disagreed with what he viewed to be a "hypertechnical" view of Rule 20.[134] He instead concluded that "[t]ransactions or occurrences satisfy the series of transactions or occurrences requirement of Rule 20(a) if there is some connection or logical relationship between the various transactions or occurrences."[135] According to Judge Davis, 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.[136] The *MyMail* opinion did acknowledge that proceedings could be severed if the products or methods differed dramatically.[137] Still, this determination could not be made until at least the close of discovery, by which time common reasons for severance, including inefficiencies and prejudice from joinder, might no longer apply.[138]

127. *See* David O. Taylor, *Patent Misjoinder*, 88 N.Y.U. L. REV. 652, 656–59 (2013).

128. FED. R. CIV. P. 20(a)(2). Rule 42 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).

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

130. *See* Ping-Hsun Chen, *Joinder of Unrelated Infringers as Defendants in Patent Litigation Under the Jurisprudence of the United States District Court for the Eastern District of Texas - A Critical Review*, 98 J. PAT. & TRADEMARK OFF. SOC'Y 155, 155 (2016).

131. 223 F.R.D. 455, 456 (E.D. Tex. 2004).

132. *Id.* at 456–47.

133. *Id.* at 456.

134. *Id.* at 457.

135. *Id.* at 456.

136. *Id.*

137. *Id.* at 457.

138. *Id.*

On the other hand, other courts squarely held that joinder of "separate companies that independently design, manufacture and sell products in competition with each other" was improper.[139] For example, in *Pergo, Inc. v. Alloc, Inc.*,[140] the Southern District of New York rejected permissive joinder of defendants that lacked a cooperative relationship, and in fact competed vigorously against each other.[141] According to Judge John Koeltl, the fact that multiple enterprises might manufacture or sell similar products that were alleged to infringe the same patent did not suffice to join them in the same lawsuit.[142]

Technology implementers howled with complaints over the *MyMail* rule.[143] Accused infringers often sell different products, cite disparate prior art references, propose distinct claim constructions, and offer unrelated theories of invalidity and noninfringement.[144] They also have varying business interests, often including directly competitive relationships and an aversion towards sharing confidential information in order to coordinate a common defense.[145] Defendants have also chafed under restrictions on the number of depositions, discovery requests, and motions practice, which potentially left them less capable of defending their individual interests.[146]

The high-technology community ultimately prevailed upon Congress to address the *MyMail* rule. The result was the extraordinary step of modifying Rule 20, but only for patent cases, through the introduction of § 299 to the Patent Act.[147] 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."[148] 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.[149] Section 299 squarely rejects the *MyMail* rule, and, as a general matter, makes voluntary joinder in patent cases more difficult than the standard developed in Rule 20(a).[150]

Careful readers of the American Invents Act quickly realized, however, that an exception applies. Section 299 expressly carves out Hatch-Waxman cases from these amendments.[151] Ironically enough, the *MyMail* rule—developed in

139. Androphy v. Smith & Nephew, Inc., 31 F. Supp. 2d 620, 623 (N.D. Ill. 1998).

140. 262 F. Supp. 2d 122, 122 (S.D.N.Y. 2003).

141. *Id.* at 128

142. *Id.* at 126–28.

143. *See, e.g.*, Dongbiao Shen, *Misjoinder or Mishap? The Consequences of the AIA Joinder Provision*, 29 BERKELEY TECH. L.J. 545, 545 n.7 (2014).

144. *Id.* at 562–63.

145. *Id.* at 578.

146. *See* Taylor, *supra* note 127, at 673–75.

147. *Id.* at 654–55.

148. 35 U.S.C. § 299(b).

149. 35 U.S.C. § 299(a).

150. *See* Motorola Mobility, Inc. v. Apple Inc., No. 1:12-cv-20271-RNS, 2012 WL 3113932, at *4 (S.D. Fla. 2012) (noting that the America Invents Act abrogated the *MyMail* rule).

151. *See, e.g.*, Shen, *supra* note 143, at 556; Tracie L. Bryant, *The America Invents Act: Slaying Trolls, Limiting Joinder*, 25 HARV. J.L. & TECH. 687, 700 n.94 (2012).

East Texas in a garden-variety patent case—lives on, but has been limited to Hatch-Waxman cases which, for the most part, proceed in Delaware and New Jersey.[152]

Certainly, each of the critiques directed towards *MyMail* apply with full force to paragraph IV ANDA cases. Generic firms may have developed distinct positions as to such issues as claim interpretation, the best prior art, and validity; their ability to represent their individual interests in such heavily consolidated patent litigation may be limited. Given that the active ingredient must be identical to that of the brand-name firm,[153] noninfringement arguments are often difficult with respect to patents on active pharmaceutical ingredients. But brand-name drug companies also obtain patents on such inventions as formulations, isomers, crystals, polymorphs, chemical intermediates, enantiomers, and combination therapies.[154] In those circumstances in particular, generic products may differ in relevant ways, and noninfringement arguments are far more viable.

Despite these factors, Congress apparently believed that consolidation of paragraph IV ANDA cases, as compared to mainstream patent litigation, was in the best interest of the nation's public health. Brand-name firms obtain considerable efficiencies in enforcing their patents against multiple generic manufacturers in a single lawsuit.[155] For their part, generic manufacturers may pool resources and share strategies in joint defense groups.[156] The burden is upon inventors and expert witnesses through duplicative depositions and trial testimony.[157] Most notably, *MyMail* substantially reduces the burdens upon the federal juridical system, as only one court need resolve the pharmaceutical patent dispute.[158]

D. Forum Selling

Finally, although New Jersey, Delaware, and East Texas have each built a distinguished record of forum selling over the years, stakeholder reaction to these practices differs markedly. For their part, the mid-Atlantic states have a long history of providing favorable tax and doctrinal advantages in an effort to attract incorporations of public companies.[159] New Jersey did so first and, prior to 1913, held the dominant share of publicly traded companies in the United States.[160] But

152. Shortly after the congressional enactment of § 299, the Federal Circuit issued *In re* EMC Corp., 677 F.3d 1351, 1351 (Fed. Cir. 2012). *In re 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," and therefore apparently did not address Hatch-Waxman cases. *Id.* at 1356, 1359–60.

153. 21 U.S.C. § 355(j)(2)(A)(ii).

154. JOHN R. THOMAS, PHARMACEUTICAL PATENT LAW 46–64 (3d ed. 2015).

155. Taylor, *supra* note 127, at 672.

156. *Id.* at 673.

157. *See id.* at 658, 672.

158. *Id.* at 680.

159. Stephen M. Bainbridge, *Fee-Shifting: Delaware's Self-Inflicted Wound*, 40 DEL. J. CORP. L. 851, 869 (2016).

160. Marcel Kahan, *Delaware's Peril*, 80 MD. L. REV. 59, 60 (2020).

facing criticism from Theodore Roosevelt, presidential candidate Woodrow Wilson, then the governor of New Jersey, drafted reform legislation known as the "Seven Sisters Acts."[161] Many business enterprises reacted by taking leave of New Jersey and setting up shop in neighboring Delaware.[162]

New Jersey and Delaware competed for corporate charters, not patent litigation, although one effect of concentrated incorporation is that patent litigation may be conveniently grounded in those jurisdictions.[163] For its part, East Texas has been accused of direct forum selling with respect to patent plaintiffs—although, interestingly enough, commentators seem hard-pressed to identify exactly how it does so. For example, although Professor Brian Love and Mr. James Yoon concede that "a single explanation for the district's popularity is surprisingly hard to articulate," they view its attractiveness of East Texas is due to "the accumulated effect of several marginal advantages, particularly with respect to the timing and success rate of important pretrial events."[164]

These actions are viewed as catering to "patent trolls"—assertion entities that allegedly engage in abusive litigation and licensing campaigns against technology implementers.[165] Viewed as predatory litigants that sell no products and drain funds from legitimate businesses,[166] trolls are said to rely upon patents of low quality and value to obstruct innovation and technological progress.[167]

But patent trolling has, thus far, played little role in the pharmaceutical field. To be sure, the industry has encountered "Pharma Bro," Martin Shkreli, who wielded the "New Property"[168] of FDA marketing approval to raise drug prices abruptly.[169] And some individuals endeavored to manipulate the stock market by challenging the validity of valuable pharmaceutical patents.[170] But these incidents have been isolated and few compared to patent trolling activity with respect to information technologies.[171] Pharmaceutical technologies simply do not have the low barriers to entry, extreme fragmentation of actors, and number of patents found in other fields of patented inventions.[172] The result is that

161. Omari Scott Simmons, *Delaware's Global Threat*, 41 J. CORP. L. 217, 246–47 (2015); *see* Kahan, *supra* note 160, at 60.

162. *See* Bainbridge, *supra* note 159, at 869.

163. *See id.*; Xuan-Thao Nguyen, *Promoting Corporate Irresponsibility? Delaware as the Intellectual Property Holding State*, 46 J. CORP. L. 717, 742 (2021).

164. Love & Yoon, *supra* note 2, at 4–5.

165. *See* Edward Lee, *Patent Trolls: Moral Panics, Motions in Limine, and Patent Reform*, 19 STAN. TECH. L. REV. 113, 115 (2015).

166. Tara Feld, *States Hold the Sword to Force "Patent Trolls" Back Under Their Bridges*, 2016 U. ILL. L. REV. 1123, 1124 (2016).

167. Miriam Marcowitz-Bitton & Emily Michiko Morris, *Unregistered Patents*, 95 WASH. L. REV. 1835, 1840 (2020).

168. *See generally* Charles A. Reich, *The New Property*, 73 YALE L.J. 733 (1964).

169. Isaac D. Buck, *The Cost of High Prices: Embedding an Ethic of Expense into the Standard of Care*, 58 B.C. L. REV. 101, 117–22 (2017).

170. *See* J. Gregory Sidak & Jeremy O. Skog, *Attack of the Shorting Bass: Does the* Inter Partes *Review Process Enable Petitioners to Earn Abnormal Returns?*, 63 UCLA L. REV. DISC. 120, 122–23 (2015).

171. *See* Andrew Moody, *Patently Obvious: A Dual Standard Solution to the Diverging Needs of the Information Technology and Pharmaceutical Patent Industries*, 39 GOLDEN GATE U. L. REV. 71, 82, 89, 92–93 (2008).

172. *See id.* at 73, 87–97.

the same practices are said to promote trolling when done in East Texas, but attract little notice when performed in the mid-Atlantic.[173]

The differing constituents of East Texas, on one hand, and Delaware and New Jersey, on the other, also go a long way to explaining the diverse reaction to the dominance of these courts. No major pharmaceutical firm has its headquarters in East Texas, and few high-technology enterprises of any sort are located there.[174] On the other hand, the large percentage of incorporations in Delaware means that many enterprises may be brought to court there in pharmaceutical patent cases. In addition, enterprises such as AstraZeneca, DuPont, and W.L. Gore maintain headquarters in Delaware.[175] For its part, New Jersey has been described as the "medicine chest of the world," a center of the global pharmaceutical industry.[176] Neither court is geographically isolated from chemical and pharmaceutical firms. Each court also hears other sorts of patent cases besides Hatch-Waxman matters.[177]

A further demonstration of the distinct views of these courts is that many accused patent infringers have been keen to leave East Texas—not just by filing motions to transfer, but by actually shuttering stores so as to avoid doing business there.[178] On the other hand, the majority of generic firms have not voiced strenuous objections to having their paragraph IV ANDA cases tried in the mid-Atlantic. One exception has been the firm previously known as Mylan,[179] the well-known generic manufacturer and provider of the EpiPen.[180] Often keen to litigate in West Virginia, the state where it was founded and is incorporated,[181] Mylan has upset the apple cart of venue in artificial infringement cases, with potentially significant consequences for the practical workings of the Hatch-Waxman Act.

173. *See* Miller, *supra* note 30, at 809–10.

174. *See* Alexander S. Krois, *The Evolution of Patent Venue in the Aftermath of* TC Heartland, 34 BERKELEY TECH. L.J. 1023, 1027 (2019); Nguyen, *supra* note 163, at 729.

175. Holly Quinn, *Manufacturing in Delaware: Why Homegrown Adesis Continues to Grow STEM Jobs*, TECHNICAL.LY (Oct. 22, 2020, 7:01 PM), https://technical.ly/delaware/2020/10/22/manufacturing-adesis-stem-jobs/ [https://perma.cc/FQ5X-KCBJ].

176. *New Jersey: The Medicine Chest of the World*, HEALTHCARE INSTITUTE OF NEW JERSEY, https://hinj.org/life-sciences-new-jersey/new-jersey-the-medicine-chest-of-the-world/ (last visited Jan. 27, 2023) [https://perma.cc/8QUS-VVXV].

177. *See* Ofer Eldar & Neel U. Sukhatme, *Will Delaware Be Different? An Empirical Study of* TC Heartland *and the Shift to Defendant Choice of Venue*, 104 CORNELL L. REV. 101, 153 (2018).

178. *See* Sarah Perez, *Apple Confirms its Plans to Close Retail Stores in the Patent Troll-Favored Eastern District of Texas*, TECHCRUNCH (Feb. 22, 2019, 2:47 PM), https://techcrunch.com/2019/02/22/apple-confirms-its-plans-to-close-retail-stores-in-the-patent-troll-favored-eastern-district-of-texas/ [https://perma.cc/6REF-8XX9].

179. *See* Patricia Sabatini, *USW Releases Details of Severance Package for Workers at Mylan Plant in Morgantown*, PITTSBURGH POST-GAZETTE (July 8, 2021, 2:36 PM), https://www.post-gazette.com/business/career-workplace/2021/07/08/USW-severance-Mylan-pharmaceuticals-plant-Morgantown-Viatris-Gouzd/stories/202107080161 [https://perma.cc/UB6V-TSRV].

180. *See* Talal Rashid, *The EpiPen Problem: Analyzing Unethical Drug Price Increases and the Need for Greater Government Regulation*, 26 U. MIA. BUS. L. REV. 129, 131 (2017).

181. *See* Newton, *supra* note 36, at 273.

III. *VALEANT* AND VENUE

Written nowhere in the Hatch-Waxman Act, but seemingly set in stone as a practical matter, has been the primacy of Delaware and New Jersey for the resolution of paragraph IV ANDA litigation.[182] A convergence of factors, many specific to paragraph IV ANDA litigation, explains the dominant role of these two courts. Further, this trend has largely been lauded, or at least not been the subject of criticism, even though the mid-Atlantic courts engage in many of the same practices as their counterpart in East Texas. Recent judicial developments have muddied the waters, however, and whether this hegemony may be maintained remains very much in doubt.

The patent law's specialized venue statute serves as the culprit. That statute, 28 U.S.C. § 1400(b), states that patent infringement suits may be brought in the district where the defendant "resides" or where the defendant has committed acts of infringement and has a regular and established place of business.[183] These two seemingly straightforward requirements have been the subject of considerable judicial ferment in recent years.

This story begins with the 1957 Supreme Court decision in *Fourco Glass Co. v. Transmirra Products Corp.*,[184] which held that for purposes of patent venue, a domestic corporation "resides" only in the state of its incorporation. The Federal Circuit reassessed this ruling in its 1990 ruling in *VE Holding Corp. v. Johnson Gas Appliance Co*.[185] There the Federal Circuit held that *Fourco Glass* had been modified by congressional amendments made to the general venue statute.[186] Those 1988 amendments reworded 28 U.S.C. § 1391(c) to provide that "[f]or purposes of venue under this chapter, a defendant that is a corporation shall be deemed to reside in any judicial district in which it is subject to personal jurisdiction at the time the action is commenced."[187] The Federal Circuit concluded that this change also applied to patent suits because the patent venue statute sits in the same chapter as the general one.[188]

In its 2017 decision in *TC Heartland LLC v. Kraft Foods Group Brands LLC*,[189] the Supreme Court held that *Fourco Glass* remained good law, effectively concluding that the Federal Circuit had been mistaken for over a quarter century.[190] The Supreme Court reasoned that the current version of 28 U.S.C. § 1391(c) did not contain any indication that Congress intended to overturn its ruling.[191] Further, although the current version of 28 U.S.C. § 1391(c) provides a default rule that applies "[f]or all venue purposes," the predecessor venue

182. *See* Rhoades, *supra* note 31, at 88.
183. 28 U.S.C. § 1400(b).
184. 353 U.S. 222, 226 (1957).
185. 917 F.2d 1574, 1574 (Fed. Cir. 1990).
186. *Id.* at 1579–80.
187. *Id.* at 1578.
188. *Id.* at 1583–84.
189. 581 U.S. 258, 261–70, 1517–21 (2017).
190. *Id.* at 1517, 1520–21.
191. *Id.* at 1520–21.

statute at issue in *Fourco Glass* was worded similarly.[192] As a result, for domestic corporations at least, the term "resides" in 28 U.S.C. § 1400(b) refers only to the state of incorporation.[193]

In addition, 28 U.S.C. § 1400(b) includes a second clause that was not at issue in *TC Heartland*. That provision calls for venue to exist where a defendant has a regular and established place of business and has committed acts of infringement.[194] Due to the liberal stance of *VE Holding*, this clause had grown moribund. Since the issuance of *TC Heartland*, the disconnect between artificial infringement and patent venue became more apparent. In particular, § 271(e)(2) of the Patent Act states that submitting an ANDA with "the purpose . . . to engage in the commercial manufacture, use, or sale of a drug . . . which is claimed in a patent before the expiration of such patent" constitutes an "act of infringement."[195] Artificial infringement is fabricated and forward-looking; but the second clause of 28 U.S.C. § 1400(b) is backward-looking, stating that venue is appropriate where the defendant maintains an established place of business and has actually committed infringing acts.[196]

Identifying the appropriate situs of infringement that occurs literally out of thin air presents enormous conceptual difficulties. In the wake of *TC Heartland*, Judge Leonard Stark of the District of Delaware made the initial effort to resolve this issue in *Bristol-Myers Squibb Co. v. Mylan Pharmaceuticals Inc.*[197] Judge Stark analyzed the "has committed acts of infringement" language of 28 U.S.C. § 1400(b) to mean:

> [A]n applicant's submission of an ANDA, in conjunction with other acts the ANDA applicant non-speculatively intends to take if its ANDA receives final FDA approval, plus steps already taken by the applicant indicating its intent to market the ANDA product in this District, must all be considered for venue purposes, and can be sufficient to demonstrate that the ANDA-filing Defendant "has committed" "acts of infringement" in this District.[198]

In that case, because Mylan had filed a paragraph IV ANDA and planned to sell its proposed generic product in Delaware, the "has committed acts of infringement" prong of the patent venue statute was deemed satisfied.[199] New Jersey subsequently aligned itself with Delaware by also adopting this lenient approach to venue in paragraph IV ANDA cases.[200]

192. *Id.*

193. *Id.* at 1520–21. This holding applies only to domestic corporations; foreign firms remain subject to venue in any judicial district where personal jurisdiction is found.

194. 28 U.S.C. § 1400(b).

195. 35 U.S.C. § 217(e)(2).

196. 28 U.S.C. § 1400(b).

197. No. 17-379-LPS, 2017 WL 3980155, at *1 (D. Del. Sept. 11, 2017).

198. *Id.* at *13.

199. *Id.* at *22.

200. *See* Celgene Corp. v. Hetero Labs Ltd., No. 17-3387 (ES) (MAH), 2018 WL 1135334, at *2–4 (D.N.J. Mar. 2, 2018).

The reasoning of *Bristol Myers v. Mylan* met with immediate disagreement in the Northern District of Texas. In *Galderma Laboratories v. Teva Pharmaceuticals USA*,[201] Judge Barbara Lynn found Judge Stark's analysis too loosely tethered to 28 U.S.C. § 1400(b), for after all, that statute speaks to the place where the defendant "has committed" acts of infringement, and not to the place where it might do so in the future.[202] Because Teva's ANDA preparation and submission had not occurred in the Northern District of Texas, Judge Lynn granted Teva's motion to dismiss for lack of venue.[203]

The Federal Circuit resolved the conflict in *Valeant Pharmaceuticals v. Mylan Pharmaceuticals*,[204] rejecting the conclusion of the mid-Atlantic courts that each and every paragraph IV ANDA lawsuit could be venued in their districts. As with many artificial infringement cases, the litigation here was complex, involving a total of nine patents and multiple paragraph IV ANDA applicants.[205] In this case, the brand-name firm filed suit against each ANDA applicant in New Jersey, as well as a protective suit in the Northern District of West Virginia against generic manufacturer Mylan.[206] Eighteen of the ANDA filers did not object to venue in New Jersey, which consolidated the case for trial.[207] Mylan was the outlier, asserting that New Jersey had insufficient hold over the matter for its case to be venued there.[208]

According to Judge O'Malley, the plain language of the Hatch-Waxman Act meant that the submission of the ANDA was the infringing act, rather than the planned future sales of a generic drug.[209] The Federal Circuit also refused to conclude that the filing of a paragraph IV ANDA constituted nationwide infringement that would occur in any judicial district, as virtually all of these cases result in an injunction against the FDA from approving the proposed generic products; or a holding that the generic manufacturers may market their products because the asserted patents are invalid, unenforceable, or not infringed.[210] The Federal Circuit instead required that a particular district possess sufficient connection to the acts that led to the filing paragraph IV ANDA in order to serve as a proper venue.[211]

Some criticisms may be directed towards the *Valeant v. Mylan* decision. First, the Federal Circuit might have considered the artificial infringement carveout for joinder under § 299 of the Patent Act. Here, Congress expressed a

201. 290 F. Supp. 3d 599, 599 (N.D. Tex. 2017).
202. *See id.* at 606–08.
203. *Id.* at 609.
204. 978 F.3d 1374, 1375 (Fed. Cir. 2020).
205. *Id.* at 1376.
206. *Id.* at 1376–77.
207. *Id.* at 1376 n.3.
208. *Id.* at 1377.
209. *Id.* at 1381.
210. *Id.* at 1382.
211. *Id.* at 1384.

preference for consolidated artificial infringement litigation, and cases are most readily joined when they are properly venued together.[212]

Second, the Federal Circuit explained that venue "is proper only in those districts that are sufficiently related to the ANDA submission—in those districts where acts occurred that would suffice to categorize those taking them as a "submitter" under § 271(e)."[213] Still, the fact that an ANDA is submitted does not qualify as artificial infringement.[214] Only an ANDA with a paragraph IV certification does so, rather than one incorporating one of the other three, less confrontational options.[215] Under this approach, the venue determination might more properly concern itself with the place where the paragraph IV certification was prepared, which would most likely occur in Washington, D.C., Northern Virginia, or Manhattan, in law firm offices where pharmaceutical patent lawyers tend to congregate.

The Federal Circuit additionally observed that the neighboring mid-Atlantic jurisdiction of Maryland, where the FDA received the paragraph IV ANDA, might also satisfy its test for Hatch-Waxman venue.[216] This observation seems at odds with an earlier Federal Circuit decision, *Zeneca Ltd. v. Mylan Pharmaceuticals*,[217] that went unmentioned. There, Judge Arthur Gajarsa held that the Maryland district court lacked personal jurisdiction over a paragraph IV ANDA applicant due to the government contacts exception, under which entry into a jurisdiction for the purpose of contacting federal government agencies cannot serve as the basis for federal jurisdiction.[218] To do otherwise, Judge Gajarsa reasoned, would violate the First Amendment right to petition, discourage nonresidents from filing paragraph IV ANDAs, and undermine the purposes of the Hatch-Waxman Act by converting Maryland into a "supercourt" serving as the "national judicial forum . . . for generic drug infringement cases."[219] Although *Zeneca v. Mylan* was a personal jurisdiction case, the same logic resonates for venue determinations as well.

But if Maryland is now the nerve center of paragraph IV ANDA cases, for good measure, the Federal Circuit might have mentioned the Eastern District of Virginia, where the USPTO headquarters sits; and perhaps Colorado, East Michigan, North California, and North Texas, where the USPTO has established satellite offices.[220] After all, without a patent covering the drug, the generic

212. *See supra* notes 151–52 and accompanying text.

213. *Valeant Pharms. N. Am. LLC*, 978 F.3d at 1384.

214. *Id.* at 1381.

215. The matter may be more subtle than this in certain cases because not all courts require a paragraph IV ANDA for artificial infringement to occur. *See supra* note 51. Suppose, for example, that the brand-name firm held a pertinent patent that could not be listed in the Orange Book—for example, a patented method of manufacturing the active ingredient. *See* 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53(c)(2) (2022). In such an event, the ANDA may be deemed to infringe even absent a paragraph IV certification.

216. *Valeant Pharms. N. Am. LLC*, 978 F.3d at 1384 n.8.

217. 173 F.3d 829, 829 (Fed. Cir. 1999).

218. *Id.* at 831–34.

219. *Id.* at 832–34.

220. *See* 35 U.S.C. § 1(b); *USPTO Locations*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/about-us/uspto-office-locations (last visited Jan. 21, 2023) [https://perma.cc/A2NL-5N7R].

manufacturer would have no need to make a paragraph IV certification. And due to that certification, the generic manufacturer has set into motion a series of events that, due to the workings of the Patent Act, results in a notice to the USPTO that an action for infringement has been brought—in essence the same notice that the FDA receives directly from the generic manufacturer.[221] Because neither the FDA nor USPTO actually participates in paragraph IV ANDA cases, that the arbitrary location of any federal government office should determine venue seems ill-considered.

Not only are these sorts of venue determinations facile and strained, they suggest disturbing implications for the very notion of artificial infringement. The right to petition the government has long held a cherished status,[222] but may nonetheless lead to ruinous consequences for the petitioner under the patent laws. *Valeant v. Mylan* nonetheless stands for the proposition that, in paragraph IV ANDA cases, brand-name drug companies must file suit in one of two places.[223] The first is where the generic manufacturer resides, which is to say, the state where it is incorporated.[224] The second is where it prepared the ANDA. Often these locations will be identical, but at times an ANDA may be submitted from a venue different than the submitter's place of incorporation.[225]

The Federal Circuit was not oblivious to the policy concerns raised by brand-name drug companies.[226] Its ruling substantially decreases the likelihood that brand-name firms may gather multiple paragraph IV ANDA applicants in a single litigation.[227] This result arguably promotes fairness for generic manufacturers, who now have an improved opportunity to control their individual cases and not be forced into unseemly cooperation with their competitors. *Valeant v. Mylan* may also promote generic availability. Patents may never be proven to be conclusively valid; but even a single invalidity ruling upends the patent for all the world.[228] All else being equal, the more opportunities afforded to challenge a patent, the more opportunities to terminate it.

Yet the holding also holds numerous deleterious consequences for orderly pharmaceutical patent litigation. Ironically, multiple parallel paragraph IV ANDA lawsuits might increase the time needed fully to resolve issues of patent validity and enforcement.[229] Brand-name firms may be expected to file motions to stay cases pending resolution of issues in parallel litigation, as they currently do when the same patent is involved in an International Trade Commission

221. 35 U.S.C. § 290.

222. *See* United Mine Workers of Am. v. Pennington, 381 U.S. 657, 669–71 (1965); E. R.R. Presidents Conf. v. Noerr Motor Freight, Inc., 365 U.S. 127, 138 (1961).

223. Valeant Pharms. N. Am. LLC v. Mylan Pharms. Inc., 978 F.3d 1374, 1375 (Fed. Cir. 2020).

224. *Id.*

225. *Id.* at 1383–84.

226. *Id.* at 1383.

227. *Id.*

228. *See* Joseph Scott Miller, *Building a Better Bounty: Litigation-Stage Rewards for Defeating Patents*, 19 BERKELEY TECH. L.J. 667, 668 (2004).

229. *Valeant Pharms. N. Am. LLC*, 978 F.3d at 1383–85.

proceeding[230] or administrative opposition proceeding at the USPTO.[231] They might also file suit in jurisdictions where venue is questionable, leading to potentially lengthy venue-related discovery.[232] If the court grants the generic manufacturer's motion to dismiss for improper venue, then the brand-name firm may simply file another infringement lawsuit elsewhere following months of delay.

In *Valeant v. Mylan*, the Federal Circuit also recognized the "cumbersome" alternative of procedures under the Multidistrict Litigation Act.[233] Under this legislation, a litigant may file a motion with the Judicial Panel on Multidistrict Litigation ("MDL"), requesting transfer to a single district for consolidated pretrial proceedings, in order to promote "the convenience of parties and witnesses and . . . just and efficient litigation."[234] Understandably, litigants encounter delays in connection with MDL consolidation that would make thirty months an unattainable deadline for completing trial. And, of course, MDL consolidates litigation for pretrial purposes only.[235]

The new order of paragraph IV ANDA litigation also suggests judicial inefficiencies and potential disorder in pharmaceutical markets. For example, in *Biogen International GmbH v. Amneal Pharmaceuticals LLC*, the brand-name firm filed twenty-four lawsuits against various paragraph IV ANDA applicants for Tecfidera, a multiple sclerosis drug.[236] Judge Noreika then conducted a five-day bench trial in Delaware involving six generics.[237] Contemporaneously, the brand-name firm sued Mylan Pharmaceuticals, Inc. in the Northern District of West Virginia.[238] Following the Delaware trial, but before Judge Noreika issued her decision, the West Virginia court held the asserted patent invalid.[239] Due to the Mylan judgment, the Delaware court issued a lengthy opinion holding that it was compelled to enter judgment against the patent owner due to collateral estoppel.[240] At that point, numerous generic firms obtained final FDA approval and entered the market, even as a Federal Circuit appeal was ongoing.[241]

230. 28 U.S.C. § 1659; *see* SanDisk Corp. v. Phison Elecs. Corp., 538 F. Supp. 2d 1060, 1063 (W.D. Wis. 2008).

231. 35 U.S.C. § 315(a)(2); 35 U.S.C. § 325(a)(2); *see* Murata Mach. USA v. Daifuku Co., Ltd., 830 F.3d 1357, 1361 (Fed. Cir. 2016).

232. *See, e.g.*, Celgene Corp. v. Hetero Labs Ltd., No. 17-3387 (ES) (MAH), 2018 WL 1135334, at *5 (D.N.J. Mar. 2, 2018).

233. *Valeant Pharms. N. Am. LLC*, 978 F.3d at 1385 n.10 (citing 28 U.S.C. § 1407); *see* Colman B. Ragan, *Saving the Lives of Drugs: Why Procedural Amendments in Hatch-Waxman Litigation and Certification of* Markman *Hearings for Interlocutory Appeal Will Help Lower Drug Prices*, 13 FED. CIR. BAR J. 411, 433–37 (2004).

234. William J. Martin, *Reducing Delays in Hatch-Waxman Multidistrict Litigation*, 71 U. CHI. L. REV. 1173, 1175–76 (2004).

235. *See id.*

236. 487 F. Supp. 3d 254, 257 n.1 (D. Del. 2020).

237. Some of the six generic firms had multiple corporate forms; lawsuits against the other generics were dismissed or stayed. *Id.* at 257.

238. *Id.* at 257–58.

239. Biogen Int'l GmbH v. Mylan Pharms. Inc., No. 1:17CV116, 2020 WL 3317105, at *1 (N.D.W. Va. June 18, 2020).

240. *Biogen Int'l GmbH*, 487 F. Supp. 3d at 269.

241. *See* Roger Morris & Lisa Davis, *Generic Drugs and Biosimilars Lower Costs and Raise Legal Questions*, ASPATORE (2013 WL 5760773), Sept. 2013, at *2.

The Tecfidera episode suggests the inefficiencies of parallel pharmaceutical patent litigation and the reality that judges vary in the length of time they take to issue a ruling following a bench trial. It also reveals the impact of state laws demanding or encouraging generic substitution for brand-name drugs.[242] Once a drug goes generic, state governments in effect aggressively market it; the result is rapid generic penetration with irrevocable consequences for the pharmaceutical marketplace.[243] Allowing the first district court invalidity ruling to forestall the rest, at least until the Federal Circuit issues a ruling on appeal, seems an odd way to run the railroad.

We might also see greater strategic behavior on behalf of generic manufacturers. As described by Professors Ofer Eldar and Neel Sukhatme, patent proprietors and technology implementers engage in a two-step process for venue selection following *TC Heartland*.[244] Within the Hatch-Waxman context, generic manufacturers undertake the first step by selecting their state of incorporation and where they will prepare a particular paragraph IV ANDA.[245] Brand-name firms then choose to bring patent enforcement suits from among these fora, and possibly Maryland as well, where they anticipate receiving the most favorable result.[246]

Eldar and Sukhatme assert that this two-step process, which grants both plaintiffs and defendants some control over venue in patent cases, should mitigate concerns over forum selling to either party.[247] Generic manufacturers seem to have far more control over venue with respect to artificial infringement, however, as venue is a paperwork-based determination in this context, rather than one concerned with the physical location of offices and factories.[248] Further, Maryland, should it develop into the "national forum" for resolving pharmaceutical patent infringement suits as some Federal Circuit jurists have feared, remains a wild card at this juncture. Although the Maryland Local Rules include a modest number of provisions relating to Hatch-Waxman,[249] only a trickle of paragraph IV ANDA cases have been filed there over the years.[250]

An irony of *TC Heartland* is that although the Supreme Court appeared eager to suppress renegade jurisdictions for patent cases, it may have done just the opposite in the context of Hatch-Waxman. We will most likely know forum selling for artificial infringement when we see it. Courts may develop local

242. *See id.*
243. *See id.*
244. Eldar & Sukhatme, *supra* note 177, at 160.
245. *See id.*
246. *See id.*
247. *See id.* at 161.
248. *See* Valeant Pharms. N. Am. LLC v. Mylan Pharms. Inc., 978 F.3d 1374, 1381–84 (Fed. Cir. 2020).
249. See Local Rule 804(3) at UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MARYLAND LOCAL RULES 89 (2021), https://www.mdd.uscourts.gov/sites/mdd/files/LocalRules.pdf, [https://perma.cc/GGN4-CZNK].
250. *See* Elizabeth Teter, *The Federal Circuit Limits Venue for Hatch-Waxman Litigation*, LEXOLOGY (Jan. 28, 2021), https://www.lexology.com/library/detail.aspx?g=3036d1c8-36f9-4086-a854-565e3d3d1b66 [https://perma.cc/827N-XHY6] (reporting that "the District of Maryland has limited experience with Hatch-Waxman litigation and, of the nine cases filed within the last five years, no plaintiffs have won on the merits").

paragraph IV ANDA rules that call for the parties to exchange contentions and proposed claim constructions promptly, timing that favors the generic manufacturer. They would promise speedy trials, and in particular, be more receptive to disposition of artificial infringement cases by summary judgment than is the usual practice. And they would quickly lift the thirty-month stay when a patent is held invalid, unenforceable, or not infringed. Although Delaware and New Jersey are currently Hatch-Waxman's renegades, other courts may join their ranks in the future.

At a minimum, the FDA should respond to *Valeant v. Mylan* by requiring each paragraph IV ANDA to identify the state of incorporation of the applicant, along with the location where the ANDA was prepared. This requirement would improve certainty about where brand-name firms may bring artificial infringement suits. The FDA, however, has chosen to severely restrict its role with respect to pharmaceutical patents,[251] and when the agency does react to developments in the patent system it does so at a glacial pace.[252] We are unlikely to see much reaction from the FDA at all to *Valeant v. Mylan*, at least within a seasonable timeframe.

Other observers have called for reforms to the patent venue statute. For example, the trade association Intellectual Property Owners suggested a legislative amendment that would establish venue in artificial infringement cases in any judicial district where personal jurisdiction exists.[253] Such a reform would merely replace an implausible inquiry with one equally as preposterous. As this Article discusses immediately below, Congress put no more thought towards personal jurisdiction than it did to venue with respect to artificial infringement when it enacted the Hatch-Waxman Act.

The current muddle over venue in Hatch-Waxman cases results from a more fundamental cause. Artificial infringement has no meaningful grounding in any discrete physical location, for the USPTO issues patents and the FDA grants marketing approvals that are effective in every judicial district of the United States.[254] As we will see, this incongruity is just one the issues raised by artificial infringement, a particularly problematic legal artifact that ought to be reconsidered.

251. Rebecca S. Eisenberg & Daniel A. Crane, *Patent Punting: How FDA and Antirust Courts Undermine the Hatch-Waxman Act to Avoid Dealing with Patents*, 21 MICH. TELECOMM. & TECH. L. REV. 197, 200 (2015).

252. The FDA issued final regulations implementing the MMA—which was signed into law on December 8, 2003—in 2016. Abbreviated New Drug Applications and 505(b)(2) Applications, 81 Fed. Reg. 69,580 (Oct. 6, 2016) (to be codified at 21 C.F.R. pts. 314, 320). They came into effect on December 5, 2016, almost thirteen years later. *Id.* at 69632.

253. *See, e.g.*, Letter from Intellectual Property Owners Association, *supra* note 24, at 4.

254. Alexander Poonai, *Hatch-Waxman in the Heartland: Achieving Fair Venue Reform in Pharmaceutical Litigation*, 27 FED. CIR. BAR J. 103, 114 (2017) ("The ANDA applicant seeks permission to market its product in every state, all at once.").

IV. REASSESSING ARTIFICIAL INFRINGEMENT

To be sure, artificial infringement is a well-worn construct that has, as a general matter, worked in a satisfactory fashion over the past four decades.[255] But cracks are starting to show, and not just with respect to venue. Artificial infringement also presents incongruities with personal jurisdiction analysis, modern remedies standards, and the international obligations of the United States. Further, developments in declaratory judgment jurisdiction have rendered artificial infringement an unnecessary legal fiction. Artificial infringement is not only problematic in multiple dimensions but also unnecessary and ought to be the subject of serious reevaluation.

A. Personal Jurisdiction

Not only does the Hatch-Waxman Act pay no heed to the specialized patent venue statute, it also lacks an explanation about how personal jurisdiction should be assessed with respect to artificial infringement. Because artificial infringement amounts to a legal fiction, identifying which courts possess personal jurisdiction in these cases amounts to a perplexing exercise.[256] Informed by *Valeant v. Mylan*, which related to the distinct but associated doctrine of venue, some apparent possibilities for personal jurisdiction include the place where the paragraph IV ANDA notification was prepared or sent, the location of the owner of the patent, the defendant's principal place of business or state of incorporation, or the District of Maryland, where the FDA campus sits.[257]

Any of these answers, surprisingly enough, is correct, for the Federal Circuit has in essence concluded that every judicial district in the country possesses specific personal jurisdiction over any generic drug company accused of artificial infringement.[258] That personal jurisdiction may be "specific" everywhere is quite puzzling, given that submitting government paperwork is all that has been done. Readers will recall that under Supreme Court precedent, a corporate party is subject to general jurisdiction in its state of incorporation or where it maintains its headquarters.[259] Alternatively, specific jurisdiction confers a narrower authority under state long-arm statutes, existing where the corporation has "minimum

255. *See* Aaron S. Kesselheim & Jonathan J. Darrow, *Hatch-Waxman Turns 30: Do We Need a Re-Designed Approach for the Modern Era?*, 15 YALE J. HEALTH POL'Y. L. & ETHICS 293, 295–96 (2015) (noting that the Hatch-Waxman Act, although worthy of reconsideration, has been a successful legislative effort).

256. *See* Michael Marusak, *Personal Jurisdiction in Hatch-Waxman Cases*, 66 CATH. U. L. REV. 189, 189–91 (2016); Eric H. Weisblatt & Claire Frezza, *Who to Sue and Where in ANDA Litigation: Personal Jurisdiction Post-*Daimler, 69 FOOD & DRUG L.J. 351, 354 (2014).

257. *See* Valeant Pharms. N. Am. LLC v. Mylan Pharms. Inc., 978 F.3d 1374, 1379–84 (Fed. Cir. 2020).

258. *See* Acorda Therapeutics Inc. v. Mylan Pharms. Inc., 817 F.3d 755, 773 (Fed. Cir. 2016).

259. Goodyear Dunlop Tires Operations, S.A. v. Brown, 564 U.S. 915, 924 (2011). Federal Rule of Civil Procedure 4(k)(2) also allows personal jurisdiction to be established on the basis of serving a summons or filing a waiver of service, if the defendant is not subject to general jurisdiction anywhere and exercising jurisdiction would comport constitutional requirements. FED. R. CIV. P. 4(k)(2).

contacts" with the forum state so that forcing it to respond to suit does not offend "traditional notions of fair play and substantial justice."[260]

The leading case of *Acorda Theapeutics Inc. v. Mylan Pharmaceuticals Inc.*[261] details the Federal Circuit's approach to personal jurisdiction in artificial infringement cases. That consolidated appeal involved several paragraph IV ANDAs that Mylan had filed with respect to drugs sold by two brand-name firms, Acorda and AstraZeneca.[262] Acorda and AstraZeneca responded by bringing claims of artificial infringement in Delaware.[263] Mylan filed a motion to dismiss for lack of personal jurisdiction in each matter.[264] The Delaware court denied each motion, but for different reasons.[265] In *Acorda*, Chief Judge Stark held that Mylan was subject to both general and specific personal jurisdiction.[266] With respect to the AstraZeneca litigation, Judge Gregory Sleet held that Mylan was subject to specific personal jurisdiction but not general personal jurisdiction.[267]

On appeal, the Federal Circuit panel concluded that Delaware possessed specific jurisdiction in each case.[268] Writing for the panel, Judge Taranto explained that Mylan's ANDA filings were matters of sufficient magnitude and cost that revealed concrete plans to market generic drugs in the near future. He further observed that Mylan's distribution channels in Delaware indicated that these marketing activities would "unquestionably take place in Delaware (at least)."[269] The Federal Circuit then concluded that the planned sales sufficed to satisfy the minimum contacts requirement and justified specific jurisdiction in Delaware.[270]

The *Acorda v. Mylan* decision does go on to say that with minimum contacts requirement satisfied, courts should weigh other considerations, including the burden on the defendant, the forum state's interest in resolving the dispute, the plaintiff's interest in obtaining convenient and effective relief, and the interstate judicial system's interest in obtaining the most efficient resolution of controversies.[271] With respect to paragraph IV ANDA cases, however, the generic manufacturer's burden will virtually always be outweighed by convenience to the courts and brand-name drug company in resolving the litigation in a single forum. As a practical matter, following *Acorda v. Mylan*, a generic drug company is subject to specific personal jurisdiction anywhere it intends to market the drug—which normally is every judicial district in the nation.[272]

260. Int'l Shoe Co. v. Washington, 326 U.S. 310, 316 (1945).
261. *Acorda Therapeutics Inc.*, 817 F.3d at 755.
262. *Id.* at 757.
263. *Id.* at 757–58.
264. *Id.*
265. *Id.*
266. Acorda Therapeutics, Inc. v. Mylan Pharms. Inc., 78 F. Supp. 3d 572, 598 (D. Del. 2015).
267. AstraZeneca AB v. Mylan Pharms., Inc., 72 F. Supp. 3d 549, 556–60 (D. Del. 2014).
268. Finding that specific personal jurisdiction existed, the Court of Appeals chose not to address the issue of general jurisdiction. *Acorda Therapeutics Inc.*, 817 F.3d at 757.
269. *Id.* at 762.
270. *Id.*
271. *Id.* at 763–64.
272. *See id.* at 762–63.

Acorda v. Mylan made the same mistake that Judge O'Malley derided in the subsequent venue decision in *Valeant v. Mylan*—namely, equating government petitioning with future infringing sales.[273] Under Hatch-Waxman, the submission of the paragraph IV ANDA constitutes the infringing act, rather than the planned future sales of a generic drug. Further, essentially every Hatch-Waxman case leads either to an injunction against the FDA from approving the proposed generic products; or a holding that the asserted patents are invalid, unenforceable, or not infringed. Infringing sales are not very likely to occur at all.[274]

The Delaware decision in *Millennium Pharmaceuticals, Inc., v. Pharmascience Inc.* nonetheless demonstrates the capacious reach of specific personal jurisdiction in artificial infringement cases.[275] In that case, the generic manufacturer accused of artificial infringement was a Canadian company with its principal place of business in Montreal.[276] It was not incorporated in Delaware, had not registered to do business in Delaware, had no employees or place of business in Delaware, had not appointed an agent for service of process in Delaware, had not prepared its ANDA in Delaware, had not sent its paragraph IV ANDA notification to Delaware, and had never sold drugs in Delaware.[277] Judge Stark nonetheless found that Delaware possessed specific jurisdiction over the suit because the generic manufacturer would engage in marketing in Delaware if the FDA approved its ANDA, because related ANDA litigation was taking place in Delaware, and because the brand-name firm "would be substantially burdened if forced to bring a lawsuit against any ANDA filer challenging its patent in the location selected by the defendant."[278]

The Supreme Court has stressed, in its most recent discussion of specific personal jurisdiction, that specific personal jurisdiction principles exist to treat defendants fairly, in particular by providing "fair warning" that an activity may subject an enterprise to jurisdiction in a particular federal court.[279] The Court expressed concerns over forum shopping by plaintiffs[280] and observed that enterprises should be fully capable of structuring their "primary conduct" to lessen or avoid exposure to the courts of a given state.[281] How *Acorda v. Mylan* upholds any of these lofty principles is hard to imagine.

The disconnect between personal jurisdiction policies and doctrine is, of course, not due to the lack of skillful advocacy or well-meaning jurists. The problem is that artificial infringement is hard to pin down, as it simply lacks a physical nexus with any particular place in the country. As with venue determinations, specific personal jurisdiction rulings become perplexing exercises in paragraph

273. *See* Valeant Pharms. N. Am. LLC v. Mylan Pharms. Inc., 978 F.3d 1374, 1381 (Fed. Cir. 2020).

274. *Id.* at 1382.

275. Millennium Pharms., Inc. v. Pharmascience Inc., No. 15-702-GMS, 2016 WL 3382131, at *1–2 (D. Del. June 10, 2016).

276. *Id.* at *8.

277. *Id.* at *8–9.

278. *Id.* at *9.

279. *See* Ford Motor Co. v. Mont. Eighth Jud. Dist. Ct., 141 S. Ct. 1017, 1025 (2021) (citation omitted).

280. *Id.* at 1031.

281. *Id.* at 1025 (citation omitted).

IV ANDA cases. This disconnect is not the only problem, however, for as this Article will assert next, artificial infringement also violates the international commitments of the United States.

B. The TRIPS Agreement

As a member of the World Trade Organization ("WTO"), the United States has committed to comply with the Agreement on Trade-Related Aspects of Intellectual Property Rights, better known as the TRIPS Agreement.[282] Among the requirements of the TRIPS Agreement is that of Article 27.1, which obliges each WTO member state to make "patent rights enjoyable without discrimination as to . . . the field of technology."[283] Because artificial infringement is limited to drugs and two other sorts of products regulated by the FDA,[284] the Hatch-Waxman Act has violated this obligation for more than a quarter-century.[285]

Although worded neutrally, the TRIPS Agreement was drafted at a time when many jurisdictions denied or limited patents on pharmaceuticals.[286] The U.S. Trade Representative, joined by envoys of like-minded nations, intended Article 27.1 to bring pharmaceuticals into the mainstream of the patent systems of WTO member states, rather than being subject to subject matter restrictions, decreased terms of protection, or special compulsory license provisions.[287] But as Professor Rebecca Eisenberg has observed, Article 27.1 does not merely prevent WTO member states from discriminating against pharmaceutical patents; it also prevents WTO member states from discriminating in favor of them.[288]

But pharmaceutical patents stand apart with respect to artificial infringement. The federal government requires an enormous array of potentially patented products to undertake pre-marketing review. Among many others, the Environmental Protection Agency so regulates certain toxic substances;[289] as does the Federal Aviation Administration with respect to aircraft;[290] the Coast Guard with respect to life preservers;[291] the Federal Communications Commission with

282. Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Apr. 15, 1994, 33 I.L.M. 1197 [hereinafter TRIPS Agreement].

283. *Id.* at Art. 27.

284. The three sorts of products are drugs, certain veterinary products, and biological products. 35 U.S.C. § 271(e)(2).

285. *See generally* Ned Milenkovich, *Deleting the Bolar Amendment to the Hatch-Waxman Act: Harmonizing Pharmaceutical Patent Protection in a Global Village*, 32 J. MARSHALL L. REV. 751 (1999).

286. Indeed, some jurisdictions continue to do so, although least-developed countries are not required to protect pharmaceuticals via patents until 2033. Council for Trade-Related Aspects of Intellectual Property Rights, *Extension of the Transition Period Under Article 66.1 of the TRIPS Agreement for Least Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products*, WTO Doc. IP/C/73 (June 11, 2015) (Decision of the Council for TRIPS of 6 November 2015-IP/C/73).

287. *See* Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 365 (2007).

288. *See id.*

289. *E.g.*, 40 C.F.R. § 799.1053 (2022) (requiring pre-marketing testing of trichlorobenzenes).

290. 14 C.F.R. § 21.127 (2022) (requiring a flight test of each aircraft produced).

291. 46 C.F.R. § 160.001–5 (2022) (requiring pre-marketing testing of life preservers).

respect to radio frequency devices;[292] the Nuclear Regulatory Commission with respect to reactors;[293] and the National Highway Traffic Safety Administration with respect to tires.[294] A single agency, the Consumer Product Safety Commission, requires pre-marketing approval of hundreds of sorts of products, ranging from bicycle helmets to lawn mowers to toys.[295]

Of all these products, artificial infringement applies to only certain FDA-regulated products, with the great bulk of the pre-marketing litigation pertaining to pharmaceuticals.[296] Artificial infringement affords pharmaceutical patent proprietors many advantages, most notably a viable cause of action prior to marketing of the accused infringement and a thirty-month stay of marketing approval.[297] Denying these benefits to other regulated products plainly violates the TRIPS Agreement obligation to make intellectual property rights enjoyable no matter what the nature of the patented invention.[298]

Professors Neel Sukhatme and Gregg Bloche put a brave face on the Hatch-Waxman Act by observing that the TRIPS Agreement is not self-enforcing.[299] In truth, WTO member states have not yet taken exception to the statute's technology-specific provisions, and no such challenge appears to be looming. But rumblings have taken place before at the WTO regarding national laws that create distinctive rules for pharmaceutical patents. The most notable example is *Canada—Patent Protection of Pharmaceutical Products*,[300] a WTO Dispute Settlement Panel Report. There, the European Communities charged Canada with violating the TRIPS Agreement by enacting a "safe harbor" exemption from patent infringement.[301] The Canadian statute read:

> It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of

292. 47 C.F.R. § 2.911 (2022) (requiring equipment authorization from the FCC).

293. 10 C.F.R. § 50.10 (2022) (requiring licensing to build a nuclear production or utilization facility).

294. 49 C.F.R. § 571.139 (2022) (requiring testing of tires).

295. *See, e.g.*, 16 C.F.R. § 1203.7 (2022) (bike helmets); 16 C.F.R. § 1205.33 (2022) (lawn mowers); 16 C.F.R. § 1251.1 (2022) (toys).

296. *See* Terry G. Mahn, *Hatch-Waxman Developments: Artificial Infringement by Artificial Drugs*, FISH & RICHARDSON (Nov. 22, 2013), https://www.fr.com/hatch-waxman-developments-artificial-infringement-by-artificial-drugs/ [https://perma.cc/R7DT-AV8R].

297. *See id.*

298. *See* Milenkovich, *supra* note 285, at 776.

299. Neel U. Sukhatme & Maxwell Gregg Bloche, *Health Care Costs and the Arc of Innovation*, 104 MINN. L. REV. 955, 1037–38 (2019). The authors also cite 35 U.S.C. § 103(b) and the Semiconductor Chip Protection Act as additional examples of industry-specific intellectual property statutes. Congress eliminated § 103(b) in 2011. *See* Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part I of II*, 21 FED. CIR. BAR J. 435, 490–91 (2011–12). In addition, Articles 35–38 of the TRIPS Agreement require WTO member states to protect topographies of integrated circuits. *See* Adrian Otten & Hannu Wager, *Compliance with TRIPS: The Emerging World View*, 29 VAND. J. TRANSNAT'L L. 391, 401–02 (1996).

300. Report of the Panel, *Canada—Patent Protection of Pharmaceutical Products*, WTO Doc. WT/DS114/R (Mar. 17, 2000) [hereinafter Report of the Panel].

301. Many readers will recognize that the Canadian "safe harbor" provision was modelled after the *Bolar* exemption originally enacted in the United States as 35 U.S.C. § 271(e)(1). *See, e.g.*, Mary Atkinson, *Patent Protection for Pharmaceuticals: A Comparative Study of the Law in the United States and Canada*, 11 PAC. RIM L. & POL'Y J. 181, 193–95 (2002).

> Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product.[302]

The WTO dispute resolution panel concluded that the Canadian regulatory review exception was not technology-specific because any patent in an industry subject to marketing approval would be subject to the challenged exemption.[303] In contrast to the Canadian legislation, however, the artificial infringement provision of the United States is explicitly limited to drugs and related products.[304]

Similarly, Canada lodged a Request for Consultations with respect to *Patent Protection for Pharmaceutical and Agricultural Chemical Products by the European Communities*.[305] In its Request of December 17, 1998, the government of Canada expressed its concern that the European Communities had violated Article 27.1 of the TRIPS Agreement by providing for supplementary protection certificates—a type of patent term extension—limited to pharmaceutical and agricultural chemical products.[306] Canada ultimately dropped the matter, however, as it began negotiations with the European Communities that resulted in the Comprehensive Economic and Trade Agreement between these jurisdictions.[307]

With the coronavirus pandemic aggravating longstanding international sensitivities over pharmaceutical patents,[308] our trading partners have a renewed interest in pondering their options with respect to patents impacting public health. They might well cite artificial infringement in support of their own derogations from the requirement of technological neutrality with respect to pharmaceuticals. For example, the United States might have little to say about the recent decision of the Brazilian Supreme Court that negatively impacted patents on pharmaceuticals and medical devices.[309] In that case, the Brazilian Supreme Court considered a provision of its domestic law establishing a patent term of the longer of either twenty years from the filing date, the minimum required by the TRIPS Agreement, or ten years from the date of grant.[310] Because the National Institute of Industrial Property of Brazil often takes more than a decade to issue a patent, and generally takes longer to issue patents on pharmaceuticals than other sorts of inventions, the ten-year term acted as a patent term guarantee.[311]

302. Report of the Panel, *supra* note 300, at 2 (quoting § 55.2(2) of the Canadian Patent Act).

303. *Id.* at 171–74.

304. 35 U.S.C. § 271(e)(2).

305. *See* Request for Consultations by Canada, *European Communities—Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WTO Doc. WT/DS153/1 (Dec. 7, 1998).

306. *Id.*

307. *See EU-Canada Comprehensive Economic and Trade Agreement (CETA)*, EUR. COMM'N, https://policy.trade.ec.europa.eu/eu-trade-relationships-country-and-region/countries-and-regions/canada/eu-canada-agreement_en (last visited Jan. 21, 2023) [https://perma.cc/47HE-YZWC].

308. *See, e.g.*, Alexandra H. Farquhar, *Redefining the TRIPS Agreement to Accommodate En Masse Compulsory Licensing of Vaccines & Other Pharmaceuticals for the Treatment of Covid-19*, 22 N.C. J.L. & TECH. 259, 259 (2020).

309. *See* Anjali Jenna Teigen, *Brazilian Supreme Court Ends Patent Term Extension and Retroactively Cuts Pharmaceutical and Medical Device Patent Terms*, JD SUPRA (May 18, 2021), https://www.jdsupra.com/legalnews/brazilian-supreme-court-ends-patent-1684162/ [https://perma.cc/YE9G-WSSR].

310. *Id.*

311. *Id.*

Following a challenge filed by the Federal Prosecutor's Office, the Brazilian Supreme Court struck down the ten-year term provision as violative of the Brazilian Constitution.[312] The Court further held that, its ruling was, for most sorts of patented inventions, prospective only.[313] But, the Court ruled that its ruling applied retroactively with respect to patents for use in healthcare.[314] The result was that many extant Brazilian pharmaceutical patents will be deemed to have expired or have their term severely truncated.[315] Should this ruling, or ones like it, be challenged as a violation of TRIPS Article 27.1, presumably the respondent would be quick to point out the technology-specific nature of artificial infringement under U.S. law. An irony of this situation is that artificial infringement, which acts to the benefit of pharmaceutical patent holders domestically, could be cited in favor of diminished protection for pharmaceutical patents abroad.

The TRIPS Agreement is arguably a conflicted instrument, for it includes both a number of provisions specific to pharmaceuticals and public health,[316] while simultaneously imposing a requirement of technological neutrality with patents. But the plain wording of Article 27.1 simply does not allow WTO member states to treat one field of technology better than the others.[317] Of course, the 98th Congress had good reason for failing to account for the TRIPS Agreement, which was finalized more than a decade after Hatch-Waxman was enacted.[318] But the patent law has advanced in other respects since 1984. As will be seen, although our understanding of the appropriate remedies for patent infringement has become more sophisticated over the years, artificial infringement has failed to progress along with it.

C. Injunctive Relief

The Patent Act includes two enabling provisions addressing injunctions. One of them, § 283, concerns garden-variety patent cases, and allows courts to "grant injunctions in accordance with the principles of equity."[319] The other, § 271(e)(4)(A), is specific to Hatch-Waxman, and states that in the event of patent infringement, the court "shall order" the effective date of FDA approval of the generic drug to be not earlier than the date of patent expiration.[320] Although the Hatch-Waxman Act reflected injunction practice in 1984, in the intervening years patent law's remedial landscape has been fundamentally altered.

312. *Id.*
313. *Id.*
314. *Id.*
315. *Id.*
316. *See* TRIPS Agreement, *supra* note 282, at Art. 8 (allowing WTO member states to adopt measures necessary to protect public health consistent with the TRIPS Agreement); TRIPS Agreement Art. 3 (compulsory license for exportation limited to pharmaceuticals); TRIPS Agreement Art. 70.8 (delayed TRIPS Agreement effective date for pharmaceutical patents).
317. TRIPS Agreement, *supra* note 282, at Art. 27.1.
318. Milenkovich, *supra* note 285, at 757–58.
319. 35 U.S.C. § 283.
320. 35 U.S.C. § 271(e)(4)(A).

At the time Congress enacted the Hatch-Waxman Act, the intellectual property community shared the understanding that, absent exceptional circumstances, courts should award a prevailing patent proprietor a permanent injunction against an adjudicated infringer.[321] Judicial opinions like *Roche v. Bolar* had certainly explained that the decision to grant an injunction was equitable in nature.[322] But at the same time, the Federal Circuit also stressed the centrality of "the right to obtain an injunction" within the patent bargain, and further concluded that the courts should presume irreparable harm when a patent is found not invalid and held to be infringed.[323]

In practice, despite the use of the word "may" and reference to equitable principles in § 283, courts for many years held that permanent injunctions should be routinely awarded to patentees that prevailed in infringement litigation.[324] Exceptions were few. In the delightfully captioned *City of Milwaukee v. Activated Sludge, Inc.*,[325] for example, the Seventh Circuit refused to grant an injunction against infringement of a patented sewage treatment method.[326] In a poignantly worded opinion that suggests its author lived or worked on the Lake Michigan shore, the Court of Appeals expressed concern over the polluted waters and deleterious health consequences that would result should it award an injunction.[327] But absent such public health or safety issues, the Federal Circuit awarded injunctions under § 283 on a customary basis.[328] As a result, courts ineffectively employed the same injunction rules for mainstream and paragraph IV ANDA patent litigation alike.

The 2006 Supreme Court decision in *eBay, Inc. v. MercExchange, LLC*[329] significantly altered the remedial landscape in patent cases. There, Justice Thomas characterized the Federal Circuit's "categorical grant" of permanent injunctions as "unique to patent disputes,"[330] unauthorized by the express wording of the Patent Act, and a departure from longstanding principles of equity practice.[331] Henceforth, the Supreme Court announced, the successful patent plaintiff must satisfy a four-factor test in order to be awarded a permanent injunction,[332]

321. Joseph R. Sozzani, *Patent Law: Redefining Equitable Injunctions*, 11 J. TECH. L. & POL'Y 341, 344 (2006).

322. 733 F.2d 858, 867 (Fed. Cir. 1984).

323. Smith Int'l, Inc. v. Hughes Tool Co., 718 F.2d 1573, 1577–79 (Fed. Cir. 1983).

324. *See* Sozzani, *supra* note 321, at 344.

325. 69 F.2d 577, 577 (7th Cir. 1934).

326. *Id.* at 593.

327. *Id.*

328. *See, e.g.*, Richardson v. Suzuki Motor Co., Ltd., 868 F.2d 1226, 1247 (Fed. Cir. 1989) (observing "the general rule that an injunction will issue when infringement has been adjudged, absent a sound reason for denying it").

329. 547 U.S. 388, 388 (2006).

330. *Id.* at 393–94.

331. *See id.* at 394.

332. More particularly, in order to obtain a permanent injunction, the prevailing patentee must demonstrate that "(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.

although in reality the lower courts effectively employ a number of proxy factors.[333] Many prevailing patentees do not obtain injunctions, particularly if they are patent trolls, do not compete directly with the adjudicated infringer, and the patented invention is just a small part of the adjudicated infringement.[334]

eBay also held significant impacts outside the patent system. That *eBay* would apply to copyright and trademark infringement cases was unsurprising.[335] But courts in virtually all classes of cases—including causes of action under the Americans with Disability Act, the Clean Water Act, constitutional challenges under 42 U.S.C. § 1983, and many others—have turned to the *eBay* factors when assessing whether to issue a permanent injunction or not.[336] Professors Mark Gergen, John Golden, and Henry Smith have appropriately described *eBay* as "a remarkable legal juggernaut" that has worked an "American revolution" of injunctive relief.[337] But back on its home turf, the *eBay* decision has done less work than may be imagined. *eBay* simply does not apply to about ten percent of patent cases, and arguably the most important ones, for the simple reason that the Hatch-Waxman Act established an obligatory injunctive remedy in favor of prevailing patent proprietors.[338]

The slate on which Hatch-Waxman's thirty-month stay was written bears great similarity to the one pertaining to permanent injunctions. Prior to the creation of the Federal Circuit, some courts were suspicious of awarding preliminary injunctions in patent infringement cases due to concerns over the reliability of USPTO procedures. In order to award a preliminary injunction, these courts sometimes required that the patent had been previously adjudicated not invalid, proof that competitors had acquiesced to it, or conclusive evidence of its validity.[339] The fledgling Federal Circuit changed these rules, swiftly declaring that preliminary injunctions were as available in patent cases as in any other, and further applying an express presumption of irreparable harm upon concluding that a plaintiff was likely to succeed on the merits of a patent infringement claim.[340]

Against this backdrop, Congress established a thirty-month stay that technically enjoins the FDA from approving a paragraph IV ANDA.[341] In practice,

333. *See* Christopher B. Seaman, *Permanent Injunctions in Patent Litigation After* eBay: *An Empirical Study*, 101 IOWA L. REV. 1949, 1969–72 (2016).

334. *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).

335. *See generally* Aurelia Hepburn-Briscoe, *Irreparable Harm in Patent, Copyright, and Trademark Cases After* eBay v. Mercexchange, 55 HOW. L.J. 643 (2012).

336. *See* Mark P. Gergen, John M. Golden & Henry E. Smith, *The Supreme Court's Accidental Revolution? The Test for Permanent Injunctions*, 112 COLUM. L. REV. 203, 214–15 (2012).

337. *Id.* at 204–06.

338. *See* Richard L. Stroup, Susan Tull & Mindy Ehrenfried, *Patent Holder's Equitable Remedies in Patent Infringement Actions Before Federal Courts and the International Trade Commission*, 99 J. PAT. & TRADEMARK OFF. SOC'Y 530, 580 (2017).

339. Smith Int'l, Inc. v. Hughes Tool Co., 718 F.2d 1573, 1578 (Fed. Cir. 1983).

340. *Id.* at 1580–81.

341. 21 U.S.C. § 355(j)(5)(B)(iii). *See generally Patent Certifications and Suitability Petitions*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/patent-certifications-and-suitability-petitions (Jan. 13, 2023) [https://perma.cc/76L2-PMNN].

however, it amounts to a preliminary injunction against generic manufacturers that the brand-name drug company obtains automatically upon bringing charges of artificial infringement. This approach stands in high relief to garden-variety patent cases, where the award of the preliminary injunction depends upon demonstration of the usual four equitable factors[342] and also requires the posting of a bond.[343]

To be clear, under the Hatch-Waxman Act, any pharmaceutical patent—which, like any other sort of patent, is already statutorily entitled to a presumption of validity[344]—is afforded not just the presumption of entitlement to a preliminary injunction, but also an actual preliminary injunction, awarded in each artificial infringement lawsuit. 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 combination of the five-year NCE exclusivity and the thirty-month stay effectively provides each eligible pharmaceutical patent with seven and a half years of protection, even if they are plainly invalid, were procured through fraud, or do not cover the proposed generic product.[345]

As with permanent injunctions, the thirty-month stay does not square well with *eBay*. There, the Supreme Court cautioned that "broad classifications" and "categorical rules[s]" have no place in judicial determinations to issue injunctions. Indeed, the Federal Circuit has acknowledged that *eBay* "jettisoned" the presumption of irreparable harm the Court of Appeals had previously applied with respect to motions for preliminary injunction.[346] The Supreme Court also recognized that the earlier "automatic injunction" rule could promote patent trolling and other strategic behaviors. Although trolling has not often been associated with pharmaceutical patents,[347] other sorts of gamesmanship have,[348] and many of them have been enabled or encouraged by mandatory injunction provisions.

These abusive behaviors have been addressed in a piecemeal way by a variety of governmental actors. Congress has enacted legislation that limited brand-name drug companies to a single thirty-month stay.[349] The Supreme Court has dealt with the antitrust implications of settlements of paragraph IV ANDA

342. Altana Pharma AG v. Teva Pharms. USA, Inc., 566 F.3d 999, 1005 (Fed. Cir. 2009) ("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.").

343. *See* FED. R. CIV. P. 65(c).

344. *See* 35 U.S.C. § 282(a); Microsoft Corp. v. i4i Ltd. P'ship, 564 U.S. 91, 100 (2011).

345. *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. 5, 11 (2009) ("During the statutory stay period, a pioneer manufacturer remains in complete control of the product market regardless of the strength of its patents.").

346. Robert Bosch LLC v. Pylon Mfg. Corp., 659 F.3d 1142, 1148–49 (Fed. Cir. 2011).

347. *See supra* notes 167–73 and accompanying text.

348. *See, e.g.*, Michael A. Carrier, *Sharing, Samples, and Generics: An Antitrust Framework*, 103 CORNELL L. REV. 1, 1 (2017).

349. 21 U.S.C. § 355(j)(5)(B)(iii).

litigation involving patents of dubious validity.[350] And the FDA and Federal Trade Commission have addressed the fraudulent listings of patents in the Orange Book.[351]

Sitting at the base of all of these abuses is the simple reality that the remedies associated with artificial infringement, enacted in an earlier era, are out of touch with our contemporary understanding of injunctions.[352] Indeed, the remedial provisions associated with artificial infringement are not just out of step with other sorts of patent cases. They conflict with prevailing approaches towards the award of injunctive relief across the entire breadth of U.S. law. Rather than dealing with the numerous machinations of actors within the pharmaceutical industry in a fragmented fashion, Congress could ameliorate, if not eliminate, much gamesmanship by placing drug patents back into the legal mainstream.

Undoubtedly, cases in which a brand-name drug company is not granted a preliminary or permanent injunction against a generic manufacturer, where one is requested, should be few.[353] But eliminating artificial infringement's automatic injunction rules should have a chilling effect upon the worst abuses of Hatch-Waxman. Most notably, brand-name drug companies may be more circumspect about enforcing bad patents, particularly because judges will review the merits of their infringement case when deciding whether to issue a preliminary injunction or not. The requirement to post a bond may also dampen enthusiasm for requesting preliminary injunctions in cases involving patents of doubtful validity. And in rare cases, perhaps where the patent proprietor cannot meet patient demand, the public interest in access to the patented pharmaceutical will outweigh reasons to grant a permanent injunction.[354]

350. *See generally* Fed. Trade Comm'n v. Actavis, Inc., 570 U.S. 136 (2013); Michael A. Carrier, *After* Actavis: *Seven Ways Forward*, 67 RUTGERS U. L. REV. 543, 543 (2015).

351. *See, e.g.*, Press Release, Wrongful "Orange Book" Listing Raises Red Flag with FTC; Leads to Consent Order with Biovail Corp. Concerning Its Drug Tiazac (Apr. 23, 2002), https://www.ftc.gov/news-events/news/press-releases/2002/04/wrongful-orange-book-listing-raises-red-flag-ftc-leads-consent-order-biovail-corp-concerning-its [https://perma.cc/V2ES-EL3M]; U.S. FOOD & DRUG ADMIN., ORANGE BOOK: QUESTIONS AND ANSWERS GUIDANCE FOR INDUSTRY (2022), https://www.fda.gov/media/160167/download [https://perma.cc/2BKW-RABH]. Congress ultimately stepped in as well, allowing generic manufacturers to bring a counterclaim to an infringement action that request delisting from the Orange Book. 21 U.S.C. § 355(j)(5)(C)(ii).

352. Notably, the International Trade Commission, which conducts investigations concerning the importation of infringed products, operates under a third remedial statute that calls for issuance of an exclusion order to prevailing patent proprietors. 19 U.S.C. § 1337(e). This provision has been likened to an automatic injunction. *See generally* Mike Heins, *Selling Congress on* eBay*: Should Congress Force the ITC to Apply the* eBay *Standard?*, 22 FED. CIR. BAR J. 589 (2013). It is noted that the President of the United States possesses the authority to disapprove of the ITC determination and void it. 19 U.S.C. § 1337(j)(2).

353. *See, e.g.*, Sanofi-Synthelabo v. Apotex, Inc., 470 F.3d 1368, 1372–73 (Fed. Cir. 2006).

354. *See* Lance Wyatt, *Rebuttable Presumption of Public Interest in Protecting the Public Health—The Necessity for Denying Injunctive Relief in Medically-Related Patent Infringement Cases After* eBay v. Mercexchange, 13 CHI.-KENT J. INTELL. PROP. 298, 319–24 (2013).

V. EXPLORING THE ALTERNATIVE OF DECLARATORY JUDGMENT JURISDICTION

With all the complications raised by artificial infringement, one might suppose it addresses a glaring jurisprudential need for pharmaceutical patents. But not only is artificial infringement problematic, it is entirely unnecessary due to the availability of actions for declaratory judgment. Put simply, brand-name drug companies do not require an odd legal fiction to vindicate their patent rights. Straightforwardly enough, when a brand-name drug company receives notice that an application for marketing approval has been filed, it could simply seek a declaratory judgment of future infringement by the generic manufacturer.[355] As will be seen, reversion to this mainstream approach holds numerous virtues over the curious artifact of artificial infringement.

The Declaratory Judgment Act provides that in "a case of actual controversy within its jurisdiction . . . any court of the United States . . . may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought."[356] Courts have been quick to note that declaratory judgment actions must satisfy Article III of the Constitution, which affords federal courts the authority to adjudicate only genuine "Cases" and "Controversies."[357] This requirement prevents the federal courts from issuing advisory opinions about hypothetical disagreements, instead allowing only adversarial litigants involved in a live dispute to resort to the federal judiciary.[358]

The few jurists that have juxtaposed the two causes of action—artificial infringement on one hand, and declaratory judgments on the other—have often been puzzled why Congress bothered to develop artificial infringement in the first place. For example, Magistrate Judge Leonard Stark of Delaware, as he was then, was left to suppose that Congress established artificial infringement because it apparently concluded that a brand-name company could not bring a declaratory judgment for traditional patent infringement against an ANDA applicant.[359] Whether or not Congress actually believed as much in 1984, it legislated exactly the opposite result two decades later.

The Medicare Prescription Drug, Improvement, and Modernization Act ("MMA") of 2003 is perhaps most notorious for the FDA's almost thirteen-year delay in developing regulations to implement it.[360] But it also stands as the single

355. *See* Takeda Pharm. Co., Ltd. v. Mylan Inc. 62 F. Supp. 3d 1115, 1117 (N.D. Cal. 2014); Takeda Pharm. Co., Ltd. v. Handa Pharms., LLC, No. C-11-00840 JCS, 2013 WL 9853725, at *61 (N.D. Cal. Oct. 17, 2013).

356. 28 U.S.C. § 2201(a).

357. *See* California v. Texas, 141 S. Ct. 2104, 2113 (2021); Henry H. Gu, *The Hatch-Waxman Act and the Declaratory Judgment Action: Constitutional and Practical Implications*, 57 RUTGERS L. REV. 771, 789–92 (2005).

358. Md. Cas. Co. v. Pac. Coal & Oil Co., 312 U.S. 270, 273 (1941).

359. *In re* Rosuvastatin Calcium Pat. Litig., No. 08-1949, 2008 WL 5046424, at *13 (D. Del. Nov. 24, 2008).

360. The MMA was signed into law on December 8, 2003, and the FDA issued final regulations implementing this legislation on December 5, 2016, almost thirteen years later. Abbreviated New Drug Applications and 505(b)(2) Applications, 81 Fed. Reg. 69,580, 69, 632 (Oct. 6, 2016).

piece of legislation that, to date, has made the most comprehensive reworking of Hatch-Waxman's "Grand Bargain."[361] One component of the MMA was a new type of declaratory judgment action called a "Civil Action to Obtain Patent Certainty," which, seemingly for good measure, Congress placed into the U.S. Code twice.[362] The Civil Action to Obtain Certainty allows generic drug manufacturers to circumvent tactical maneuvers by brand-name drug companies, typically by suing on one relevant patent but holding others in reserve.[363]

Both legislative versions of the Civil Action to Obtain Patent Certainty state that when a generic manufacturer has filed a paragraph IV ANDA, and the brand-name drug company does not file a timely suit for patent infringement, the courts "shall have" subject matter jurisdiction brought by the generic manufacturer for a declaratory judgment that such patent is invalid or not infringed.[364] The Patent Act codification adds a reference to the constitutional "case or controversy" requirement for federal justification.[365] As Senator Ted Kennedy explained:

> We fully expect that, in almost all situations where a generic applicant has challenged a patent [by filing an ANDA with a paragraph IV certification] and not been sued for patent infringement, a claim by the generic applicant seeking declaratory judgment on the patent will give rise to a justiciable "case or controversy" under the Constitution. We believe that the only circumstance in which a case or controversy might not exist would arise in the rare circumstance in which the patent owner and brand drug company have given the generic applicant a covenant not to sue, or otherwise formally acknowledge that the generic applicant's drug does not infringe.[366]

Subsequent to the enactment of the MMA, the Supreme Court issued an opinion that further relaxed prevailing requirements for declaratory judgment jurisdiction. *MedImmune, Inc. v. Genentech Inc.* directed the lower courts to examine "all the circumstances" to determine whether "there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment."[367] The Court further explained that the dispute must be "definite and concrete, touching the legal relations of the parties having adverse legal interests"; and that it be "real and

361. 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, 309 (2009).

362. 21 U.S.C. § 355(c)(3)(D); 35 U.S.C. § 271(e)(5).

363. *See, e.g.*, *infra* notes 370–75.

364. 35 U.S.C. § 271(e)(5).

365. *Id.* ("Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.").

366. 149 CONG. REC. S15885 (daily ed. Nov. 25, 2003) (statement of Sen. Kennedy).

367. 549 U.S. 118, 127 (2007).

substantial" and "admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts."[368] Notably, the Supreme Court explicitly rejected the prevailing Federal Circuit standard that a party seeking a declaratory judgment must demonstrate a reasonable apprehension of being sued for patent infringement.[369]

The Federal Circuit first applied *MedImmune* in the context of Hatch-Waxman in *Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.*[370] In that case, Novartis listed five patents in the Orange Book with respect to famciclovir, a treatment for shingles.[371] When Teva filed a paragraph IV certification with respect to each of the five patents, Novartis responded by bringing an infringement suit against Teva based upon a single patent, but chose to hold the other four in reserve.[372] Teva responded by filing a Civil Action to Obtain Patent Certainty.[373]

Following an appeal, the Federal Circuit acknowledged that the Supreme Court had rejected the "reasonable apprehension of suit" test in *MedImmune* and replaced it with an "all the circumstances" standard.[374] Writing for himself and Judge Haldane Robert Mayer, Judge Arthur Gajarsa instead identified five circumstances that, in combination, suggested that a justiciable controversy existed under Article III: (1) the listing of the patents in the Orange Book,[375] (2) a paragraph IV ANDA,[376] (3) congressional enactment of the Civil Action to Obtain Patent Certainty as fulfilling the purposes of the Hatch-Waxman Act,[377] (4) the charge of artificial infringement on one patent,[378] and (5) the possibility of future litigation on the four remaining patents.[379] Notably, save for element (4), each circumstance identified by Judge Gajarsa will occur in every artificial infringement case.[380]

In a concurrence, Judge Daniel Friedman agreed that declaratory judgment jurisdiction was appropriate, but explained that he would have taken "a somewhat different, and shorter, path than the court does in reaching that conclusion."[381] In his view, the first two factors above—an Orange Book listing and paragraph IV ANDA—by themselves established declaratory judgment jurisdiction.[382] According to the concurrence, the fact that Novartis had filed an

368. *Id.*
369. *See id.* at 132 n.11, 146.
370. 482 F.3d 1330, 1334 (Fed. Cir. 2007).
371. *Id.*
372. *See id.* at 1334–35.
373. *Id.* at 1335.
374. *Id.* at 1337–39.
375. *Id.* at 1341–42.
376. *Id.* at 1342.
377. *Id.* at 1342–44.
378. *Id.* at 1344–45.
379. *Id.* at 1345.
380. *See id.* at 1344.
381. *Id.* at 1346.
382. *Id.* at 1347.

infringement suit based upon one of its five patents merely confirmed the existence of a case or controversy.[383]

The *Teva v. Novartis* opinions hold implications not just for generic manufacturers as the moving party, but also for brand-name firms. As courts have recognized, if a cause of action creates a justiciable controversy for one party to litigation, then it establishes a justiciable controversy for the other.[384] Stated differently, in cases involving a paragraph IV ANDA, if an actual case or controversy exists for the generic manufacturer via the Civil Action to Obtain Patent Certainty, then it exists for the brand-name drug company as well. Brand-name drug companies, therefore, possess broad authority to bring declaratory judgment actions against generic manufacturers that seek to obtain FDA approval to sell potentially infringing products.[385] As a result, even if artificial infringement served some useful purpose in 1984, it no longer fills an unmet need in the jurisprudence of patents today.

To be sure, Judge Friedman's reasoning lies at the edge of current understanding of declaratory judgment jurisdiction.[386] The grant of a patent, by itself, is not generally understood to establish a case or controversy.[387] Certainly the great bulk of patents exist in obscurity, and are never licensed or litigated.[388] Ordinarily the patentee must make some affirmative act, such as accusing another of infringement outside the courtroom, in order to trigger declaratory jurisdiction.[389] And although brand-name drug companies list some of their pertinent patents in the Orange Book, the Hatch-Waxman Act requires them to do so.[390] Orange Book listings can hardly be said to consist of an additional, voluntary act consistent with traditional understandings in the patent field.

Judge Friedman nonetheless took the most sensible pathway for our patent and public health systems. Prompt generic entry, consistent with respect for intellectual property rights, has been a persistent national goal for decades.[391] Resolving potential patent disputes with a minimum of jurisprudential fuss serves these twin goals of the Hatch-Waxman Act. But even under Judge Gajarsa's less compact approach, courts should recognize the heavy dependence of the pharmaceutical industry upon patents, the seriousness of purpose that generic manufacturers express when filing a paragraph IV ANDA, and the long track record of brand-name firms in staving off generic competition for as long as possible.

383. *Id.*

384. *Id.* at 1342.

385. *See id.*

386. The subsequent Federal Circuit case law regarding declaratory judgment jurisdiction in pharmaceutical patent cases has been complex, often involving the implications of generic exclusivity and the issuance of covenants not to sue. *See* Matthew Avery & Mary Nguyen, *The Roadblock for Generic Drugs: Declaratory Judgment Jurisdiction for Later Generic Challengers*, 15 N.C. J.L. & TECH. 1, 12–13, 46 (2013); Grace Lillian Wang, Teva v. Eisai*: What's the Real "Controversy"?*, 66 FOOD & DRUG L.J. 631, 631 (2011).

387. AIDS Healthcare Found., Inc. v. Gilead Scis., Inc., 890 F.3d 986, 991 (Fed. Cir. 2018).

388. *See* Moore, *supra* note 85, at 1521.

389. Prasco, LLC v. Medicis Pharm. Corp., 537 F.3d 1329, 1339 (Fed. Cir. 2008).

390. 21 U.S.C. § 355(b)(1).

391. Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S, 566 U.S. 399, 405 (2012) (noting that the goal of Hatch-Waxman is to "facilitate the approval of generic drugs as soon as patents allow").

Each of these factors support the grant of declaratory judgment jurisdiction, for brand-name drug companies and generic manufacturers alike.

Through a small number of issued judicial opinions, the district courts have expressed division over the use of actions for declaratory judgment in paragraph IV ANDA cases. Some courts have allowed declaratory judgment jurisdiction;[392] others have recognized the possibility of declaratory judgment jurisdiction but denied it on discretionary grounds on the view that it is duplicative of artificial infringement.[393] Judge Rodney Gilstrap of East Texas appeared the most hostile to this alternative, concluding that where a plaintiff cannot present an artificial patent infringement claim "inside the blanket of a declaratory judgment action."[394] But the better view is that a request for a declaratory judgment of garden-variety patent infringement is cut from a different cloth. Due to distinct approaches to remedies and venue, it is not the same as a cause of action for artificial infringement.

Critics of this approach might assert that courts generally look to specific facts to determine whether declaratory judgment jurisdiction exists.[395] Such factors as the brand-name drug company's history of patent enforcement, the generic manufacturer's representations to the FDA, the likelihood of generic approval, and the manufacturer's ability to produce and distribute the generic product might play a role.[396] In contrast, as it is currently framed, artificial infringement allows brand-name drug companies to assert their patent rights without the necessity of such a particularized showing. This argument proves too much, however, as Article III standing must exist for artificial infringement cases to proceed as well. The Supreme Court made that much clear in its most recent decision on Article III standing, *TransUnion LLC v. Ramirez*.[397]

In *TransUnion v. Ramirez*, the Court clarified that even if a defendant has violated a federal statute, that violation alone does not amount to a concrete harm for purposes of Article III standing.[398] Rather, the violation must have caused the plaintiff a physical, monetary, or cognizable intangible injury, in contrast to the risk of a possible future harm.[399] In that case, the Court held that although TransUnion had technically run afoul of the Fair Credit Reporting Act by reporting inaccurate information on the credit reports of thousands of class members, most of them did not suffer a "concrete injury" from the statutory transgression because TransUnion had not disseminated that information to anyone.[400] The

392. Takeda Pharm. Co., Ltd. v. Handa Pharms., LLC, No. C-11-00840 JCS, 2013 WL 9853725, at *61 (N.D. Cal. Oct. 17, 2013); Cephalon, Inc. v. Watson Pharms., Inc., 629 F. Supp. 2d 338, 351 (D. Del. 2009).

393. Takeda Pharm. Co., Ltd. v. Mylan Inc., 62 F. Supp. 3d 1115, 1123–26 (N.D. Cal. 2014).

394. Apicore US LLC v. Beloteca, Inc., No. 2:19-CV-00077-JRG, 2019 WL 1746079, at *7 (E.D. Tex. Apr. 18, 2019).

395. *See, e.g.*, Innovative Therapies, Inc. v. Kinetic Concepts, Inc., 599 F.3d 1377, 1382 (Fed. Cir. 2010).

396. *See generally id.*

397. 141 S. Ct. 2190, 2190 (2021).

398. *Id.* at 2205.

399. *Id.* at 2203.

400. *Id.* at 2209–10.

Court, therefore, dismissed the claims of the majority of the class members for lack of standing.[401]

Applied to Hatch-Waxman, *TransUnion v. Ramirez* implies one of two things. One option is that the filing of a paragraph IV ANDA by itself does not inflict a particularized harm, and therefore, no brand-name drug company possesses Article III standing to pursue a cause of action for artificial infringement. Alternatively, as the courts have concluded over the past four decades, a paragraph IV certification does impose an immediate, concrete harm upon the brand-name drug company, allowing causes of action for both artificial infringement and declaratory judgments to proceed.[402]

Permissive resort to declaratory judgments in paragraph IV ANDA cases would bring many benefits. Doing so would take us to much the same place with respect to personal jurisdiction—broad availability in judicial districts throughout the United States—but without conflating government petitioning with future sales. In turn, use of declaratory judgment jurisdiction would solve the venue problem created by *Valeant v. Mylan* by sidestepping *TC Heartland*. Courts apply the general venue statute for civil actions, 28 U.S.C. § 1391, to declaratory judgment actions, rather than the patent-specific venue statute codified at 28 U.S.C. § 1400(b).[403] Under the general venue statute, a corporation may be subject to a declaratory judgment action in any court where it is subject to personal jurisdiction—which in the context of proposed generic drugs, is any federal district in the nation.[404]

Further recognition of the broad application of declaratory judgment actions would also ease the scofflaw status of the United States with respect to the TRIPS Agreement, for they apply to patents in all fields of technology. Pharmaceutical patents would also be restored to the mainstream of the law of injunctive relief in the United States. These advantages could be achieved without the need for further legislative intervention, through judicial recognition of law Congress has already enacted.

Legislative amendment of the specialized patent venue statute presents another option for dealing with *Valeant v. Mylan.*[405] But much as heliocentrism wholly displaced a geocentric model of the solar system that increasingly had to be propped up by epicycles, deferents, and other complex supportive constructs,[406] artificial infringement should also be shown the door in its entirety. This situation brings to mind Judge Gregory Sleet's perceptive observation that "ANDA litigation reaches the federal courts through specialized legislation enacted by Congress, perhaps without the prescience of the maze it would be creating, and the ingenuity of motivated business persons and lawyers to capitalize

401. *See id.* at 2209.

402. *See* Teva Pharms. USA, Inc. v. Novartis Pharms. Corp., 482 F.3d 1330, 1346 (Fed. Cir. 2007).

403. *See, e.g.*, D2L Ltd. v. Blackboard, Inc., 671 F. Supp. 2d 768, 778 n.10 (D. Md. 2009).

404. *See* Chester S. Chuang, *Offensive Venue: The Curious Use of Declaratory Judgment to Forum Shop in Patent Litigation*, 80 GEO. WASH. L. REV. 1065, 1073 (2012).

405. *See supra* note 253 and accompanying text.

406. *See generally* ALLAN CHAPMAN, STARGAZERS: COPERNICUS, GALILEO, THE TELESCOPE AND THE CHURCH (2014).

on its imperfections."[407] To these concerns, he might have added the incompatibility of artificial infringement with international law, the lack of legislative awareness of the timing and location of the patent litigation involving it, and its outmoded remedial provisions. Four decades of artificial infringement have been enough, and the time has come to restore pharmaceutical patents to the mainstream of the patent law.

VI. CONCLUSION

The history of legal reform has taught us that the quaint but antiquated artifacts of years past must yield to modern sensibilities. One likely roadblock for reform of Hatch-Waxman is the persistent assertion that Hatch-Waxman established a singular "Grand Bargain" in 1984, and that any amendments to the legislation would disturb a delicate balance. Brand-name firms recently advanced this argument in support of the introduced, but unenacted Hatch-Waxman Integrity Act.[408] That bill would have required generic manufacturers to choose between either petitioning for *Inter Partes* Review of an issued pharmaceutical patent at the USPTO, or alternatively filing a paragraph IV ANDA at the FDA.[409] These advocates did not highlight that Congress has provided for post-grant administrative revocation proceedings at the USPTO as early as 1980, even prior to the enactment of Hatch-Waxman.[410]

More fundamentally, this view of the statute is misplaced, for the story of Hatch-Waxman is not one of a singular "Grand Bargain." It is instead a deal that has been subject to continuous legislative revisiting and revision. Some of these changes have benefitted brand-name firms, such as the growing number of regulatory exclusivities[411] and the codification of permissive joinder rules.[412] But others have favored generics, including limitations upon the thirty-month stay,[413] authorization of actions to delist patents,[414] and generic exclusivity forfeiture events.[415]

Many other shifts to the Hatch-Waxman framework have not been specifically directed towards pharmaceutical patents at all.[416] Although Congress has amended Hatch-Waxman on numerous occasions over the past four decades, even more fundamental changes have arguably arisen from more general

407. Merck & Co., Inc. v. Apotex, Inc., 488 F. Supp. 2d 418, 425 (D. Del. 2007).

408. S. 344, 116th Cong. (2019).

409. *See* Carlos A. Garcia & Jonathan Stroud, *Ships in the Night: Resolving Administrative Conflict Between FDA- and Patent-Related Legislation*, 68 AM. U. L. REV. 1111, 1176–77 (2019).

410. *See* Nora Xu, *AIA Proceedings: A Prescription for Accelerating the Availability of Generic Drugs*, 66 EMORY L.J. 1007, 1035–36 (2017).

411. *See* Yaniv Heled, *Regulatory Competitive Shelters*, 76 OHIO ST. L.J. 299, 303–04 (2015).

412. 35 U.S.C. § 299.

413. 21 U.S.C. § 355(j)(5)(B)(iii); *see* Robin C. Feldman, *Perverse Incentives: Why Everyone Prefers High Drug Prices—Except for Those Who Pay the Bills*, 57 HARV. J. LEGIS. 303, 372 n.298 (2020).

414. 21 U.S.C. § 355(j)(5)(C)(ii); *see* Bruce N. Kuhlik, *The Assault on Pharmaceutical Intellectual Property*, 71 U. CHI. L. REV. 93, 102 (2004).

415. 21 U.S.C. § 355(j)(5)(D)(i); *see* Lietzan & Post, *supra* note 75, at 330.

416. *See* Thomas, *supra* note 21, at 41–42.

developments in patents and food and drug law. These include judicial decisions addressing such subjects as patentable subject matter[417] and nonobviousness,[418] as well as such legislation as the America Invents Act[419] and the Generic Drug User Fee Amendments.[420] *TC Heartland*, a venue case involving a patented low-calorie sweetener, demonstrates the sensitivity of our system of pharmaceutical innovation incentives to external developments.[421]

One possibility is to more fully seal the system off, a concept pioneered by the MODDERN Cures Act.[422] That introduced but not yet enacted legislation would allow brand-name pharmaceutical firms to swap patents claiming dormant therapies in exchange for a fifteen-year period of regulatory exclusivity.[423] This legislation would therefore remove select therapies entirely from the whims of the patent system altogether and leave pharmaceutical innovation incentives to the FDA.[424]

A better option is to return pharmaceutical patents to the fold. We should recognize that the patent system has been subject to considerable refinement over the past four decades.[425] Modern understandings of jurisdiction and remedies, the availability of administrative redress, and the international commitments of the United States have rendered artificial infringement a problematic and obsolete principle. Repeal of artificial infringement, thereby subjecting pharmaceutical patents to the same infringement standards as other sorts of inventions, would eliminate these incongruities.

Finally, a new locus of patent litigation has emerged in recent years. The appointment of Judge Alan Albright to the U.S. District Court for the Western Texas in 2018 has resulted in a surge of patent cases brought in Waco.[426] As with the renegade jurisdictions before it, West Texas engages in forum selling, has been reluctant to grant motions to transfer venue, provides speedy trials, disfavors summary judgment, and offers predictability and uniformity of trial

417. *See, e.g.*, Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc., 566 U.S. 66, 70 (2012).

418. *See* KSR Int'l Co. v. Teleflex Inc, 550 U.S. 398, 406 (2007); *see* Rebecca S. Eisenberg, *Pharma's Nonobvious Problem*, 12 LEWIS & CLARK L. REV. 375, 375 (2008).

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

420. Pub. L. No. 112-144, 126 Stat. 993 (2012) (commonly known as "GDUFA I"); Pub. L. No. 115-52, 131 Stat. 1005 ("GDUFA II"); *see* Ernst R. Berndt, Rena M. Conti & Stephen J. Murphy, *The Generic Drug User Fee Amendments: An Economic Perspective*, 5 J.L. & BIOSCIENCES 103, 103 (2018).

421. *See* TC Heartland LLC v. Kraft Foods Grp. Brands LLC, 581 U.S. 258, 261 (2017).

422. Modernizing Our Drug & Diagnostics Evaluation and Regulatory Network Cures Act of 2013, H.R. 3116, 113th Cong. (2013).

423. *Id.*

424. *See* Robert A. Armitage, *The Hatch-Waxman Act: A Path Forward for Making It More Modern*, 40 WM. MITCHELL L. REV. 1200, 1214 (2014).

425. *See* John R. Thomas, *Into a Silver Age: U.S. Patent Law 1992–2012*, 23 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 525, 527 (2013).

426. *See* Ronald Lemieux & Steven Auvil, *Move Over Marshall, There's a New Sheriff in Town—The Rise of Waco and the Western District of Texas*, SQUIRE PATTON BOGGS: GLOBAL IP & TECH. L. BLOG (Mar. 28, 2021), https://www.iptechblog.com/2021/03/move-over-marshall-theres-a-new-sheriff-in-town-the-rise-of-waco-and-the-western-district-of-texas/ [https://perma.cc/B695-XJ4F].

practices.[427] These practices are much the same as those deployed in East Texas in mill run patent cases, and in Delaware and New Jersey in Hatch-Waxman cases, but with widely varying stakeholder reactions. Views are still being formed about West Texas, and we shall see on which side of the ledger public opinion places the latest renegade jurisdiction.[428] In the law, as in life, context matters, and perception often precedes reality.

427. *See* J. Jonas Anderson & Paul R. Gugliuzza, *Federal Judge Seeks Patent Cases*, 71 DUKE L.J. 419, 422 (2021).

428. *See* Michael Shapiro, *West Texas Still Tops Patent Venues, Even After Cases Randomized*, BLOOMBERG LAW (Dec. 27, 2022, 4:15 AM) https://news.bloomberglaw.com/ip-law/west-texas-still-tops-patent-venues-even-after-cases-randomized [https://perma.cc/2T48-XNE8] (observing that at the end of 2022, West Texas remains the most active court for patent lawsuits in the United States despite certain changes to local practices).