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Personal Jurisdiction in Hatch-Waxman Cases

Cover Page Footnote

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PERSONAL JURISDICTION IN HATCH-WAXMAN CASES

Michael Marusak⁺

Historically, pharmaceutical companies hoping to produce “generic” versions of newly-patented drugs were required to wait for patents to expire before they could begin testing their drug—let alone release it to market—otherwise their actions likely constituted patent infringement.¹ But ever since Congress enacted the Hatch-Waxman Act (Hatch-Waxman or the Act) in 1984,² generic drug companies have been able to get lower-cost drugs to market faster, providing the public with an important benefit.³ One way Hatch-Waxman helps generic drugs get to market faster is by streamlining the process for approval by the Food and Drug Administration (FDA). Specifically, the Act allows generic companies to file an abbreviated new drug application (ANDA), which states that the company is going to make a chemical equivalent of a patent owner’s drug.⁴ In addition, the company may fill out a “Paragraph IV certification,” stating that it intends to market its drug before the patent’s expiration because the patent is invalid or not infringed by the generic company’s drug.⁵

Patent owners can typically file infringement suits in any state the generic drugs are sold because specific personal jurisdiction is satisfied.⁶ However, the analysis is more complicated in ANDA cases because, at the time suit is filed,

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1. See JOHN R. THOMAS, PHARMACEUTICAL PATENT LAW 9–11 (3d ed. 2015).

2. Drug Price Competition and Patent Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 15 U.S.C. §§ 68b-68c, 70b; 21 U.S.C. §§ 301 note, 355, 360cc; 28 U.S.C. § 2201; 35 U.S.C. §§ 156, 271, 282 (2012)).

3. See THOMAS, *supra* note 1, at 15; see also, e.g., Colleen Kelly, *The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond*, 66 FOOD & DRUG L.J. 417, 417–18 (2011); Elizabeth Stotland Weiswasser & Scott D. Danzis, *The Hatch-Waxman Act: History, Structure, and Legacy*, 71 ANTITRUST L.J. 585, 607 (2003).

4. 21 U.S.C. § 355(j)(2)(A)(iv) (2012) (providing that an ANDA needs to contain “information to show that the new drug is bioequivalent to the listed drug”).

5. *Id.* at § 355(j)(2)(A)(vii).

6. Kimberly A. Moore, *Forum Shopping in Patent Cases: Does Geographic Choice Affect Innovation?* 79 N.C. L. REV. 889, 895 (2001) [hereinafter Moore, *Forum Shopping*]; see also *Beverly Hills Fan Co. v. Royal Sovereign Corp.*, 21 F.3d 1558, 1571 (Fed. Cir. 1994) (finding that the exercise of personal jurisdiction was appropriate in the forum where a defendant’s infringing products competed with the plaintiff’s patented products because it was the place where “infringing activity directly impact[ed] on the interests of the patentee,” i.e., “the place of infringing sales”).

the generic company has not sold the allegedly infringing product anywhere.⁷ Instead, the generic has committed an “artificial” act of infringement simply by filing an ANDA with a Paragraph IV certification.⁸

Until recently, federal courts solved this problem by relying on a theory of general, rather than specific, personal jurisdiction in ANDA cases,⁹ because patent owners could sue in any state under a “doing business” theory of general jurisdiction.¹⁰ In *Goodyear Dunlop Tires Operations, S.A. v. Brown*,¹¹ and *Daimler AG v. Bauman*,¹² however, the Supreme Court overhauled the general jurisdiction doctrine. Specifically, the Court held that continuous and systematic contacts alone are insufficient to subject a defendant to general jurisdiction in a forum.¹³ Rather, the defendant’s contacts with the state must be sufficient to render it “essentially at home.”¹⁴ For a corporation, “home” is where it is incorporated or headquartered.¹⁵

This heightened standard raises important questions regarding personal jurisdiction in ANDA cases.¹⁶ The problem is demonstrated by two federal court cases decided by different judges in the U.S. District Court for the District of

7. Eric H. Weisblatt & Claire Frezza, *Who to Sue and Where in ANDA Litigation: Personal Jurisdiction Post-Daimler*, 69 FOOD & DRUG L.J. 351, 352 (2014).

8. 35 U.S.C. § 271(e)(2) (2012); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990) (“That is what is achieved by § 271(e)(2) – the creation of a highly artificial act of infringement that consists of submitting an ANDA . . . containing the fourth type of certification that is in error as to whether commercial manufacture, use, or sale of the new drug . . . violates the relevant patent.”); *see also* Weisblatt & Frezza, *supra* note 7, at 352.

9. *See, e.g., In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 693 F. Supp. 2d 409, 420–21 (D. Del. 2010); *Cephalon, Inc. v. Watson Pharms., Inc.*, 629 F. Supp. 2d 338, 348–49 (D. Del. 2009); *Abbott Labs. v. Mylan Pharms., Inc.*, No. 05C6561, 2006 WL 850916, at *3–5 (N.D. Ill. Mar. 28, 2006); *see also* Weisblatt & Frezza, *supra* note 7, at 352, 355–56.

10. *See, e.g., Cephalon*, 629 F. Supp. 2d at 343, 348–49 (finding that an ANDA filer’s historical sales and business dealings in Delaware meant it regularly did business there, constituting systematic and continuous contacts with the forum, and subjecting it to the court’s exercise of general jurisdiction even though it was incorporated in Nevada and headquartered in California); *Abbott*, 2006 WL 850916, at *3–5 (finding that the historical volume of an ANDA filer’s sales in Illinois meant it was “doing business” there, subjecting it to general jurisdiction though it was a West Virginia corporation).

11. 131 S. Ct. 2846 (2011).

12. 134 S. Ct. 746 (2014).

13. *Goodyear*, 131 S. Ct. at 2851.

14. *Id.*

15. *Daimler*, 134 S. Ct. at 760 (concluding that a corporation is at home where it is incorporated and where it has its “principal place of business”); *Hertz Corp. v. Friend*, 559 U.S. 77, 80–81 (2010) (determining that a corporation’s principal place of business is the place where its “high level officers direct, control, and coordinate the corporation’s activities . . . which will typically be found at a corporation’s headquarters”).

16. Weisblatt & Frezza, *supra* note 7, at 352–56 (recognizing that *Daimler* “dramatically affects where patent holders are able to file suit in ANDA litigations,” and suggesting ways specific and general jurisdiction will be treated differently post-*Daimler*).

Delaware.¹⁷ In both cases, Mylan, a generic drug manufacturer headquartered and incorporated in West Virginia, filed an ANDA with the FDA (located in Maryland), and was sued in Delaware for patent infringement under Hatch-Waxman.¹⁸ As the Federal Circuit had already established that Maryland courts could not exercise personal jurisdiction over generics solely on the basis of the FDA's location,¹⁹ the patent owners, AstraZeneca and Acorda, both filed suit against Mylan in their state of incorporation, Delaware.²⁰ Mylan moved to dismiss for lack of personal jurisdiction in both cases.²¹ Although Mylan is registered to do business in Delaware, sells products (i.e., generic drugs) through distributors in the state, and frequently litigates in Delaware courts,²² Mylan challenged whether such contacts were sufficient to render it "at home" in the state.²³ Mylan also argued that it was not subject to specific jurisdiction because it had not yet sold the products at issue in Delaware or anywhere else.²⁴ Rather, it had only filed an ANDA.²⁵

The district courts both agreed, post-*Daimler*, that Mylan was no longer subject to general jurisdiction in Delaware based on its continuous and systematic business contacts with the state.²⁶ Yet, because the Delaware Supreme Court had long-held that registering to do business in the state constitutes consent to general jurisdiction,²⁷ one court found that Mylan consented to general jurisdiction in the forum.²⁸ Moreover, even though Mylan had limited contacts with Delaware beyond its registration to do business, both courts found Mylan's contacts with Delaware sufficient to exercise specific personal jurisdiction.²⁹ Accordingly, Mylan's motions to dismiss were denied.³⁰

17. *Acorda Therapeutics, Inc. v. Mylan Pharms. Inc.*, 78 F. Supp. 3d 572 (D. Del. 2015); *AstraZeneca AB v. Mylan Pharms. Inc.*, 72 F. Supp. 3d 549 (D. Del. 2014).

18. *Acorda*, 78 F. Supp. 3d at 577–79 (involving a patent held by Acorda Therapeutics, Inc., incorporated in Delaware and headquartered in New York); *AstraZeneca*, 72 F. Supp. 3d at 552 (involving a patent held by Swedish corporation AstraZeneca AB, whose American subsidiary AstraZeneca Pharmaceuticals LP was incorporated and headquartered in Delaware).

19. *Zeneca Ltd. v. Mylan Pharms., Inc.*, 173 F.3d 829, 832, 836 (Fed. Cir. 1999).

20. *Acorda*, 78 F. Supp. 3d at 577–79; *AstraZeneca*, 72 F. Supp. 3d at 552.

21. *Acorda*, 78 F. Supp. 3d at 579; *AstraZeneca*, 72 F. Supp. 3d at 551.

22. *Acorda*, 78 F. Supp. 3d at 577–78; *AstraZeneca*, 72 F. Supp. 3d at 552.

23. *Acorda*, 78 F. Supp. 3d at 576; *AstraZeneca*, 72 F. Supp. 3d at 552–54.

24. *Acorda*, 78 F. Supp. 3d at 576; *AstraZeneca*, 72 F. Supp. 3d at 552–53.

25. *Acorda*, 78 F. Supp. 3d at 576–77; *AstraZeneca*, 72 F. Supp. 3d at 552, 554.

26. *Acorda*, 78 F. Supp. 3d at 576; *AstraZeneca*, 72 F. Supp. 3d at 554.

27. *Sternberg v. O'Neil*, 550 A.2d 1105, 1115–16 (Del. 1988); *but see* *Genuine Parts Co. v. Cepec*, 137 A.3d 123, 148 (Del. Apr. 18, 2016) (reviewing *Sternberg* "in light of the U.S. Supreme Court's clarification of the due-process limits on general jurisdiction in *Goodyear* and *Daimler*," and concluding that Delaware's registration statutes "provid[e] a means for service of process and [do] not confer[] general jurisdiction").

28. *Acorda*, 78 F. Supp. 3d at 587; *but see AstraZeneca*, 72 F. Supp. 3d at 556–57 (concluding that Mylan did not consent to jurisdiction simply by registering to do business in Delaware).

29. *Acorda*, 78 F. Supp. 3d at 597; *AstraZeneca*, 72 F. Supp. 3d at 560.

30. *Acorda*, 78 F. Supp. 3d at 599; *AstraZeneca*, 72 F. Supp. 3d at 560.

In light of the important questions raised by these cases, the U.S. Court of Appeals for the Federal Circuit granted interlocutory review.³¹ In *Acorda Therapeutics, Inc. v. Mylan Pharmaceuticals, Inc.*³² (“*Acorda IP*”), the majority declined to reach the general jurisdiction question but found that Mylan was subject to personal jurisdiction in Delaware on a theory of specific jurisdiction alone.³³ Although the Federal Circuit declined to review the decision *en banc*,³⁴ Mylan petitioned the U.S. Supreme Court for certiorari on September 19, 2016.³⁵

While *Acorda II* raises important questions regarding both general and specific jurisdiction in Hatch-Waxman cases, a number of scholars are already discussing the issue of general jurisdiction.³⁶ Thus, this Comment focuses only on the specific jurisdiction findings in *Acorda II* and the Delaware cases leading up to it, while also proposing a way forward in subsequent Hatch-Waxman cases.

Part I of this Comment discusses the history and policies underlying the Hatch-Waxman Act. Part II describes personal jurisdiction jurisprudence as it stands in the United States today. Part III explains how the personal jurisdiction analysis differs in Hatch-Waxman cases. In Part IV, this Comment discusses the two Delaware cases and the Federal Circuit’s decision in *Acorda II*. Part V analyzes the Federal Circuit’s reasoning and argues that the standards for specific personal jurisdiction in Hatch-Waxman cases should be relaxed in response to the recent tightening of general jurisdiction requirements.

I. THE HISTORY AND IMPACT OF THE HATCH-WAXMAN ACT

A. *The Regulatory Environment before Hatch-Waxman*

Like other inventions, pharmaceuticals are afforded patent protection if certain requirements are satisfied. Specifically, the inventor—the “pioneer”³⁷—must prove that the pharmaceutical has proper subject matter, that it has utility,

31. *Acorda Therapeutics v. Mylan Pharms., Inc.*, 817 F.3d 755, 759 (Fed. Cir. 2016).

32. 817 F.3d 755 (Fed. Cir. 2016).

33. *Id.* at 757.

34. See Kevin Penton, *Full Fed. Circ. Won’t Review Generics Jurisdiction Ruling*, LAW360 (June 21, 2016, 12:25 PM), <http://www.law360.com/articles/809105/full-fed-circ-won-t-review-generics-jurisdiction-ruling>.

35. *Mylan Pharms. Inc. v. Acorda Therapeutics Inc.*, — U.S. — (2016).

36. See, e.g., Kevin D. Benish, Note, *Penmoyer’s Ghost: Consent, Registration Statutes, and General Jurisdiction after Daimler AG v. Bauman*, 90 N.Y.U. L. REV. 1609, 1622–23 (2015) (considering whether registration to do business in a state constitutes consent to general jurisdiction and citing the *Acorda I* and *AstraZeneca* cases); see also Tanya J. Monestier, *Registration Statutes, General Jurisdiction, and the Fallacy of Consent*, 36 CARDOZO L. REV. 1343, 1358–59 (2015) (same); Cassandra Burke Robertson & Charles W. “Rocky” Rhodes, *A Shifting Equilibrium: Personal Jurisdiction, Transnational Litigation, and the Problem of Nonparties*, 19 LEWIS & CLARK L. REV. 643, 661–66 (2015) (same).

37. See *Takeda Pharm., U.S.A., Inc. v. Burwell*, 78 F. Supp. 3d 65, 71 (D.D.C. 2015).

and that it is new, non-obvious, and adequately disclosed.³⁸ If the requirements are met and a patent is issued, the drug is afforded patent protection for a limited period of time.³⁹ As a result, the patent owner can prevent others, including producers of less expensive “generic” drugs “from making, using, offering to sell, or selling” products that infringe during the patent term.⁴⁰ However, patenting is just the first step of a long process that a pioneering drug company must take before marketing pharmaceutical products.

Enacted in 1938, the Federal Food, Drug, and Cosmetic Act (FDCA)⁴¹ empowered the FDA to review all “new drugs” for safety before authorizing release to the general public,⁴² setting the modern regulatory framework for the pharmaceutical industry.⁴³ The legislation required manufacturers to submit a new drug application (NDA) to the FDA when seeking authorization and to support their application with the results of scientific testing to prove the safety of the product.⁴⁴ Moreover, testing information was kept confidential out of concern that the publication of testing results would de-incentivize innovators from bringing new drugs to market by handing competitors a blueprint to create similar versions of the drug at a significantly lower cost.⁴⁵

In 1962, Congress amended the FDCA,⁴⁶ increasing the burden on drug manufacturers to show effectiveness in addition to safety.⁴⁷ The new standard generally required two or more “adequate and well-controlled clinical investigations” to show that the drug was significantly beneficial to customers.⁴⁸ However, because efficacy testing was time-consuming, these new laws limited the time pioneering drug manufacturers were allotted to profit on new drugs

38. See Joshua McGuire, *Nonobviousness: Limitations on Evidentiary Support*, 18 BERKELEY TECH. L.J. 175, 175 (2003).

39. THOMAS, *supra* note 1, at 350. In 1995, the general length of patent terms was modified from 17 to 20 years from the date the patent application was filed. See *id.* See also 35 U.S.C. § 154(a)(2) (2012). However, this general patent term is subject to some exceptions. In particular, pharmaceutical patents may be extended beyond 20 years to include the time the company lost to testing and the FDA approval process. THOMAS, *supra* note 1, at 18.

40. 35 U.S.C. § 154(a)(1) (2012).

41. Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301–399f (2012)).

42. Weiswasser & Danzis, *supra* note 3, at 587; see also 21 U.S.C. § 355 (2012).

43. Weiswasser & Danzis, *supra* note 3, at 587.

44. *Id.*

45. *Id.*

46. Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (1962) (codified as amended in scattered sections of 21 U.S.C.).

47. Weiswasser & Danzis, *supra* note 3, at 588 (defining the requirement as demanding proof that the drug was “effective for its intended use, i.e., that the drug provided some health benefit to the consumer”).

48. Hearing Regulations and Regulations Describing Scientific Content of Adequate and Well-Controlled Clinical Investigations, 35 Fed. Reg. 7250 (May 8, 1970) (to be codified at 21 C.F.R. pts. 130, 146); see Weiswasser & Danzis, *supra* note 3, at 588.

during the lives of the underlying patents.⁴⁹ Consequently, the legislation significantly reduced incentives for companies to undertake drug innovation and scientific testing.⁵⁰

Generic companies also faced many hurdles when bringing their products to market. Accordingly, in 1970, the FDA implemented the ANDA process to approve generic drugs if those drugs were shown to be similarly safe and effective to their pioneer counterparts.⁵¹ However, eligible products were limited to generic drugs approved prior to 1962 and reviewed under the rigorous Drug Efficacy Study Implementation program.⁵² In 1980, the FDA initiated the “paper-NDA” process by which generic manufacturers could prove safety and efficacy by supplementing their application with reliable publicly-available information rather than with the results of costly scientific testing.⁵³ Yet, manufacturers remained hesitant to bring generic drugs to market because there was so little reliable data publicly available.⁵⁴ In 1984, the Federal Circuit provided the last straw with its decision in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*,⁵⁵ in which it concluded that any unauthorized use—even experimental use for federally mandated testing—of a patented drug by a generic manufacturer before patent expiration constituted infringement.⁵⁶ With so few generic products entering the market⁵⁷ and the average price of drugs skyrocketing, Congress decided that increasing pharmaceutical competition was necessary.⁵⁸

B. The Hatch-Waxman Act

With the introduction of the Drug Price Competition and Patent Term Restoration Act of 1984,⁵⁹ or the Hatch-Waxman Act,⁶⁰ Congress sought to balance “two competing policy interests: (1) inducing pioneering research and

49. Weiswasser & Danzis, *supra* note 3, at 588.

50. *Id.*

51. *Id.* at 589.

52. *Id.*

53. *Id.*

54. *Id.* at 589–90.

55. 733 F.2d 858 (Fed. Cir. 1984).

56. *Id.* at 860–61; *see also* THOMAS, *supra* note 1, at 10–12.

57. Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187, 187 (1999) (referencing 1984 congressional testimony indicating the existence of 150 off-patent pioneer drugs without generic competitors, and only fifteen paper-NDAs filed for generic versions of pioneer drugs approved by the FDA after 1962).

58. Weiswasser & Danzis, *supra* note 3, at 590.

59. Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 15 U.S.C. §§ 68b-68c, 70b; 21 U.S.C. §§ 301 note, 355, 360cc; 28 U.S.C. § 2201; 35 U.S.C. §§ 156, 271, 282 (2012)).

60. The Act is named after its congressional co-sponsors, Senator Orrin Hatch and Representative Henry Waxman. *See* H. REP. NO. 98-857 (Pt. II), at 3 (1984); S. REP. NO. 98-547, at 1 (1984); *see also* AstraZeneca Pharms. LP v. FDA, 872 F. Supp. 2d 60, 89 (D.D.C. 2012).

development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market.”⁶¹ To achieve its first goal, the Act extended the patent term for pharmaceuticals to make up for lost time due to FDA review, and introduced exclusivity periods for certain drug innovations.⁶² To accomplish the second, the Act made significant changes to the drug approval process, allowing generics to piggyback on the pioneer’s safety and efficacy testing results during the NDA approval process,⁶³ so long as the generic demonstrated that its version was the “bioequivalent” of the pioneer drug.⁶⁴

In addition, the Act established a means for resolving disputes between patent-holders (i.e., pioneers) and prospective patent-infringers (i.e., generics) prior to the release of the generic product into the market.⁶⁵ Specifically, it required the FDA to maintain and periodically publish a list of all approved drugs and their related patents for both new and generic products.⁶⁶ Thus, the FDA created the “Approved Drug Products with Therapeutic Equivalence Evaluations,” known more commonly as the “Orange Book.”⁶⁷

Under the Act, a manufacturer filing an ANDA for a generic version of a pioneer drug is not only required to provide evidence of bioequivalence,⁶⁸ it must also make one of four “certifications” with respect to each patent for the pioneer drug in the Orange Book.⁶⁹ Specifically, the generic must certify:

(I) that there are no patents listed in the Orange Book for the drug (a “Paragraph I” certification); (II) that the relevant patents have expired (a “Paragraph II” certification); (III) that the generic manufacturer will not seek approval of the ANDA until after expiration of the relevant patent (a “Paragraph III” certification); or (IV) that such a patent is invalid or will not be infringed by the manufacture, use, or sale of the

61. *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002).

62. Pub. L. No. 98-417, 98 Stat. 1590, 1598 (codified as amended at 21 U.S.C. §§ 355(c)(3)(E)(ii), (j)(5)(F)(ii); 35 U.S.C. § 156(c) (2012)); *see also* Weiswasser & Danzis, *supra* note 3, at 590, 592.

63. Pub. L. No. 98-417, 98 Stat. 1593 (codified as amended at 21 U.S.C. § 355(b)(2) (2012)); *see also* Weiswasser & Danzis, *supra* note 3, at 585, 593.

64. Pub. L. No. 98-417, 98 Stat. 1586 (codified as amended at 21 U.S.C. § 355(j)(2)(A)(iv) (2012)); *see also* Kelly, *supra* note 3, at 423.

65. Weiswasser & Danzis, *supra* note 3, at 595.

66. Pub. L. No. 98-417, 98 Stat. 1592 (codified as amended at 21 U.S.C. § 355(b)(1) (2012)); *see also* Kelly, *supra* note 3, at 422.

67. Kelly, *supra* note 3, at 422.

68. 21 U.S.C. §§ 355(j)(2)(A)(i)–(iii) (2012); *see also* Kelly, *supra* note 3, at 423 (explaining that the generic company must show that “(1) the active ingredient of the generic drug is the same as that of the pioneer drug; (2) the generic drug has the same route of administration, dosage form and strength as the pioneer drug; and (3) the generic drug’s labeling [is the] same as the labeling of the pioneer drug”).

69. 21 U.S.C. § 355(j)(2)(A)(vii) (2012); *see also* Kelly, *supra* note 3, at 423.

new drug for which the ANDA is submitted (a “Paragraph IV” certification).⁷⁰

Paragraph I, II, and III certifications are generally uncontroversial,⁷¹ but a Paragraph IV certification often leads to significant litigation.⁷² By making this certification, the generic indicates that it (1) intends to release its drug into the market during the pioneer’s patent term,⁷³ and (2) believes the release is appropriate because the pioneer’s patent is either invalid—meaning the patent never should have been granted in the first place—or will not be infringed by the generic’s product.⁷⁴ Consequently, an ANDA filer making a Paragraph IV certification is required to notify patent owners of the certification⁷⁵ and to state the “factual and legal basis of [its] opinion . . . that the patent is invalid or will not be infringed.”⁷⁶

Additionally, the Act made two modifications to the law governing which actions constitute patent infringement by generics.⁷⁷ First, it overturned the *Bolar* decision, which had held that the “limited use of a patented drug for testing and investigation strictly related to FDA drug approval requirements” constituted patent infringement,⁷⁸ generating a rule known today as the “Bolar Amendment.”⁷⁹ Second, the Act established that the mere filing of an ANDA with a Paragraph IV certification constitutes an “artificial” act of infringement,⁸⁰ and thus, created the factual basis for a patent infringement suit between generics and pioneers.⁸¹ In other words, the generic’s act of filing an ANDA with a Paragraph IV certification generates an actual case or controversy sufficient for either the pioneer company to sue for patent infringement or for the generic company to sue for declaratory relief in federal court.⁸²

Congress also included certain provisions in the Act to incentivize litigation⁸³—the idea being that Congress wanted courts to resolve questions

70. Weiswasser & Danzis, *supra* note 3, at 600 (citing 21 U.S.C. § 355(j)(2)(A)(vii) (2012)).

71. *Id.*

72. *Id.*

73. *Id.*

74. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2012).

75. Kelly, *supra* note 3, at 423.

76. 21 U.S.C. § 355(j)(2)(B)(iv)(II) (2012).

77. 35 U.S.C. § 271(e)(1)–(2) (2012); *see* Weiswasser & Danzis, *supra* note 3, at 604–05.

78. *Roche Prods. Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 861 (Fed. Cir. 1984).

79. 35 U.S.C. § 271(e)(1) (2012); *see* Weiswasser & Danzis, *supra* note 3, at 605.

80. 35 U.S.C. § 271(e)(2) (2012).

81. *Id.*; Kelly, *supra* note 3, at 424.

82. 35 U.S.C. § 271(e)(5) (2012); *see also* Emily Michiko Morris, *The Myth of Generic Pharmaceutical Competition Under the Hatch-Waxman Act*, 22 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 245, 264 (2012). Federal courts have exclusive subject matter over all patent cases. U.S. CONST. art. III, § 2, cl. 1; *see also* THOMAS, *supra* note 1, at 5.

83. THOMAS, *supra* note 1, at 17–18. ANDA filers must notify the patent-holder of an ANDA submission with a Paragraph IV certification. 21 U.S.C. § 355(j)(2)(B)(i) (2012). After receiving notice, the patent-holder has 45 days to bring a suit for patent infringement. *Id.* § 355(j)(5)(B)(iii).

about patent validity and infringement related to pioneer drugs.⁸⁴ From the pioneer's perspective, filing a lawsuit is beneficial under the Act because it slows down the ANDA approval process.⁸⁵ Moreover, Congress provided important incentives to encourage generic companies to file ANDAs with Paragraph IV certifications. Specifically, under the Act, the first generic company to file an ANDA with a Paragraph IV certification and invalidate the pioneer's patent is granted a six-month period of marketing exclusivity,⁸⁶ during which time the generic and pioneer companies are the only providers.⁸⁷

A generic company can make a substantial amount of profit during six months of exclusivity,⁸⁸ and thus, pharmaceutical patent litigation can be a high stakes game.⁸⁹ Accordingly, companies must be strategic before filing suits. One very important part of that calculus is where to file the suit, which depends in part on where the defendant is subject to personal jurisdiction.

II. AN OVERVIEW OF PERSONAL JURISDICTION JURISPRUDENCE

Since the Supreme Court's holding in *Pennoyer v. Neff*,⁹⁰ courts have sought to clarify the power they have under the Fifth and Fourteenth Amendments to exercise personal jurisdiction over defendants in a suit.⁹¹ Yet, it took nearly seventy years after *Pennoyer* for the Supreme Court to begin to refine the scope of jurisdictional authority.⁹² In the canonical case *International Shoe Company v. Washington*,⁹³ the Court took important steps towards defining the scope of personal jurisdiction, and in the process, created the two broad categories of

If it complies with this requirement, the FDA will suspend approving the ANDA until either the litigation is resolved in favor of the ANDA filer, the patent term expires, or 30 months from the date notice was received. *Id.* Moreover, if the patent-holder fails to bring a suit within 45 days, the ANDA filer may bring a declaratory judgment action against the patent-holder regarding the validity of the patent. *Id.* at §§ 355(j)(5)(C)(i)(I)–(II); *see also* THOMAS, *supra* note 1, at 24.

84. *See* Kelly, *supra* note 3, at 434.

85. *See* 21 U.S.C. §§ 355(j)(5)(B)(iii), 355(j)(5)(C)(i)(I)–(II) (2012); *see also* AstraZeneca AB v. Mylan Pharms. Inc., 72 F. Supp. 3d 549, 558 (D. Del. 2014).

86. 21 U.S.C. § 355(j)(5)(B)(iv) (2012).

87. *See* Kelly, *supra* note 3, at 424 (“FDA will not approve subsequent ANDAs for the same pioneer drug until the expiration of the 180 days.”).

88. *Id.* at 424–25.

89. *See, e.g.,* Morris, *supra* note 82, at 252 (remarking that companies in the pharmaceutical industry are highly “dependent on patent protection to recoup [their] enormous research, development, regulatory, and post-marketing costs”).

90. 95 U.S. 714, 720 (1877) (finding that “[t]he authority of every tribunal is necessarily restricted by the territorial limits of the State in which it is established”).

91. U.S. CONST. amend. XIV (“No State shall . . . deprive any person of life, liberty, or property, without due process of law”); *see also* Megan M. La Belle, *Patent Litigation, Personal Jurisdiction, and the Public Good*, 18 GEO. MASON L. REV. 43, 62–63 (2010) (explaining that “the jurisdiction of courts considering state law cases is constrained by the Fourteenth Amendment, while the Fifth Amendment limits jurisdiction in patent and other federal question cases”).

92. *See* Int'l Shoe Co. v. Washington, 326 U.S. 310 (1945).

93. 326 U.S. 310 (1945).

personal jurisdiction that form the basis of nearly every personal jurisdiction inquiry today: general and specific jurisdiction.⁹⁴ In *International Shoe*, the State of Washington brought suit in state court against a non-resident defendant corporation for failure to contribute to the state's unemployment fund.⁹⁵ The corporation, incorporated in Delaware and principally operating out of Missouri, employed eleven to thirteen salesmen in Washington but had otherwise limited operations in the state.⁹⁶ As *Pennoyer* had established the principle that a defendant must be present in a forum for the court to render a judgment personally binding him,⁹⁷ the Court engaged in an examination of what constitutes a corporation's "presence" within a forum.⁹⁸

First, the Court reasoned that a corporate defendant's "presence" has "never been doubted" in a forum in which a corporation's activities are "continuous and systematic."⁹⁹ From this passage, the doctrine of general jurisdiction was born.¹⁰⁰ Next, it determined that where a defendant's activities in a forum are not "continuous and systematic," but instead "irregular" or "casual,"¹⁰¹ due process requires only that the defendant have minimum suit-related contacts with the forum, so long as maintenance of the suit is consistent with "traditional notions of fair play and substantial justice."¹⁰² This concept of "minimum contacts" eventually became the cornerstone for the doctrine of specific jurisdiction.¹⁰³

A. General Personal Jurisdiction

After *International Shoe*, the Supreme Court revisited general jurisdiction on only a few occasions, leaving "systematic and continuous" as an enigmatic governing standard for several decades.¹⁰⁴ However, by 2011, the Court finally began to refine the scope of the doctrine for corporations.¹⁰⁵ In *Goodyear*, two 13 year-old boys from North Carolina were killed in a bus accident in Paris, France.¹⁰⁶ The boys' parents sued Goodyear, the manufacturer of the bus's tires, specifically naming Goodyear's American parent company and three of its

94. *Id.* at 317, 319.

95. *Id.* at 311.

96. *Id.* at 313–14.

97. *Id.* at 316 (citing *Pennoyer v. Neff*, 95 U.S. 714, 733 (1877)).

98. *Id.* at 316–21.

99. *Id.* at 317.

100. See *Goodyear Dunlop Tires Operations, S.A. v. Brown*, 564 U.S. 915, 919 (2011) (citing *Int'l Shoe Co.*, 326 U.S. at 317).

101. *Int'l Shoe Co.*, 326 U.S. at 320.

102. *Id.* at 316.

103. See *Goodyear*, 564 U.S. at 923 (citing *Int'l Shoe Co.*, 326 U.S. at 316).

104. *Id.* at 925.

105. *Id.* at 919.

106. *Id.* at 918.

foreign subsidiaries as defendants in North Carolina state court.¹⁰⁷ Goodyear's American parent company did not challenge the exercise of jurisdiction because it had established manufacturing operations in North Carolina and had regularly engaged in commercial activity there.¹⁰⁸ However, the foreign subsidiaries sought dismissal for lack of personal jurisdiction because they had no business relations or manufacturing operations in North Carolina, and the tires at issue had never been distributed in the state.¹⁰⁹ Finding the foreign subsidiaries' arguments persuasive, the Court ruled that a corporate defendant will only be subject to a state's exercise of general jurisdiction when the corporation's contacts with the state are so "continuous and systematic" that the corporation is "essentially at home" there.¹¹⁰ Accordingly, the Supreme Court found that the North Carolina court's exercise of general jurisdiction was inappropriate, as the foreign subsidiaries were "in no sense at home in North Carolina."¹¹¹

Three years later, in *Daimler*, the Supreme Court clarified that a corporation is "essentially at home" in two locations: (1) where it is incorporated, and (2) where it has its principle place of business.¹¹² According to the Court's finding in *Hertz Corp. v. Friend*,¹¹³ a corporation's principle place of business exists at its metaphorical "nerve center," which is generally found at the corporation's headquarters.¹¹⁴ With this set of cases, the Supreme Court significantly curtailed the reach of general jurisdiction, forcing plaintiffs in many cases to turn to specific jurisdiction as the grounds for suing defendants in their chosen forum.¹¹⁵

B. The Specific Personal Jurisdiction Inquiry

During the decades of relatively stagnant growth in general jurisdiction jurisprudence,¹¹⁶ specific jurisdiction had "become the centerpiece of modern jurisdictional theory" in the years following *International Shoe*.¹¹⁷ Through a series of cases,¹¹⁸ the Supreme Court layered several inquiries on top of the

107. *Id.*

108. *Id.*

109. *Id.* at 921.

110. *Id.* at 919.

111. *Id.* at 929.

112. *Daimler AG v. Bauman*, 134 S. Ct. 746, 760 (2014).

113. *Hertz Corp. v. Friend*, 559 U.S. 77 (2010).

114. *Id.* at 80–81 ("[W]e conclude that the phrase 'principal place of business' refers to the place where the corporation's high level officers direct, control, and coordinate the corporation's activities.")

115. *See, e.g., supra* notes 9–13 and accompanying text.

116. *See Goodyear*, 564 U.S. at 925 (citing *Helicopteros Nacionales de Colombia, S.A. v. Hall*, 466 U.S. 408 (1984)).

117. *Id.* at 924–25 (quoting Mary Twitchell, *The Myth of General Jurisdiction*, 101 HARV. L. REV. 610, 628 (1988)).

118. *See Asahi Metal Indus. Co. v. Superior Court of Cal.*, 480 U.S. 102 (1987); *Burger King Corp. v. Rudzewicz*, 471 U.S. 462 (1985); *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S.

traditional “minimum contacts” analysis, giving courts a framework to consider “the relationship among the defendant, the forum, and the litigation” when determining whether the exercise of jurisdiction over a defendant is appropriate.¹¹⁹

Under this framework, first, the litigation must “arise out of or relate to” the defendant’s contacts with the forum.¹²⁰ Often referred to as the “connectedness,”¹²¹ “relatedness,”¹²² or “nexus”¹²³ requirement, this prong considers the connection between the defendant’s forum contacts and the plaintiff’s claim.¹²⁴ Second, the defendant must have purposefully availed itself of the privileges of the forum, thereby receiving the benefits and protections afforded under the State’s laws.¹²⁵ Third, the exercise of specific jurisdiction must comport with traditional notions of fair play and substantial justice.¹²⁶ To make such a determination, a defendant’s contacts may be balanced against a set of factors: the defendant’s burden, the state’s interest in the dispute, the plaintiff’s interest in convenience and effective relief, the judicial system’s interest in efficiency, and the shared state interest in furthering social policies.¹²⁷ Upon a “lesser showing” of minimum contacts, the existence of these considerations in favor of a plaintiff may “serve to establish the reasonableness of jurisdiction.”¹²⁸ But when a defendant’s purposeful availment of a forum is more clearly established, a defendant may only defeat jurisdiction by presenting a “compelling case” that the exercise of jurisdiction would be unfair.¹²⁹

286 (1980); *Hanson v. Denckla*, 357 U.S. 235 (1958); *McGee v. Int’l Life Ins. Co.*, 355 U.S. 220 (1957).

119. *Shaffer v. Heitner*, 433 U.S. 186, 204 (1977).

120. *Helicopteros*, 466 U.S. at 414 n.8.

121. See Charles W. “Rocky” Rhodes & Cassandra Burke Robertson, *Toward a New Equilibrium in Personal Jurisdiction*, 48 U.C. DAVIS L. REV. 207, 230–31 (2014).

122. See Ryne H. Ballou, Note, *Civil Procedure – Be More Specific: Vague Precedents and the Differing Standards by Which to Apply “Arises out of or Relates to” in the Test for Specific Personal Jurisdiction*, 35 U. ARK. LITTLE ROCK L. REV. 663, 667–68 (2013); Flavio Rose, Comment, *Related Contacts and Personal Jurisdiction: The “But for” Test*, 82 CALIF. L. REV. 1545, 1546 (1994).

123. See generally Linda Sandstrom Simard, *Meeting Expectations: Two Profiles for Specific Jurisdiction*, 38 IND. L. REV. 343, 348–73 (2005).

124. *Ticketmaster-N.Y., Inc. v. Alioto*, 26 F.3d 201, 206 (1st Cir. 1994).

125. *Hanson v. Denckla*, 357 U.S. 235, 253 (1958) (citing *Int’l Shoe Co. v. Washington*, 326 U.S. 310, 319 (1945)).

126. See *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 476 (1985) (citing *Int’l Shoe Co.*, 326 U.S. at 320).

127. *Id.* at 476 (citing *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 292 (1980)).

128. *Id.* at 477.

129. *Id.* at 477–78 (“[M]inimum requirements inherent in the concept of fair play and substantial justice may defeat the reasonableness of jurisdiction even if the defendant has purposefully engaged in forum activities. As we have previously noted, jurisdictional rules may not be employed in such a way as to make litigation so gravely difficult and inconvenient that a party unfairly is at a severe disadvantage in comparison to his opponent.”) (internal quotations and citations omitted).

C. Unanswered Questions in the “Nexus” Context

Though the second and third prongs of the specific jurisdiction analysis (purposeful availment and fairness, respectively) have been the subject of much litigation and, at least in some respects, are well-settled areas of law,¹³⁰ the Supreme Court has said comparatively little about the nexus requirement and has explicitly left it open to interpretation.¹³¹

1. The Supreme Court’s Approach in Helicopteros

In *Helicopteros Nacionales de Colombia, S.A. v. Hall*,¹³² a Colombian corporation that provided helicopter transportation services in South America was sued in Texas by the families of four American citizens who died in a crash in Peru.¹³³ Although the company held business negotiations, purchased helicopters, and sent pilots to train in Texas,¹³⁴ the plaintiffs relied exclusively on a general jurisdiction theory, leaving the Court room to decide the case only on those grounds.¹³⁵ The Court ultimately dismissed the case, holding that the defendant corporation lacked sufficient contacts with Texas to subject it to general jurisdiction in the state.¹³⁶

Yet, the Court made it a point to note that its decision left some issues about specific jurisdiction—and, in particular, the nexus requirement—unsettled. In a footnote, the Court raised and then declined to answer the questions (1) whether “arise out of or relate to” refers to two different types of connections between the litigation and the defendant’s contacts, (2) what type of connection is necessary to satisfy either one, and (3) if a situation occurs which implicates the “relate to” language alone, whether a court’s assertion of specific jurisdiction would be appropriate in that case.¹³⁷ In his dissent, Justice Brennan criticized the Court’s unwillingness to distinguish between the two types of

130. In *Asahi*, the Supreme Court split over whether the purposeful availment prong could be “premised on the placement of a product into the stream-of-commerce,” with Justice Brennan’s faction determining that mere awareness that the product would end up in the forum was sufficient and Justice O’Connor’s plurality concluding that a defendant must also purposefully serve the market in the forum in some manner. *Asahi Metal. Indus. Co. v. Superior Court of Cal.*, 480 U.S. 102, 104, 112, 117 (1987).

131. *Helicopteros Nacionales de Colombia, S.A. v. Hall*, 466 U.S. 408, 416 n.10 (1984).

132. 466 U.S. 408 (1984).

133. *Id.* at 409–10.

134. *Id.* at 410–11.

135. *Id.* at 414 n.9 (“When a State exercises personal jurisdiction over a defendant in a suit not arising out of or related to the defendant’s contacts with the forum, the State has been said to be exercising ‘general jurisdiction’ over the defendant.”).

136. *Id.* at 418.

137. *Id.* at 414 n.9; *see also* *Ticketmaster-N.Y., Inc. v. Alioto*, 26 F.3d 201, 206 (1st Cir. 1994) (considering whether “the two halves of the relatedness requirement are merely two ways of expressing the same thought or . . . meant to import different values into the jurisdictional equation”).

connections.¹³⁸ Specifically, he argued that limiting specific jurisdiction to actions arising immediately from the defendant's contacts with the forum would unjustifiably "subject constitutional standards under the Due Process Clause to the vagaries of the substantive law or pleading requirements of each State."¹³⁹

2. Differing Approaches in the Wake of *Helicopteros*

Unsurprisingly, lower courts have significantly differed in their approaches to the nexus questions posed in *Helicopteros*.¹⁴⁰ Yet, these questions remain unresolved three decades after *Helicopteros* was decided because, before *Goodyear* and *Daimler*, plaintiffs and courts could rely on broad theories of general jurisdiction.¹⁴¹ But given the recent constriction of general jurisdiction, some predict the emergence of the nexus requirement "as the central battleground in personal jurisdiction."¹⁴²

At least one circuit employs a "proximate cause" test,¹⁴³ which is considered one of the more restrictive approaches.¹⁴⁴ Borrowing from tort law causation standards, the test asks whether a reasonable person would have foreseen that the defendant's activities would produce the injury.¹⁴⁵ Effectively, however, the test derives from the "arise out of" language alone.¹⁴⁶ Consequently, support for the rigid standard has waned.¹⁴⁷ Some circuits apply the less rigorous, but still quite restrictive, "but for" test,¹⁴⁸ whereby specific jurisdiction exists if the injury would not have occurred "but for" the defendant's activities in the forum.¹⁴⁹ Broader than proximate cause,¹⁵⁰ the test requires courts to consider all necessary antecedent causes of the injury, not just the immediate cause.¹⁵¹

138. *Helicopteros*, 466 U.S. at 425 (Brennan, J., dissenting).

139. *Id.* at 427; see also *Avocent Huntsville Corp. v. Aten Int'l Co., Ltd.*, 552 F.3d 1324, 1330 (Fed. Cir. 2008) (interpreting the *Helicopteros* nexus standard by citing Justice Brennan's dissent and emphasizing that the "constitutional catch-phrase is disjunctive in nature").

140. See Victor N. Metallo, "Arise out of" or "Related to": *Textualism and Understanding Precedent Through Interpretatio Objectificata*, "Objectified Interpretation" – A Four Step Process to Resolve Jurisdiction Questions Utilizing the Third Circuit Test in *O'Connor as a Uniform Standard*, 17 WASH. & LEE J. CIVIL RTS. & SOC. JUST. 415, 416–17 (2011).

141. See Rhodes & Robertson, *supra* note 121, at 213–14.

142. *Id.* at 228.

143. See *Nowak v. Tak How Invs, Ltd.*, 94 F.3d 708, 715 (1st Cir. 1996); Metallo, *supra* note 140, at 417.

144. Rhodes & Robertson, *supra* note 121, at 232.

145. *Id.*

146. Metallo, *supra* note 140, at 416–17.

147. See *Myers v. Casino Queen, Inc.*, 689 F.3d 904, 912–13 (8th Cir. 2012) (rejecting a strict proximate cause test and adopting a more flexible standard that considers the totality of the circumstances).

148. Metallo, *supra* note 140, at 417–18.

149. Simard, *supra* note 123, at 356.

150. *Id.*

151. *Id.*

Several circuits remove causation from the analysis and use a more permissive “sliding scale” or “hybrid” approach instead.¹⁵² This test considers the totality of the circumstances,¹⁵³ balancing the closeness of the contacts to the claim with the quality and quantity of those contacts, so that the more related they are, the less quality and quantity is required.¹⁵⁴

Some scholars have advocated for the “substantive relevance” test, whereby the exercise of specific jurisdiction is appropriate if the defendant’s forum contacts “bear on the substantive legal dispute between the parties,” meaning that the contacts would normally be alleged as part of the complaint.¹⁵⁵ Others have suggested a “similarity test,” which compares the defendant’s contacts in the forum with his contacts in another state.¹⁵⁶ The similarity test is grounded in the theory that a defendant engaging in similar activities across multiple forums should expect the exercise of jurisdiction in all of them.¹⁵⁷ This approach is considered the most lenient standard.¹⁵⁸

Other courts simply require proof of a “substantial connection” between the defendant’s contacts with the forum and the litigation.¹⁵⁹ In fact, the Supreme Court recently utilized this language in *Walden v. Fiore*,¹⁶⁰ a personal jurisdiction case decided just two terms ago. That said, *Walden* was what is known as an “effects test” case, so it is unclear whether *Walden*’s “substantial connection” test applies to a traditional minimum contacts analysis.¹⁶¹ In any

152. Metallo, *supra* note 140, at 418, 434.

153. *Id.* at 418; *see* Ticketmaster-N.Y., Inc. v. Alioto, 26 F.3d 201, 206 (1st Cir. 1994); *see also* Myers v. Casino Queen, Inc., 689 F.3d 904, 912–13 (8th Cir. 2012).

154. Lawrence W. Moore, *The Relatedness Problem in Specific Jurisdiction*, 37 IDAHO L. REV. 583, 593 (2001) [hereinafter Moore, *The Relatedness Problem*].

155. Rhodes & Robertson, *supra* note 121, at 231–32. The test considers the required geographical components relevant for asserting the cause of action, rather than the location of the injury. *Id.* at 231. For example, in one case, though the New York long-arm statute granted jurisdiction over airplane pilots involved in a collision because both planes had stopped over at an airport in New York, the court found that the stopover was not of “substantive relevance” to the suit because the complaint did not state that any negligence had occurred during that time. Lea Brilmayer, *How Contacts Count: Due Process Limitations on State Court Jurisdiction*, 1980 SUP. CT. REV. 77, 83.

156. Simard, *supra* note 123, at 367.

157. *Id.* at 368. Under this test, for example, a driver traveling from Connecticut to Maine (through Massachusetts and New Hampshire) who gets in an accident in Massachusetts could be subject to the exercise of personal jurisdiction in Connecticut, New Hampshire, or Maine because his contacts were similar to the contacts giving rise to the suit in Massachusetts. *Id.* at 368–69.

158. *Id.* at 367; *see also* Brilmayer, *supra* note 158, at 83–84.

159. Rhodes & Robertson, *supra* note 121, at 233.

160. 134 S. Ct. 1115, 1121 (2014).

161. In *Walden*, the Supreme Court addressed the scope of the “effects test,” a doctrine the Court first introduced in *Calder v. Jones*. *See Walden*, 134 S. Ct. at 1123–26 (reviewing *Calder v. Jones*, 465 U.S. 783 (1984)). The test considers whether a defendant can be subject to personal jurisdiction in the forum where the plaintiff feels the “effects” of the defendant’s intentionally tortious conduct. Lee Goldman, *From Calder to Walden and Beyond: The Proper Application of the “Effects Test” in Personal Jurisdiction Cases*, 52 SAN DIEGO L. REV. 357, 358 (2015). In

event, *Walden* stated (1) that a defendant's "suit-related conduct" must create a "substantial connection" with the forum,¹⁶² and (2) that this connection "must arise out of" the defendant's contacts with the forum.¹⁶³ But the Court did not explain what, if any, effect this "substantial connection" test has on the "arise out of or relate to" nexus test articulated in *Helicopteros*.¹⁶⁴ Thus, until the Court provides additional clarification, the "substantial connection" appears to be less like an independent nexus test, and more like a general restatement of the *Helicopteros* rule.

3. The Federal Circuit's Approach to the Nexus Requirement

Prior to *Acorda II*, the Federal Circuit never explicitly adopted one of the tests enumerated above, though it hinted that it favored a more permissive approach, specifically within the context of patent infringement actions.¹⁶⁵ The Circuit first addressed the issue in 1995 in *Akro Corp. v. Luker*.¹⁶⁶ In *Akro*, the court noted that the Supreme Court purposefully left the "arise from or relate to" language open for interpretation, reasoning that its disjunctive nature was of significance.¹⁶⁷ In the court's view, the Supreme Court must have intended a more flexible interpretation than a strict "arise out of" standard.¹⁶⁸ To reach a conclusion in the case, the court considered whether the quantity, quality, and nature of the defendant's contacts with the forum were substantial enough to warrant the exercise of personal jurisdiction.¹⁶⁹ In other words, the court

Walden, the Court ultimately concluded that the defendant could not be subject to personal jurisdiction in Nevada solely on the basis that he "directed his [tortious] conduct at plaintiffs whom he knew had Nevada connections," because "it is the defendant, not the plaintiff . . . , who must create contacts with the forum State." *Walden*, 134 S. Ct. at 1125–26.

162. *Id.* at 1121 (emphasis added).

163. *Id.* at 1122 (emphasis added).

164. See Bernadette Bollas Genetin, *The Supreme Court's New Approach to Personal Jurisdiction*, 68 SMU L. REV. 107, 157 (2015) ("The *Walden* Court ultimately failed to provide guidance to lower courts regarding whether a defendant has the requisite 'substantial connections' with the forum, . . . [instead] obscur[ing] the basis for the decision, continu[ing] the ambiguity that has characterized the Court's minimum contacts analysis, and provid[ing] no principled basis for lower courts to assess subsequent cases."); Rhodes & Robertson, *supra* note 121, at 234–35 ("The 'substantial connection' model . . . offers no meaningful tutelage [and] engenders conflicting holdings . . .").

165. See *Avocent Huntsville Corp. v. Aten Int'l Co., Ltd.*, 552 F.3d 1324, 1337 (Fed. Cir. 2008); *Inamed Corp. v. Kuzmak*, 249 F.3d 1356, 1362 (Fed. Cir. 2001); *Red Wing Shoe Co., Inc. v. Hockerson-Halberstadt, Inc.*, 148 F.3d 1355, 1359–61 (Fed. Cir. 1998); *Akro Corp. v. Luker*, 45 F.3d 1541, 1547 (Fed. Cir. 1995).

166. *Akro*, 45 F.3d at 1544.

167. *Id.* at 1547 (quoting *Ticketmaster-N.Y., Inc. v. Alioto*, 26 F.3d 201, 206 (1st Cir. 1994)).

168. *Id.* (quoting *Ticketmaster*, 26 F.3d at 206); see also *Inamed*, 249 F.3d at 1362 (confirming the *Akro* flexibility approach as authoritative in the Federal Circuit).

169. *Akro*, 45 F.3d at 1547–48 (quoting *B & J Mfg. Co. v. Solar Indus., Inc.*, 483 F.2d 594, 598–99 (8th Cir. 1973)) ("It is evident . . . that the quantity, quality and nature of the defendant's contacts with the jurisdiction are substantial . . . [I]n view of the defendant's extensive contacts with the forum, we believe that the contacts are sufficiently connected with the cause of action to

apparently applied a totality of the circumstances test (a “sliding scale” or “hybrid” approach).

After *Akro*, the Federal Circuit did not stray from its permissive interpretation of nexus,¹⁷⁰ though it suggested that its feelings on the subject were not completely settled.¹⁷¹ Still, because Federal Circuit law is authoritative over the regional circuits in the patent context—even when considering personal jurisdiction, so long as the issue relates to substantive patent law¹⁷²—the *Akro* test should have been the standard around the country.¹⁷³ However, because courts have historically relied on general jurisdiction in ANDA cases,¹⁷⁴ a definitive interpretation of the nexus requirement in the Hatch-Waxman context has never been given.

III. APPLICATIONS OF SPECIFIC JURISDICTION IN HATCH-WAXMAN CASES

A. Specific Jurisdiction in Patent Infringement Cases

For years, the “situs” of patent injuries, and thereby, one of the forums in which an infringement suit could be brought, was an ambiguous legal concept,¹⁷⁵ drifting between the competing theories of “injury at the place of patent” and “injury at the place of infringing acts.”¹⁷⁶ However, in *Beverly Hills Fan, Co. v. Royal Sovereign Corp.*,¹⁷⁷ the question was resolved in favor of the latter approach.¹⁷⁸ In *Beverly Hills Fan*, a Delaware corporation with its principal place of business in California brought a patent infringement suit in the Eastern

satisfy due process.”) (emphasis removed); see also *Pfizer, Inc. v. Synthon Holding, B.V.*, 386 F. Supp. 2d 666, 675 (M.D.N.C. 2005) (recognizing that Federal Circuit personal jurisdiction law governs patent cases and identifying the nexus test applied by the *Akro* court).

170. *Avocent Huntsville Corp. v. Aten Int’l Co., Ltd.*, 552 F.3d 1324, 1337 (Fed. Cir. 2008); see also *Inamed Corp. v. Kuzmak*, 249 F.3d 1356, 1362 (Fed. Cir. 2001).

171. *Avocent*, 552 F.3d at 1336–37 (“While we are bound by our precedent, it is not without controversy . . . Our own interpretation of the ‘arise out of or related to’ language is far more permissive than either the ‘proximate cause’ or the ‘but for’ analyses However, we need not confront the [issue] in the case at hand”).

172. *Akro*, 45 F.3d at 1543; *Beverly Hills Fan Co. v. Royal Sovereign Corp.*, 21 F.3d 1558, 1564 (Fed. Cir. 1994).

173. See, e.g., *Pfizer*, 386 F. Supp. 2d at 675.

174. See *supra* note 9 and accompanying text (listing pre-*Daimler* and pre-*Goodyear* ANDA cases decided on general jurisdiction grounds).

175. John C. O’Quinn, Note, *There’s No Place Like Home: Finding Personal Jurisdiction in ANDA Patent Cases After Zeneca v. Mylan Pharmaceuticals*, 13 HARV. J.L. & TECH. 129, 129 (1999); see also *Beverly Hills Fan*, 21 F.3d at 1570 (finding that a precedent-setting Seventh Circuit decision could be read to hold “that the injury occurred where infringing sales were made . . . [but could] also be read to mean that the situs of the injury is the situs of the intangible property interest, which is determined by where the patent owner resides”).

176. O’Quinn, *supra* note 175, at 129.

177. 21 F.3d 1558 (Fed. Cir. 1994).

178. O’Quinn, *supra* note 175, at 129–30.

District of Virginia.¹⁷⁹ The patent owner named as defendants a Chinese ceiling fan manufacturer and the New Jersey corporation that imported and distributed the fans throughout the United States.¹⁸⁰ The defendants were not incorporated or headquartered in Virginia and had not established agents for service of process or obtained licenses to do business in the state.¹⁸¹ Yet, the plaintiff sued in Virginia federal court on the grounds that the defendants' infringing products were placed into the stream of commerce, and sold to Virginia customers.¹⁸²

Ultimately, the Federal Circuit concluded that the district court's exercise of specific jurisdiction over the defendants was appropriate because "the situs of the injury is the location, or locations, at which the infringing activity directly impacts on the interests of the patentee" and "the place of the infringing sales [was] Virginia."¹⁸³ Several months later, in *North American Philips Corp. v. American Vending Sales, Inc.*,¹⁸⁴ the Federal Circuit expanded its definition of infringing activity to include "the making, using, or selling of an infringing article."¹⁸⁵ Thus, unless it would be unfair or unreasonable, defendants in most patent infringement cases will be subject to personal jurisdiction anywhere that they make, use, or sell the allegedly infringing products, which is often every state in the country.¹⁸⁶

179. *Beverly Hills Fan*, 21 F.3d at 1559–60.

180. *Id.* at 1560.

181. *Id.*

182. *Id.* at 1560, 1564.

183. *Id.* at 1571; *see also* O'Quinn, *supra* note 175, at 130. The court also determined that the exercise of jurisdiction fell within the parameters of Virginia's "long-arm" statute. VA. CODE ANN. § 8.01-328.1 (1992) (allowing personal jurisdiction over an out-of-state defendant that causes an injury within the state and derives substantial revenue from the sale of goods within the state). When a court reaches beyond its territorial borders to assert personal jurisdiction over a non-resident defendant, it is said to be exercising "long-arm" jurisdiction. Douglas D. McFarland, *Dictum Run Wild: How Long-Arm Statutes Extended to the Limits of Due Process*, 84 B.U. L. REV. 491, 493 (2004). In the wake of *International Shoe*, all states have enacted long-arm statutes which add an additional inquiry to the traditional personal jurisdiction analysis, whereby a court must ask first whether the court's exercise of jurisdiction is authorized by the statute before inquiring into its harmony with due process. *Id.* at 493–96. Some statutes extend jurisdiction to the "limits of due process," while others restrict it to non-residents that have engaged in a specific set of enumerated acts. *Id.* at 496–97. Though Virginia has an enumerated-act statute, courts have construed the statute to reach to the limits of due process. *Id.* at 526–27.

184. 35 F.3d 1576 (Fed. Cir. 1994).

185. *Id.* at 1579.

186. *See Moore, Forum Shopping, supra* note 6, at 894–95.

B. Specific Jurisdiction in Pharmaceutical Patent Cases

After *Daimler*,¹⁸⁷ the test for general jurisdiction is the same in pharmaceutical patent infringement cases as in any other.¹⁸⁸ A court may only exercise general jurisdiction over the defendant corporation if it is “essentially at home” in the forum state¹⁸⁹—that is, where the corporation is incorporated or headquartered.¹⁹⁰ Thus, plaintiffs can no longer rely on a “doing business” theory of general jurisdiction, and must establish instead either that the defendant is subject to general jurisdiction in some other way¹⁹¹ or that the defendant is subject to specific jurisdiction.¹⁹²

However, analyzing specific jurisdiction in the Hatch-Waxman context is complicated. As the filing of an ANDA with a Paragraph IV certification constitutes only an “artificial” act of infringement,¹⁹³ patent infringement in the generic pharmaceutical context “is distinct from other types of patent infringement.”¹⁹⁴ Moreover, because the manufacture, use, or sale of the “infringing article”¹⁹⁵ (i.e., the generic drug) in ANDA cases is by nature not certain to occur, determining the location of the artificial act of infringement is particularly imprecise.¹⁹⁶ Consequently, identifying forums that can exercise specific jurisdiction over defendant corporations is rather difficult.¹⁹⁷

Because all ANDA filers must submit their applications to FDA headquarters in Rockville, Maryland,¹⁹⁸ one likely forum seemed to be the federal courts of

187. 134 S. Ct. 746 (2014).

188. Weisblatt & Frezza, *supra* note 7, at 356 (“Previous justifications for general jurisdiction that rely on an ANDA filer’s ‘substantial, continuous, and systematic course of business’ in a state from sales of drugs, without more, will no longer suffice for the exercise of general jurisdiction.”).

189. *Goodyear Dunlop Tires Operations, S.A. v. Brown*, 131 S. Ct. 2846, 2851 (2011).

190. *Daimler*, 134 S. Ct. at 760; *Hertz Corp. v. Friend*, 559 U.S. 77, 80-81 (2010).

191. For example, a plaintiff might argue that a defendant consented to general jurisdiction in a forum by registering to do business there. *See, e.g., Acorda Therapeutics, Inc. v. Mylan Pharms. Inc.*, 78 F. Supp. 3d 572, 587 (D. Del. 2015) (finding that Mylan had consented to general jurisdiction in Delaware simply by registering to do business there); *but see AstraZeneca AB v. Mylan Pharms. Inc.*, 72 F. Supp. 3d 549, 556–57 (D. Del. 2014) (reaching the opposite conclusion); *see also supra* note 36 and accompanying text.

192. Rhodes & Robertson, *supra* note 121, at 229–30.

193. 35 U.S.C. § 271(e)(2) (2012); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990).

194. O’Quinn, *supra* note 175, at 130 (“ANDA infringement arises from certain filings with the FDA, rather than the ‘making, using, or selling of an infringing article’ described in *North American Phillips*.”).

195. *See Eli Lilly*, 496 U.S. at 678.

196. Weisblatt & Frezza, *supra* note 7, at 352.

197. *Id.* (“Specific jurisdiction . . . permits a plaintiff to hale a defendant into court where the injury took place. Finding that district court is not always an easy task for patent holders in ANDA litigations.”).

198. *Id.*; *Zeneca Ltd. v. Mylan Pharms., Inc.*, 968 F. Supp. 268, 269 (W.D. Pa. 1997), *rev’d*, 173 F.3d 829 (Fed. Cir. 1999).

Maryland.¹⁹⁹ Accordingly, in *Zeneca Ltd. v. Mylan Pharmaceuticals, Inc.*,²⁰⁰ the Federal Circuit addressed whether an out-of-state defendant who merely filed an ANDA in Maryland was subject to personal jurisdiction in that state.²⁰¹ In *Zeneca*, Mylan Pharmaceuticals, Inc. submitted an ANDA with a Paragraph IV certification to the FDA in Maryland, seeking approval to market a generic version of a drug patented and owned by Zeneca Ltd., a British corporation.²⁰² Because Mylan's parent company was incorporated in West Virginia and headquartered in Pennsylvania, Zeneca sued in a Pennsylvania federal court.²⁰³ A "jurisdictional ping pong match" ensued.²⁰⁴ On interlocutory appeal, the Federal Circuit considered whether Maryland could exercise personal jurisdiction over Mylan on the sole basis of Mylan's act of filing an ANDA with the FDA.²⁰⁵

Two Federal Circuit judges concluded that Maryland could not assert personal jurisdiction over Mylan, but differed in rationale.²⁰⁶ Judge Rader determined that Mylan's activities were purposefully directed at the federal government rather than Maryland, and thus, Mylan had not availed itself of the benefits and protections of the forum.²⁰⁷ Judge Gajarsa declined to adopt Judge Rader's

199. See *Zeneca*, 968 F. Supp. at 278 (granting plaintiff's motion to transfer to the Maryland federal district court).

200. 173 F.3d 829 (Fed. Cir. 1999).

201. *Id.* at 831, 834.

202. *Id.* at 830.

203. *Id.*

204. *Id.* at 830, 834. *Zeneca* successfully transferred to Maryland on the grounds that the ANDA submission to the FDA meant Zeneca had been injured in Maryland, and that Mylan had purposefully availed itself to the forum, even though the ANDA submission constituted Mylan's only contacts with the state. *Zeneca Ltd. v. Mylan Pharms., Inc.*, 968 F. Supp. 268, 274 (W.D. Pa. 1997) ("When a defendant purposefully targets its conduct to cause harm in a forum state, it can reasonably expect to be haled into that state's courts. Thus, even a single contact may be sufficient to create jurisdiction, provided that the principle of 'fair play and substantial justice' is observed."). The Maryland district court dismissed the case and sent it back to Pennsylvania for lack of personal jurisdiction. *Zeneca*, 173 F.3d at 830.

205. *Zeneca*, 173 F.3d at 830–31.

206. *Id.* at 831, 834 (Gajarsa, J. concurring & Rader, J. concurring) (concurring in judgment but differing as to whether or not the act of filing an ANDA generates a cause of action and, thus, a contact with Maryland). A third judge gave a silent dissent. *Id.* at 834.

207. *Id.* at 835. Moreover, Judge Rader concluded that the act of submitting an ANDA with a paragraph IV certification did not result in a tangible injury to the patentee at all. *Id.* at 836. Therefore, Mylan was not fairly warned that submitting an ANDA to the FDA might generate litigation in the forum, and the exercise of jurisdiction was unfair. *Id.* With this point, Judge Rader's opinion seems inherently inconsistent. See O'Quinn, *supra* note 175, at 133–34. While he could have reached a finding of no personal jurisdiction solely on the grounds that Mylan did not purposefully direct its activities at Maryland, he made it a point to conclude that the submission of an ANDA did not create a tangible injury, unlike manufacture, use, offers for sale, and sales of infringing products, which form the basis of normal infringement actions. *Id.* Following this line of reasoning, Judge Rader seems to suggest that litigation should not arise from an ANDA submission at all, because of the "artificial" nature of the injury. *Id.* Yet, if "artificial" injury were insufficient for litigation to arise, the appropriate disposition would have been dismissal for lack of

views regarding the location of Mylan's contacts,²⁰⁸ reasoning that Mylan purposefully committed patent infringement in Maryland, and thus, the court could exercise personal jurisdiction over Mylan.²⁰⁹ However, out of concern that granting jurisdiction solely on the basis of ANDA submissions to the FDA would create a "supercourt" for generic infringement cases,²¹⁰ Judge Gajarsa invoked the "government contacts exception," whereby entry into a jurisdiction for the sole purpose of petitioning a federal agency does not form a basis for personal jurisdiction.²¹¹ Though *Zeneca* eliminated Maryland as a viable forum for cases resting solely on the grounds that the ANDA was submitted to the FDA,²¹² the Federal Circuit left open the possibility that additional contacts could have existed which would have warranted the exercise of personal jurisdiction.²¹³

IV. ANALYZING THE ASTRAZENECA AND ACORDA I OPINIONS

Since *Zeneca*, other federal courts have analyzed ANDA filers' contacts under different theories of specific personal jurisdiction, with a somewhat mixed bag of results.²¹⁴ Two recently-decided cases in Delaware federal court, *AstraZeneca AB v. Mylan Pharmaceuticals, Inc.*²¹⁵ and *Acorda Therapeutics,*

standing (i.e., for lack of an injury-in-fact), not personal jurisdiction. But such a conclusion contradicts the express language of the Hatch-Waxman Act establishing an "act of infringement" and the Supreme Court's holding in *Eli Lilly*, calling it a "highly artificial act of infringement." *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). And moreover, if the act of submitting an ANDA with a paragraph IV certification did not "give rise" to the litigation in *Zeneca*, then what activities did is unclear.

208. *Zeneca*, 173 F.3d at 833–34. More specifically, Judge Gajarsa disagreed with Judge Rader's conclusion that the act of submitting an ANDA with a Paragraph IV certification did not create an injury. *Id.* Instead, he reasoned that the submission is both a "highly artificial" act of infringement and a "real act with actual consequences," and that more specifically, it generates a cause of action of patent infringement in federal court. *Id.*

209. *Id.* at 830, 833–34.

210. *Id.* at 832 (observing that "[n]ot even *Zeneca* attempts to argue that the purpose of the Hatch-Waxman Act was to create such a supercourt").

211. *Id.* at 831–32 (reasoning that Mylan's singular contact with Maryland was a result of its intent to petition the government for the right to market its generic drug and a consequence of the fact that the FDA resides in Maryland).

212. O'Quinn, *supra* note 175, at 135. It should be noted, however, that had it not been for his concerns of a supercourt, Judge Gajarsa explicitly stated that Mylan did in fact have sufficient contacts in Maryland for the exercise of specific jurisdiction. *Zeneca*, 173 F.3d at 833–34. Considering a third judge gave a silent dissent, had Judge Gajarsa not invoked the government contracts exception, Maryland would likely be an appropriate forum today for most, if not all, ANDA cases.

213. *See id.* at 834.

214. *See Weisblatt & Frezza, supra* note 7, at 352–53 (determining that courts have generally found an ANDA filer's "intention to sell drugs within the state . . . insufficient to exercise specific jurisdiction" but that "[p]atent holders have successfully asserted specific jurisdiction over ANDA filers based on where the ANDA was prepared").

215. 72 F. Supp. 3d 549 (D. Del. 2014).

Inc. v. Mylan Pharmaceuticals, Inc. (“*Acorda I*”),²¹⁶ highlighted that the law was far from settled.

A. *AstraZeneca and Acorda I Case Facts*

In *AstraZeneca*, Mylan filed two ANDAs with Paragraph IV certifications seeking FDA approval to market generic versions of AstraZeneca’s diabetes medication ONGLYZA® prior to the expiration of AstraZeneca’s patents, prompting infringement litigation.²¹⁷ Though Mylan was incorporated and headquartered in West Virginia²¹⁸ and its parent incorporated and headquartered in Pennsylvania,²¹⁹ AstraZeneca filed its suit in Delaware federal district court, where its U.S. subsidiary was incorporated and had its principal place of business.²²⁰ Mylan had prepared both of its ANDAs in West Virginia and filed them with the FDA in Maryland, but mailed a “notice letter” to AstraZeneca in Delaware, informing AstraZeneca of the ANDA filing.²²¹ Additionally, while Mylan did not own property in Delaware, it derived substantial revenue from product sales there, registered to do business there, and appointed an agent for service of process²²² in accordance with two Delaware statutes governing foreign corporations seeking to do business in the state.²²³ In addition, Mylan registered with the Delaware Board of Pharmacy as a licensed wholesaler and distributor/manufacture of pharmaceutical products.²²⁴ In the twenty years leading up to the litigation with AstraZeneca, Mylan initiated six lawsuits in Delaware, but defended several more in Delaware during that time.²²⁵

Acorda I presented a similar set of facts and procedural history. In that case, Mylan filed an ANDA with a Paragraph IV certification seeking FDA approval to market a generic version of Acorda’s Ampyra®,²²⁶ a drug that treats Multiple Sclerosis, prior to the expiration of Acorda’s patents.²²⁷ Mylan, again, was incorporated and headquartered in West Virginia.²²⁸ It prepared its ANDA in West Virginia, and submitted the ANDA to the FDA in Maryland.²²⁹ It also

216. 78 F. Supp. 3d 572 (D. Del. 2015).

217. *AstraZeneca*, 72 F. Supp. 3d at 551.

218. *Id.* at 552.

219. *Acorda*, 78 F. Supp. 3d at 578.

220. *AstraZeneca*, 72 F. Supp. 3d at 552.

221. *Id.* at 552, 559.

222. *Id.* at 552.

223. *Id.* at 556 (citing DEL. CODE ANN. tit. 8 §§ 371, 376 (West 2016)).

224. *Acorda*, 78 F. Supp. 3d at 577.

225. *AstraZeneca*, 72 F. Supp. 3d at 555.

226. *Acorda*, 78 F. Supp. 3d at 577 (referring to Ampyra® as Acorda’s “flagship drug product”).

227. *Id.* at 577–78.

228. *Id.* at 577.

229. *Id.* at 578.

mailed a notice letter to Acorda at its principal place of business in New York.²³⁰ Acorda brought a patent infringement suit in federal district court in Delaware, Acorda's state of incorporation.²³¹

Mylan filed a motion to dismiss in both cases on the grounds that it was not subject to the Delaware courts' exercise of personal jurisdiction.²³² Though both district court judges ultimately decided that Mylan was subject to specific personal jurisdiction in Delaware,²³³ they split on the issue of whether Mylan consented to general personal jurisdiction by registering to do business in Delaware.²³⁴ The general jurisdiction issue is an important one that ultimately needs to be resolved,²³⁵ but these two cases raise key questions about specific jurisdiction that will substantially affect Hatch-Waxman cases in the future.

B. The Delaware Courts' Approaches to Specific Jurisdiction

Each court took a similar approach to resolving the specific jurisdiction inquiry. First, it applied the minimum contacts analysis to Mylan's contacts with the State of Delaware.²³⁶ Second, it discussed the policies underlying the Hatch-Waxman Act and the effect that the failure to exercise personal jurisdiction in the state would have on those policies, asking *if not in Delaware, then where?*²³⁷

The court in *AstraZeneca* began its minimum contacts analysis by engaging in a general discussion of the unique nature of ANDA litigation.²³⁸ It recognized that the "highly artificial" nature of the infringement generated by filing an ANDA with a Paragraph IV certification made it difficult to find a location from

230. *Id.* at 579.

231. *Id.* at 577, 579.

232. *Id.* at 579; *AstraZeneca AB v. Mylan Pharms., Inc.*, 72 F. Supp. 3d 549, 552 (D. Del. 2015).

233. *Acorda*, 78 F. Supp. 3d at 592–97; *AstraZeneca*, 72 F. Supp. 3d at 557–60.

234. *Acorda*, 78 F. Supp. 3d at 583–92; *AstraZeneca*, 72 F. Supp. 3d at 555–57.

235. It should be noted again, however, that the Delaware Supreme Court recently reversed its long-standing rule that registration to do business in Delaware constitutes consent to general jurisdiction in the forum. *See supra* note 27 and accompanying text. Accordingly, the issue has been resolved in Delaware. However, it still requires resolution in other jurisdictions. *See generally* John D. Donovan, Jr. & Gregg L. Weiner, *Genuine Parts Co. v. Cepec: Business Registration and Personal Jurisdiction*, HARV. L. SCH. F. ON CORP. GOVERNANCE & FIN. REG. (May 14, 2016), <https://corpgov.law.harvard.edu/2016/05/14/genuine-parts-co-v-cepec-business-registration-and-personal-jurisdiction/> (arguing that the Delaware Supreme Court "got it right" and explaining that "the issue is still being tested in other courts").

236. *Acorda*, 78 F. Supp. 3d at 592–98; *AstraZeneca*, 72 F. Supp. 3d at 557–60.

237. *Acorda*, 78 F. Supp. 3d at 596 ("[I]dentifying a physical place where Acorda is injured by an ANDA submission is difficult, as a corporation is not a natural person, and [the] injury here is 'highly artificial.' Mylan argues this means Acorda is not injured anywhere. But it is more logical to conclude that Acorda is injured, *somewhere*." (citations omitted); *AstraZeneca*, 72 F. Supp. 3d at 558–59 ("Mylan argues its activities are not purposefully directed at the state of Delaware, where AstraZeneca U.S. is organized. Mylan's argument, however, creates the untenable position that its conduct is not directed to any jurisdiction.") (citations omitted).

238. *AstraZeneca*, 72 F. Supp. 3d at 557–60.

which the injury “arises,” but refused to accept Mylan’s “untenable” position that the “abstract” nature of the injury meant that its conduct was not directed at any jurisdiction.²³⁹ Rather, as Maryland was eliminated as an appropriate forum by the Federal Circuit in *Zeneca*, and because the consequences of Mylan’s conduct were suffered in Delaware, the court concluded that the only possible alternative forum was the patent-holder’s state of residence.²⁴⁰ Moreover, the court noted that Mylan had more than just “illusory” contacts²⁴¹ because it had sent its Paragraph IV certification letter to AstraZeneca in the state.²⁴² Accordingly, it found that the cause of action arose immediately from Mylan’s contacts in Delaware, and the first prong of the minimum contacts test—the nexus requirement—was satisfied.²⁴³ Next, the court rejected Mylan’s argument that it did not reasonably anticipate being haled into Delaware court because patent litigation was integral to Mylan’s business, and thus, found that Mylan had purposefully availed itself of the forum.²⁴⁴ Finally, because Mylan was a frequent litigator in Delaware,²⁴⁵ and in light of the substantial burden that would be placed on AstraZeneca if it were forced to sue in every ANDA filer’s home state,²⁴⁶ the court concluded that Delaware’s exercise of personal jurisdiction comported with traditional fairness principles.²⁴⁷ Thus, the court was “convinced” that Mylan’s acts provided contacts sufficient to support the exercise of specific jurisdiction in Delaware.²⁴⁸

The *Acorda I* court reached the same conclusion through slightly different means.²⁴⁹ First, the court determined that the litigation arose from and was related to Mylan’s contacts that had been and were expected to be directed towards Delaware.²⁵⁰ More immediately, the litigation derived from the notice letter Mylan had sent to Acorda, a Delaware corporation that had already started litigating disputes against generic versions of Ampyra® in the forum.²⁵¹ Thus,

239. *Id.* at 558–59.

240. *Id.*

241. *Id.* at 559.

242. *Id.*

243. *Id.* at 558–59. The court did not consider whether Mylan’s other contacts were sufficient to satisfy the nexus requirement’s “relate to” language, presumably because, after concluding that Mylan’s contacts met the more demanding “arise from” language, any such determination would have just been dicta.

244. *Id.* at 559.

245. *Id.* at 560.

246. *Id.*

247. *Id.*

248. *Id.* at 559.

249. *Acorda*, 78 F. Supp. 3d at 593.

250. *Id.* (“This suit arises from Mylan’s ANDA filing, which is a prerequisite to obtaining FDA approval, which is necessary in order to sell Mylan’s generic product in the United States, including in Delaware.”).

251. *Id.* The *Acorda I* court recognized the fact that Mylan’s certification letter was sent into New York rather than Delaware, like it was in *AstraZeneca*. *Id.* at 595–96. However, it reasoned that while mailing a notification into Delaware undoubtedly serves as a contact with the state, its

Mylan knew or should have known that Acorda was almost certain to sue in Delaware.²⁵² Moreover, as Mylan had registered to do business there, had appointed an agent for service of process there, had registered with the Delaware Board of Pharmacy, and was a frequent litigant in the state, the court found that Mylan had purposefully directed its activities at Delaware.²⁵³ Finally, finding Mylan's burden slight given its frequent presence in the state, Delaware's interest significant given its ongoing relationship with Acorda, and Acorda's interest substantial given the location of other Ampyra® litigation, the court concluded that the exercise of specific jurisdiction was fair and reasonable.²⁵⁴

C. Framing the Issues in Acorda II

Acorda I and *AstraZeneca* presented the Federal Circuit with a gluttony of issues, manifested by a schizophrenic line of questioning at oral argument.²⁵⁵ Yet, the richest set of questions existed in the specific jurisdiction context. Across both cases, Mylan's uncontroverted contacts within Delaware were relatively consistent.²⁵⁶ Mylan registered to do business and appointed an agent for service of process in Delaware, and registered with the Delaware Board of Pharmacy.²⁵⁷ It had previously sold drugs in the state, and had been involved in other lawsuits there as well.²⁵⁸ Mylan filed ANDAs with respect to patents owned by two Delaware companies, and sent notice to *AstraZeneca* in Delaware—though it sent notice to Acorda in New York.²⁵⁹ Beyond that, Mylan's contacts were a bit more controversial.

One potential contact with Delaware was debatable—that is, the location where the infringement occurred.²⁶⁰ The Federal Circuit could have decided that the submission of an ANDA with a Paragraph IV certification creates an artificial act of infringement in every state where the patent-holder sells any of

absence does not eliminate the possibility of suit there. *Id.* at 596. In particular, the *Acorda I* court found that, by filing the ANDA, Mylan caused an injury to Acorda which was felt in its state of incorporation, Delaware. *Id.*

252. *Id.* at 593.

253. *Id.*

254. *Id.* at 595.

255. Oral Argument, *Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, 78 F. Supp. 3d 572 (D. Del. 2015) (No. 2015-1456), <http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2015-1456.mp3>; Oral Argument, *AstraZeneca AB v. Mylan Pharms. Inc.*, 72 F. Supp. 3d 549 (D. Del. 2014) (No. 2015-1460), <http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2015-1460.mp3>.

256. *Acorda*, 78 F. Supp. 3d at 577; *AstraZeneca*, 72 F. Supp. 3d at 552.

257. *Acorda*, 78 F. Supp. 3d at 577; *AstraZeneca*, 72 F. Supp. 3d at 552.

258. *AstraZeneca*, 72 F. Supp. 3d at 552, 555.

259. *Acorda*, 78 F. Supp. 3d at 579; *AstraZeneca*, 72 F. Supp. 3d at 552, 559.

260. *Acorda*, 78 F. Supp. 3d at 596 (“[I]t seems logical to conclude that the state of incorporation is at least one place in which a corporation whose patents are artificially infringed by an ANDA filing is injured. For Acorda, that is Delaware.”); *AstraZeneca*, 72 F. Supp. 3d at 558 (“ANDA litigation is unlike other patent infringement litigation: The injury is abstract, making it difficult to point to a location out of which the injury ‘arises’ for jurisdictional purposes.”).

its drugs (including Delaware),²⁶¹ or that it creates an artificial act of infringement only in the place where the patent-holder holds the patent (Delaware),²⁶² or that it creates an artificial act of infringement where the generic intends to sell, which for generic drug companies would presumably be all fifty states.²⁶³ If the court reached any of these conclusions, the nexus requirement would likely be satisfied under *any* nexus test in Hatch-Waxman cases, because the injury would likely be a contact with the forum “giving rise” to the litigation.²⁶⁴ In any event, the question seemed unnecessary to decide because, under a broad interpretation of the nexus requirement, the litigation “related to” Mylan’s uncontroverted contacts in the forum, and thus, Mylan was subject to specific jurisdiction in Delaware.

D. The Federal Circuit’s Ruling in *Acorda II*

A Federal Circuit panel issued one ruling for both cases on March 18, 2016.²⁶⁵ Giving the opinion of the court, Judge Richard Taranto decided the cases on specific jurisdiction grounds alone.²⁶⁶ More critically, the analysis turned substantially upon Mylan’s contacts under the nexus requirement.²⁶⁷ However, the court declined to adopt a particular nexus test, avoiding the *Helicopteros* language almost entirely and relying instead on the ambiguous requirements

261. This finding has been reached in other infringement contexts. For instance, a New York court recently found that the uploading of a copyrighted work to the Internet creates an act of copyright infringement in every state where the copyrighted work is sold, because it could be downloaded anywhere. *See Penguin Grp. (USA) Inc. v. Am. Buddha*, 946 N.E.2d 159, 163–64 (N.Y. 2011).

262. This seemed less likely before *Acorda II* because of the Federal Circuit’s holding in *Beverly Hills Fan*, which concluded that a patent holder suffers the infringement injury in the place where competing sales are made, not where the patent is held, though that case is distinguishable because it did not involve an ANDA-created infringement. *See Beverly Hills Fan Co. v. Royal Sovereign Corp.*, 21 F.3d 1558, 1571 (Fed. Cir. 1994). However, in *Acorda I*, the court found that the “highly artificial” infringement injury generated by submission of an ANDA with a paragraph IV certification must occur *somewhere*, and that, given the Supreme Court’s holding in *Daimler* that a corporation is “at home” where incorporated, it “seems logical to conclude that the state of incorporation is at least one place in which a corporation whose patents are artificially infringed by an ANDA filing is injured.” *Acorda*, 78 F. Supp. 3d at 596.

263. This approach also seemed a bit unlikely to be favored by the Federal Circuit in *Acorda II* because intent to make future sales seems rather difficult to quantify.

264. *See Calder v. Jones*, 465 U.S. 783, 791 (1984) (finding that defendants were subject to personal jurisdiction in a forum because their intentional out-of-forum conduct was “calculated to cause injury” to the plaintiff in the forum, even though they had no other relevant contacts there); *but see Walden v. Fiore*, 134 S. Ct. 1115, 1125 & n.9 (2014) (reasoning that “[t]he proper question is not where the plaintiff experienced a particular injury or effect but whether the defendant’s conduct connects him to the forum in a meaningful way[.]” but leaving open the question whether a defendant’s conduct and “virtual ‘presence’” in a forum could translate into contacts).

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

266. *Id.* at 757.

267. *Id.* at 759–63.

from *Walden* that a defendant's "suit-related" conduct must create a "substantial connection" with the forum.²⁶⁸

At the crux of the court's "substantial connection" analysis was its understanding of what filing an ANDA means in practical terms.²⁶⁹ ANDA filings, it reasoned, are "tightly tied, in purpose and planned effect, to the deliberate making of sales" in a generic's intended marketing forum.²⁷⁰ Moreover, as the corresponding suit involves "whether that in-State activity will infringe valid patents," an ANDA filing is a reliable indicator of a generic's plans to market the drug in its intended forum.²⁷¹ Thus, where intent to market is evident, the connection would be substantial, and the conduct would be "suit-related."²⁷²

The court found Mylan's intent to market in Delaware without much trouble. In particular, Mylan registered to do business, appointed an agent for process, and registered with the Delaware Board of Pharmacy, representing on its certificate of registration that it "intend[ed] to engage in pharmaceutical manufacturing, distribution and sales" in the state.²⁷³ Moreover, Mylan admitted that it develops drugs for the entire country and that it "does some business in every State, either directly or indirectly."²⁷⁴ Thus, the court reasoned that Mylan "undisputedly" planned to sell *these particular* drugs in Delaware once its ANDAs were approved.²⁷⁵ Furthermore, the court was unconvinced that a finding of specific jurisdiction could not be reached on the basis of planned future conduct.²⁷⁶ Thus, because the connection between Mylan's planned acts and the litigation was "close enough," Mylan's conduct "[g]ave rise and [was] related to the suit."²⁷⁷

The court also made a point to address the concurrence's concern that Mylan's allegedly infringing drugs might never actually be marketed in Delaware.²⁷⁸ It reasoned that, even if Mylan never sells directly in Delaware, the purposeful availment prong would still be satisfied in light of Mylan's network of wholesalers and distributors in the state, which demonstrated that Mylan places products in the stream-of-commerce with the intent of reaching Delaware.²⁷⁹ Lastly, the court reasoned that the fairness prong of the specific jurisdiction

268. *Id.* at 760 (citing *Walden*, 134 S. Ct. at 1121).

269. *Id.*

270. *Id.*

271. *Id.*

272. *Id.*

273. *Id.* at 763 (internal alterations omitted).

274. *Id.*

275. *Id.* at 760.

276. *Id.* at 762.

277. *Id.*

278. *Id.* at 763; *see also id.* at 770 (O'Malley, J., concurring).

279. *Id.* at 763 (citing *Beverly Hills Fan Co. v. Royal Sovereign Corp.*, 21 F.3d 1558, 1565 (Fed. Cir. 1994)).

analysis was satisfied, given the “modest” burden on Mylan and the more significant countervailing interests of the plaintiffs and the State of Delaware.²⁸⁰ Accordingly, Delaware’s exercise of specific personal jurisdiction was deemed appropriate.²⁸¹

Concurring in the judgment, Judge Kathleen O’Malley found Delaware’s exercise of personal jurisdiction appropriate on both general and specific jurisdiction grounds.²⁸² Concerned with Judge Taranto’s reliance on Mylan’s “expressions of future intent,”²⁸³ however, Judge O’Malley found specific jurisdiction by ruling that Mylan’s ANDA filings were acts “calculated and directed to cause harm to the intellectual property rights” of Acorda and AstraZeneca in their place of incorporation, Delaware.²⁸⁴ Though the “intent” concerns were certainly valid, this ruling would lead to an untenable position, whereby specific jurisdiction would never be warranted at the “place of the patent” because of an *actual* patent infringement,²⁸⁵ but could always occur at the “place of the patent” if the patent infringement is merely *artificial*.²⁸⁶ In any event, neither the majority nor the concurrence issued the type of finding that ANDA cases so desperately need—a clarification of the Federal Circuit’s nexus standard.

280. *Id.* at 763–64.

281. *Id.* at 764.

282. *Id.* at 773 (O’Malley, J., concurring).

283. *Id.* at 770 (emphasis omitted).

284. *Id.* at 772.

285. *See Beverly Hills Fan Co. v. Royal Sovereign Corp.*, 21 F.3d 1558, 1571 (Fed. Cir. 1994) (finding that the situs of patent injuries is at the place of infringing sales, not the place of the patent); *AstraZeneca AB v. Mylan Pharms. Inc.*, 72 F. Supp. 3d 549, 558-60 (D. Del. 2014).

286. *See Acorda*, 817 F.3d at 772 & n.2 (O’Malley, J., concurring). Even though this theory was advanced by the concurrence only, at least one court has interpreted the *Acorda II* majority’s ruling to stand for this proposition as well. In a recent Delaware District Court decision, Judge Gregory M. Sleet (notably, the author of the *AstraZeneca* opinion) determined that the *Acorda II* court held that “the act of filing an ANDA application that potentially infringes the patent of a Delaware entity provides sufficient minimum contacts with the state of Delaware under a specific jurisdiction analysis.” *Millenium Pharms., Inc. v. Pharmascience Inc.*, No. 15-702-GMS, 2016 WL 3382131, at *1 (D. Del. Jun. 10, 2016). In fact, even though the defendant Millenium Pharmaceuticals, Inc. was a Canadian corporation which did not have its principal place of business in Delaware, was not incorporated in Delaware, had not registered to business in Delaware, did not have an agent for service of process in Delaware, had not prepared its ANDA in Delaware, had not sent its Paragraph IV notification letter to Delaware, and had never sold drugs in Delaware—it had never even imported drugs into the United States—the court found that Delaware’s exercise of personal jurisdiction was appropriate under *Acorda II*. *Millenium*, 2016 WL 3382131, at *3.

V. A PERMISSIVE NEXUS STANDARD IS NEEDED IN ANDA CASES

A. *The Federal Circuit Should Have Used Acorda II to Clarify its Preferred Nexus Test*

In the patent context, Federal Circuit law governs over regional circuits, even when considering procedural questions like the requirements of personal jurisdiction,²⁸⁷ unless of course Supreme Court precedent dictates otherwise. As the Supreme Court has not yet resolved the issue in general,²⁸⁸ going forward, the Federal Circuit's nexus approach under *Acorda II* is authoritative in all ANDA cases. Thus, under *Acorda II*, a court must ask whether a defendant's "suit-related" conduct created (or rather, would create) a "substantial connection" to the forum.²⁸⁹ From *Acorda II*, we know that the "substantial connection" will be satisfied when the evidence "reliably indicates" that the generic intends to direct its products at the forum.²⁹⁰ In particular, that intent for future conduct can be established by showing that the ANDA filer registered to do business, provided an agent for service of process, and registered with a Board of Pharmacy in the forum, so long as the company also develops its drugs for the entire U.S. market.²⁹¹

Yet, basing personal jurisdiction on potential future conduct is problematic, as it is unclear whether future contacts should even be considered in a personal jurisdiction analysis.²⁹² And to the extent future contacts are relevant to the

287. *Akro Corp. v. Luker*, 45 F.3d 1541, 1543 (Fed. Cir. 1995); *Beverly Hills Fan*, 21 F.3d at 1564.

288. *See Avocent Huntsville Corp. v. Aten Int'l Co., Ltd.*, 552 F.3d 1324, 1330 (Fed. Cir. 2008) (observing that "the nexus necessary to satisfy the 'arise out of or related to' requirement of the due process inquiry has not been clearly delineated by the Supreme Court," and proceeding to set forth the governing law of the Federal Circuit).

289. *Acorda*, 817 F.3d at 760.

290. *Id.*

291. *Id.* at 763.

292. *See, e.g., Eli Lilly & Co. v. Nang Kuang Pharm. Co., Ltd.*, No. 1:14-cv-01647-TWP-DKL, 2015 WL 3744557, at *1 (S.D. Ind. Jun. 15, 2015) (denying a request for discovery related to the jurisdictional contacts that would exist upon defendants' ANDA approval, because "personal jurisdiction cannot be based on future contacts, even if such contacts are allegedly inevitable") (internal alterations omitted); *Koninklijke Phillips N.V. v. Digital Works, Inc.*, No. 2:13-cv-01341-JAD-NJK, 2014 WL 3816395, at *3 (D. Nev. Aug. 4, 2014) (finding no specific jurisdiction where the "jurisdictional basis [was] one of potential future contacts only"); *see also* *Petition for Writ of Certiorari*, *supra* note 35, at *19–20 (highlighting backward-looking language in the Supreme Court's line of personal jurisdiction cases, and arguing that "to determine whether a claim arises out of a contact with the forum state, one must necessarily look back, not forward"); *but see, e.g., Acorda*, 817 F.3d at 762 ("Mylan does not meaningfully develop an argument that a rigid past/future dividing line governs the minimum-contacts standard. Specifically, Mylan does not show that a State is forbidden to exercise its judicial power to prevent a defendant's planned future conduct in the State, but must wait until the conduct occurs."); *Pervasive Software, Inc. v. Lexware GMBH & Co. KG*, 688 F.3d 214, 223 (5th Cir. 2012) (in a breach of contract suit, finding that "contemplated future consequences" of prior negotiations "must be evaluated in determining whether the defendant purposefully established minimum contacts with the forum").

analysis, “expressions of future intent” will not always be so obvious.²⁹³ For instance, even if a generic could introduce reliable evidence to show that it has absolutely no intent to sell a particular drug in a particular forum, arguably, a pioneer could always trump the generic’s showing by pointing to the same “undisputed” evidence of intent that was relied upon by the *Acorda II* majority.²⁹⁴ While any due process concerns should ultimately be caught in the “fairness” prong of the minimum contacts inquiry, disallowing evidence of non-intent simply because the “substantial connection” analysis indicates the existence of intent is counterintuitive.

Moreover, if a future defendant’s contacts do not directly mirror Mylan’s (e.g., because a state’s regulatory scheme differs), a court’s “substantial connection” analysis is completely unpredictable.²⁹⁵ Accordingly, the Federal Circuit missed an excellent opportunity to clear up confusion for litigants involved in an already-complex area of procedural and substantive law. Instead, *Acorda II* just added another layer of complexity.

B. The Federal Circuit Should Have Officially Adopted the “Sliding Scale” Test

An easier, and more effective, approach for the Federal Circuit to take would have been to reaffirm (or at least clarify) its previous nexus standard. Prior to *Acorda II*, the Federal Circuit preferred a permissive interpretation which emphasized the disjunctive nature of the “arise out of or relate to” language, and which was more flexible than a strict “arise out of” standard.²⁹⁶ This approach was arguably akin to the “sliding scale” test adopted in some circuits, whereby courts consider the totality of the circumstances, balancing (1) the closeness of a defendant’s contacts to the litigation, with (2) the quality and quantity of those contacts.²⁹⁷ Accordingly, the less related the contacts are, the more quality and quantity is needed to support the exercise of jurisdiction, and *vice versa*.²⁹⁸ Under this test, the Federal Circuit would have likely found that Mylan’s uncontroverted contacts with Delaware satisfied the nexus requirement of the specific jurisdiction analysis, without needing to reach an “undisputed” finding of future intent.

Specifically, Mylan registered to do business in Delaware, registered with the Delaware Board of Pharmacy, derived significant revenues from previous sales of its products in Delaware, and filed ANDAs with the FDA that threatened to

293. *Id.* at 770 (O’Malley, J., concurring) (emphasis removed).

294. *See id.* at 759–60, 762–63.

295. *See supra* note 164 and accompanying text.

296. *See Avocent Huntsville Corp. v. Aten Int’l Co., Ltd.*, 552 F.3d 1324, 1337 (Fed. Cir. 2008); *Inamed Corp. v. Kuzmak*, 249 F.3d 1356, 1362 (Fed. Cir. 2001); *Akro Corp. v. Luker*, 45 F.3d 1541, 1547 (Fed. Cir. 1995).

297. Moore, *The Relatedness Problem*, *supra* note 154, at 593.

298. *Id.*

cut short the patent terms of drugs held by two Delaware companies.²⁹⁹ Though it could not be said that any of those contacts immediately “gave rise” to the litigation, they are certainly closely “related to” Acorda and AstraZeneca’s claims. In fact, considering ANDA litigation arises from the “highly artificial act of infringement” generated *at the moment* a generic company files an ANDA with the FDA, Mylan’s contacts are about as “close” as it gets.³⁰⁰ Moreover, under the sliding scale, Mylan’s contacts are of the requisite “quality and quantity.”³⁰¹ Specifically, as one of the biggest generic drug manufacturers in the country, Mylan sells its drugs in every state, including Delaware.³⁰² Pursuant to Delaware’s statutory registration scheme, it is set up to continue selling pharmaceuticals in the state, provided that whatever drugs it intends to sell are first approved and determined by the FDA to not infringe another company’s patents.³⁰³ By filing ANDAs against Acorda and AstraZeneca’s patents, Mylan seeks to convince the FDA of exactly that.³⁰⁴

In effect, Mylan is locked and loaded, ready to start selling in Delaware as soon as it is legally permitted. Thus, on balance, Mylan’s contacts would have been “substantial” enough to warrant the exercise of personal jurisdiction in Delaware under the “sliding scale” test.³⁰⁵ Though the *Acorda II* “substantial connection” analysis ultimately reached the same conclusion, adopting the “sliding scale” would have confirmed the Federal Circuit’s preference for a permissive nexus standard, and more importantly, it would have given lower courts a cognizable standard which could have been easily replicated. In any event, some important policy considerations weigh in favor of confirming a permissive nexus test in future ANDA cases.

299. *AstraZeneca AB v. Mylan Pharms., Inc.*, 72 F. Supp. 3d 549, 552–53 (D. Del. 2014).

300. *Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, 78 F. Supp. 3d 572, 596 (D. Del. 2015). This argument is even stronger for AstraZeneca, as Mylan actually sent notification of the Paragraph IV certification to AstraZeneca in Delaware. However, as the court was quick to make clear in *Acorda I*, though mailing such a letter is undoubtedly an “additional activity” directed at the forum, it is not an outcome determinative one for the purposes of specific jurisdiction. *Id.* And in either case, Mylan’s other contacts would be sufficiently “close” to satisfy the test.

301. *See Metallo*, *supra* note 140, at 434.

302. *Acorda Therapeutics, Inc. v. Mylan Pharms., Inc.*, 817 F.3d 760, 763 (Fed. Cir. 2016).

303. *AstraZeneca*, 72 F. Supp. 3d at 556 (citing DEL. CODE ANN. tit. 8 §§ 371, 376 (2016)); *see also* *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002).

304. *AstraZeneca*, 72 F. Supp. 3d at 551.

305. Notably, the Supreme Court of California actually considers the substantial connection test and the sliding scale test to be interchangeable legal standards. *Bristol-Myers Squibb Co. v. Superior Court of San Francisco Cty.*, 377 P.3d 874, 885 (Cal. Aug. 29, 2016) (“Under the substantial connection test, the intensity of the forum contacts and the connection of the claim to those contacts are inversely related. The more wide ranging the defendant’s forum contacts, the more readily is shown a connection to the forum contacts and the claim.”); *see also id.* at 889 (recognizing that the court had previously “made clear that [it] had adopted a sliding scale approach to specific jurisdiction in which [it] recognized that the more wide ranging the defendant’s forum contacts, the more readily is shown a connection to the forum contacts and the claim.”).

C. Public Policy Considerations Favor a Lenient Nexus Test in Hatch-Waxman Cases

Disregarding the various approaches to the nexus requirement for just a moment, the Supreme Court explicitly *left open* the question whether “arise out of” and “relate to” are interchangeable or distinctive terms in *Helicopteros*, and has refused to address the question since then.³⁰⁶ Thus, even though many courts view the nexus requirement through the prism of tort law causation standards—using tests that sound much more like “arise out of” than “arise out of or relate to”³⁰⁷—it is certainly possible that the Court intended the nexus requirement to treat some or all plaintiffs’ claims with leniency, at least at such an early phase of the specific jurisdiction analysis. In fact, when considered within the context of the other specific jurisdiction prongs, it seems likely that leniency is exactly what the Court had in mind. Specifically, even if the litigation were to only “relate to” the defendant’s contacts with the forum, the defendant would still need to have purposefully availed itself to the forum, and the exercise of jurisdiction would still need to pass the fairness test.³⁰⁸ In fact, the Supreme Court has arguably adopted a sliding scale-like balancing test for the other prongs of the specific jurisdiction analysis already.³⁰⁹

A rigid nexus standard would make the exercise of specific jurisdiction nearly impossible in certain instances, an outcome which is hard to swallow, especially in light of the recent tightening of general jurisdiction under *Daimler* and *Goodyear*. Paragraph IV certification litigation highlights this problem, and calls to mind Justice Brennan’s premonitions in his *Helicopteros* dissent—a rigid nexus requirement “subject[ing] constitutional standards under the Due Process Clause to the vagaries of the substantive law. . . .”³¹⁰ Because, by definition, infringement arises almost out of thin air upon the submission of an ANDA to the FDA, there are no physical contacts *giving rise* to the litigation other than the ANDA submission. Though Mylan willingly admitted it was subject to general jurisdiction in West Virginia and conceded that it was subject to specific jurisdiction in West Virginia because it engaged in its pre-submission activities there, can it really be said that the mere act of filling out an ANDA “gave rise” to the litigation?³¹¹ Considering all filers must submit their ANDAs

306. See *supra* Sections II.C.1–2.

307. See *supra* Section II.C.2.

308. See *supra* Section II.B.

309. See *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 477–78 (1985) (explaining that a “lesser showing” of minimum contacts can be overcome with a strong demonstration of fairness, and that where purposeful availment is clearly satisfied, a defendant must make a “compelling case” that the exercise of personal jurisdiction would be unfair).

310. *Helicopteros Nacionales de Colombia, S.A. v. Hall*, 466 U.S. 408, 427 (1984) (Brennan, J., dissenting).

311. See *AstraZeneca AB v. Mylan Pharms., Inc.*, 72 F. Supp. 3d 549, 559–60 n.13 (D. Del. 2014) (stating that “[s]everal district courts have found that the state in which the ANDA is prepared . . . is the proper forum for the exercise of specific jurisdiction [but t]he court is not convinced that the focus should be on [this] factor[.]” and reasoning that “the act of merely *preparing* an ANDA

to FDA headquarters, the most logical place for Hatch-Waxman litigation would seemingly be Maryland. However, the Federal Circuit explicitly shut Maryland down as a viable forum in *Zeneca* out of fear that it would become a “supercourt.”³¹²

Thus, had the Federal Circuit not identified the forums in which a generic intends to sell as proper, patent holders would have been left with only two forums in which they could plausibly obtain relief under a rigid nexus standard—the defendant’s principal place of business, or its place of incorporation.³¹³ In other words, in an ANDA litigation context, a rigid nexus test would limit the exercise of personal jurisdiction to general jurisdiction *only*. Such a result would be far-removed from the original intent of the Hatch-Waxman Act, which again, sought to *balance* two interests: “(1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market.”³¹⁴ Yet, when a generic files a Paragraph IV certification, which effectively means that it (1) intends to release a competing drug into the market during the pioneer’s patent term,³¹⁵ and (2) believes the patent is “invalid or will not be infringed” by the drug’s release,³¹⁶ the generic would be afforded the right to “hole up” in its home forum and let the pioneer bring the fight to it. In the wrong jurisdiction, that could easily become a perpetually losing fight for pioneer drug companies. In fact, were such a generic-friendly forum to come into existence, it might likely attract other generic companies to incorporate and set up their headquarters there, which in turn might attract more litigation.³¹⁷ In other words, such a forum could plausibly lead to a “supercourt,” much like the one Judge Gajarsa sought to avoid in Maryland in his *Zeneca* opinion.³¹⁸

What would the pioneer’s options be at that point? (1) Sue in the generic’s home state, where it would likely be subject to a greater risk of losing.³¹⁹ (2)

does not create a harm[, rather, o]nly the act of *filing* the ANDA, and thus triggering the patent-holder’s forty-five days to initiate a lawsuit, is recognized as an injury giving rise to potential infringement liability”) (citation omitted); *but see, e.g.,* Pfizer Inc. v. Synthron Holding, B.V., 386 F. Supp. 2d 666, 674-75 (M.D.N.C. 2005); *Intendis, Inc. v. River’s Edge Pharms., LLC*, No. 11-2838 (FSH) (PS), 2011 WL 5513195, at *7-9 (D.N.J. Nov. 10, 2011).

312. *Zeneca Ltd. v. Mylan Pharms., Inc.*, 173 F.3d 829, 832 (Fed. Cir. 1999).

313. *See* *Daimler AG v. Bauman*, 134 S. Ct. 746, 759 (2014).

314. *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002).

315. *Weiswasser & Danzis*, *supra* note 3, at 600.

316. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2012).

317. *See* Moore, *Forum Shopping*, *supra* note 6, at 917.

318. *See* *Zeneca Ltd. v. Mylan Pharms., Inc.*, 173 F.3d 829, 831-32 (Fed. Cir. 1999).

319. Professor Kimberly A. Moore, now a Judge on the Federal Circuit, published a study in 2001 regarding choice of forum in patent cases. Among other findings, she determined that patent cases are not evenly distributed across jurisdictions. Rather, they are concentrated in only a few courts, suggesting that parties are actively seeking certain locations to file their infringement suits. Moore, *Forum Shopping*, *supra* note 6, at 903-04. For example, the empirical evidence showed that the Northern District of California was the second-most popular forum for patent cases from 1995-1999. *Id.* at 903. In that district, patent-holders had a significantly higher chance of winning

Don't sue, and wait for the generic to file a declaratory judgment action in a forum it chooses³²⁰—again, presumably in the generic's home state. Or (3), don't sue, and let the generic company release its competing drug into the market, ending the patent term that was awarded to the pioneer for taking a revolutionary drug through various levels of research and development.³²¹ Limiting a patent-holder's choice to only these three options would be legitimately unfair. More importantly, such an outcome would impermissibly tip the Hatch-Waxman balancing scales significantly in favor of generic companies seeking to produce and sell low-cost copies of pioneer drug products, de-incentivizing pioneering research and development, and undermining the entire purpose of the Act.

VI. CONCLUSION

Acorda II presented the Federal Circuit with a rich set of possible questions to answer, but it should have used the case to confirm its preference for a lenient nexus test in Hatch-Waxman cases, considering the Federal Circuit's own sound precedent on the matter, and the strong public policy implications in favor of such an interpretation. Still, given the unique "artificial" nature of the cause of action in ANDA suits and the contacts that Mylan has with the state of Delaware, the Federal Circuit properly found that the Delaware courts' exercise of specific personal jurisdiction over Mylan was appropriate because the nexus requirement was satisfied, Mylan had purposefully availed itself to the forum, and the court's exercise of jurisdiction was fair. Yet, if the Federal Circuit is ever presented with the question again, it should take the opportunity to add some much-needed procedural clarity to an already-complicated ANDA litigation process.

infringement suits as compared to other jurisdictions. Given the concentration of technology companies residing there, Moore suggests that perhaps this result is not surprising. *Id.* at 917.

320. Moore's data also suggests that the party choosing the forum is more likely to win, regardless of whether it is the patent-holder in an infringement suit, or the alleged infringer in a declaratory judgment action. *Id.* at 920–21.

321. See *supra* notes 39–40, 88–89 and accompanying text.