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THERE'S NO PLACE LIKE HOME: FINDING PERSONAL JURISDICTION IN ANDA PATENT CASES AFTER *ZENECA V. MYLAN PHARMACEUTICALS*

John C. O'Quinn[*]

The Federal Circuit's recent decision in *Zeneca Ltd. v. Mylan Pharmaceuticals, Inc.*[1] raises new questions over the situs of patent injuries. The court reversed the transfer of an Abbreviated New Drug Application ("ANDA") patent infringement suit to the U.S. District Court for Maryland.[2] The court found that filing an ANDA paragraph IV certification with the U.S. Food and Drug Administration ("FDA") offices in Maryland did not confer to Maryland personal jurisdiction over the petitioner.[3] Judge Gajarsa applied the government contacts exception to reverse a transfer order because "[t]he Petition was not called an act of infringement in order to . . . create a national forum in Maryland,"[4] while Judge Rader, concurring, concluded that the defendant's contacts with Maryland were insufficient to establish personal jurisdiction.[5] In rejecting personal jurisdiction where the paragraph IV certification was filed, the Federal Circuit reopens the debate over the situs of patent injuries it had apparently settled in *Beverly Hills Fan Co. v. Royal Sovereign Corp.*[6] and *North American Philips Corp. v. American Vending Sales, Inc.*[7]

I. HISTORICAL OVERVIEW OF SITUS OF INJURY IN PATENT CASES

Prior to *Beverly Hills Fan* and *North American Philips*, the case law was ambiguous between two competing interpretations in determining where injury occurs when a patent is infringed[8] — "Injury at the Place of Patent" and "Injury at the Place of Infringing Acts."[9] More recently,

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* Harvard Law School, Class of 2001. This Note is dedicated to the memory of my grandmother, Lida Renn O'Quinn.

1. 173 F.3d 829 (Fed. Cir. 1999).
2. *See id.* at 830.
3. *See id.* at 833.
4. *Id.* at 833.
5. *Id.* at 836 (Rader, J., concurring).
6. 21 F.3d 1558 (Fed. Cir. 1994).
7. 35 F.3d 1576 (Fed. Cir. 1994).
8. *See* Honeywell, Inc. v. Metz Apparatewerke, 509 F.2d 1137 (7th Cir. 1975).
9. *See* David Wille, *Personal Jurisdiction over Aliens in Patent Infringement*

the Federal Circuit appeared to resolve this difference in favor of "Injury at the Place of Infringing Acts." In *Beverly Hills Fan,* the court held that "in a case such as this, the situs of the injury is the location, or locations, at which the infringing activity directly impacts on the interests of the patentee, here the place of the infringing sales in Virginia."[10] Similarly, in *North American Philips* the Federal Circuit noted that "liability . . . arises upon the making, using, or selling of an infringing article. Thus . . . the 'tort' of patent infringement occurs where the offending act is committed and not where the injury is felt."[11] This conclusion as to where injury occurs brought "patent infringement actions into line with the rule applied in trademark and copyright cases."[12]

II. PATENT INFRINGEMENT IN ANDA CASES

Patent infringement in an ANDA case is distinct from other types of patent infringement and is defined separately in 35 U.S.C. § 271(e).[13] ANDA infringement arises from certain filings with the FDA, rather than the "making, using, or selling of an infringing article" described in *North American Philips*. Section 271(e) was added by the Drug Price Competition and Patent Term Restoration Act of 1984,[14] commonly known as the Hatch-Waxman Act. The Act created a regulatory mechanism to reduce the delay in FDA approval of generic versions of drugs already approved for market.[15] If it can be shown that "the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a [listed] drug," the new drug applicant need only file an "Abbreviated New Drug Application."[16] The Act, codified in part at 21 U.S.C. § 355(j), delineates the requirements for an ANDA and effectively exempts an

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Actions: A Uniform Approach Toward the Situs of the Tort, 90 MICH. L. REV. 658, 666–67 (1991). While focusing on jurisdictional issues related to alien patent infringers, Wille's article examines three approaches to determining the situs of patent infringement. These are "injury at the place of patent," "injury at the place of infringing sales," and "injury at the place of the infringing action." Wille examines each approach and concludes that "the 'Injury at Place of Infringing Sales' rule better characterizes the nature of [patent infringement] injuries." *Id.* at 680. This was the approach ultimately adopted by the Federal Circuit in *Beverly Hills Fan* and *North American Philips*. *See infra* notes 10–13 and accompanying text.

10. *Beverly Hills Fan*, 21 F.3d at 1571.
11. *North Am. Philips*, 35 F.3d at 1579.
12. *Beverly Hills Fan*, 21 F.3d at 1571.
13. 35 U.S.C. § 271 (1994) (defining "Infringement of patent").
14. Pub.L. No. 98-417, 98 Stat. 1585 (1984).
15. *See* 21 U.S.C. § 355(j) (1994).
16. *Id.* at § 355(j)(2)(A)(i).

ANDA applicant from having to perform the exhaustive clinical studies required for a standard new drug application. Instead, the applicant need only show, for example, that the "bioequivalen[ce]," "labeling," "route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug" to obtain FDA approval.[17] The ANDA applicant must also make one of four certifications as to the status of any patent "which claims the listed drug . . . or which claims a use for such listed drug for which the applicant is seeking approval . . . ."[18] Three of these certifications — that there is no patent, that any relevant patents have expired, or simply asking for approval contingent upon the expiration of the patent — raise no special problems for the applicant.[19] It is the final certification, the so-called paragraph IV certification, "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted," that delays the approval process.[20] If the patent *is* valid or *will* be infringed by such manufacture, use, or sale, then filing the certification is itself an act of patent infringement under § 271(e).[21] Furthermore, the Federal Circuit has held that filing a paragraph IV certification gives patentees the right to sue the applicant under § 271(e).[22] Thus, an ANDA applicant is subject to suit for patent infringement merely by filing a paragraph IV certification. The applicant need not make, use, offer to sell or sell any patented invention, as in *Beverly Hills Fan* and *North American Philips*.[23]

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17. *Id.* at § 355(j)(2)(A)(iii)–(v).
18. *Id.* at § 355(j)(2)(A)(vii).
19. *See id.* at § 355(j)(2)(A)(vii)(I)–(III).
20. *Id.* at § 355(j)(2)(A)(vii)(IV).
21. Section 271(e)(2)(A) provides: "It shall be an act of infringement to submit — (A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act [,codified at 21 U.S.C. § 355(j),] or described in section [355(b)(2)] of such Act for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent."
22. *See* Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1569 (Fed. Cir. 1997). ("[Section] 271(e)(2) provide[s] patentees with a defined act of infringement sufficient to create case or controversy jurisdiction to enable a court to promptly resolve any dispute concerning infringement and validity.")
23. *See id.*

III. THE *ZENECA* OPINIONS

Zeneca v. Mylan Pharmaceuticals addresses personal jurisdiction issues in the context of ANDA patent infringement. At the district court level,[24] Judge Lee granted a transfer of the case to Maryland because the defendant "committed an intentional tort in Maryland pursuant to 35 U.S.C. § 271(e)(2)."[25] Judge Lee reasoned that "Zeneca's cause of action arises directly out of Mylan's activities in Maryland" because Zeneca's patent was infringed when Mylan filed its ANDA with the FDA in Maryland.[26] He noted that "Congress chose to define the tort as occurring simultaneously with the filing of the ANDA and paragraph IV certification."[27] Thus, the act of filing "itself results in a tort, which is a 'contact' with the forum state that satisfies the exercise of personal jurisdiction under Maryland's long-arm statute."[28] This approach follows the Federal Circuit's earlier pronouncement that "the 'tort' of patent infringement occurs where the offending act is committed."[29]

The Court of Appeals for the Federal Circuit reversed.[30] The court nullified the order to transfer and found that Maryland did not have personal jurisdiction over Mylan based solely on the grounds of its filing an ANDA in Maryland.[31] However, the Court of Appeals did not offer a unified theory for its departure from the consensus developed in *Beverly Hills Fan* and *North American Philips*. Judge Gajarsa delivered the opinion of the court. He expressed concern over the creation of a "national judicial forum in Maryland for generic drug infringement cases,"[32] "ar[ising] out of the mere fortuity that the government agency that must receive the Petition is located in Maryland."[33] Yet he noted that while "the Supreme Court has viewed the tortious act as 'highly artificial' in different contexts [this] is not a proper reason for us to conclude that the ANDA filing is not a 'real act' with 'actual consequences.'"[34] So, under "traditional personal jurisdiction analysis, . . . the exercise of personal jurisdiction over [the defendant] in

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24. Zeneca Ltd. v. Mylan Pharms., Inc., 968 F. Supp. 268 (W.D. Pa. 1997).
25. *Id.* at 278.
26. *Id.* at 276.
27. *Id.*
28. *Id.*
29. North Am. Philips v. American Vending Sales, Inc., 35 F.3d 1576, 1579 (Fed. Cir. 1994).
30. *See* Zeneca Ltd. v. Mylan Pharms., Inc., 173 F.3d 829, 834 (Fed. Cir. 1999).
31. *See id.*
32. *Id.* at 832 (Gajarsa, J.).
33. *Id.*
34. *Id.* at 833–34.

Maryland would be permissible."[35] In order to avoid creating such a "supercourt,"[36] Judge Gajarsa invoked the "government contacts exception."[37] Thus the government contacts exception, not the 'highly artificial' nature of tortious ANDA filings, precluded a finding of personal jurisdiction in Maryland.

Judge Rader, concurring, agreed with the decision to reverse the transfer to Maryland, "but without recourse to the so-called 'government contacts exception' to personal jurisdiction."[38] Judge Rader argued that the defendant's "contacts are not actually with the state of Maryland at all. Rather [the defendant's] contacts involve the federal government[,] whose office for receipt of ANDAs happens to be within that state."[39] Thus Rader concluded that the applicant had "not purposefully availed itself of the benefits of the laws of Maryland or purposefully directed its activities at Maryland residents."[40] Rader also felt that filing an ANDA, while technically a tort, is a highly artificial legal fiction, and so the "exercise of personal jurisdiction over Mylan also would not comport with 'traditional notions of fair play and substantial justice.'"[41]

Judge Rader's concurrence seems to suggest that filing an ANDA with a paragraph IV certification is not a "real tort." It submits that the "mere filing of an ANDA does not at that point even cause a tangible injury to the patent holder."[42] Thus, the concurrence distinguishes the "[m]anufacture, use, offers for sale, and sales, unlike the filing of an ANDA," as "real acts with actual consequences. . . . fall[ing] within our traditional understanding of patent infringement . . . and subject[ing] a defendant to full liability under the law."[43] The concurrence embraces Justice Scalia's characterization of ANDA patent infringement as "artificial" in *Eli Lilly & Co. v. Medtronic, Inc.*[44] However, some might suggest it goes too far in that it could be construed to characterize ANDA filings as inferior torts. Such a characterization would contradict the plain language of the Hatch-Waxman Act, which made it "an act of infringement" to submit an ANDA paragraph IV certification,[45] as well

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35. *Id.* at 834.
36. *Id.* at 832.
37. *Id.* at 834.
38. *Id.* at 834 (Rader, J., concurring).
39. *Id.* at 835.
40. *Id.*
41. *Id.* at 836.
42. *Id.*
43. *Id.*
44. *See* Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 678 (1990). ("[W]hat is achieved by §271(e)(2) [is] the creation of a highly artificial act of infringement that consists of submitting an ANDA . . . containing the [paragraph IV] certification . . . .").
45. 35 U.S.C. § 271(e)(2) (1994).

as legislative intent,[46] and even the Supreme Court's interpretation of the Hatch-Waxman regime in *Eli Lilly*.[47]

The opinions of Judges Gajarsa and Rader are contradicted only by a silent dissent from the late Judge Rich. Unfortunately, the Federal Circuit has not clearly resolved the conflict in the *Zeneca* opinions.[48] Thus, barring intervention by the Supreme Court,[49] it would appear that *Zeneca* will preclude an "act of infringement" approach to obtaining personal jurisdiction over ANDA patent infringers, such as that endorsed by *Beverly Hills Fan* and *North American Philips*.

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46. The Hatch-Waxman Act allows for the making, use, or sale of a patented invention "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of drugs or veterinary biological products." 35 U.S.C. § 271(e)(1) (1994). Such activities were previously held to constitute infringement under *Roche Prodocts, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984). This change in the law was to foster the timely development of affordable generic drugs. *See* H.R. REP. NO. 98-857, pt. 1, at 14–15 (1984) (stating that one of the purposes of the legislation is "to make available more low cost generic drugs . . . ."). Making the petition an act of infringement "permits the commencement of a legal action for patent infringement before the generic drug maker has begun marketing," thus protecting the rights of the patent holder. *Id.*, pt. 1, at 27–28. The House Committee "believe[d] this procedure fairly balances the rights of a patent owner to prevent others from making, using, or selling its patented product and the rights of third parties to contest the validity of a patent or to market a product which they believe is not claimed by the patent." *Id.* Further, the Committee "intend[ed] that a patent would have the same statutory presumption of validity as is afforded under current law." *Id.* In contrast, Judge Rader's concurrence could be interpreted to give patents less protection in an ANDA setting than in other contexts.

47. *See Eli Lilly*, 496 U.S. 661.

48. The Federal Circuit declined requests for a rehearing and a rehearing en banc on June 3, 1999, a somewhat surprising decision given its mandate to create increased uniformity and certainty in the United States Patent System. *See* Panduit Corp. v. All States Plastic Mfg. Co., 744 F.2d 1564, 1573–74 (Fed. Cir. 1984).

49. Zeneca filed a motion to stay the Court of Appeals' mandate to the District Court pending the filing of a petition for a writ of certiorari to the Supreme Court, indicating an intent to appeal the Federal Circuit's decision. While the Supreme Court might grant certiorari to address the First Amendment issues implicated in the right to petition the government encompassed by the "government contacts exemption," it is unlikely. *See* Zeneca Ltd. v. Mylan Pharms., Inc., 173 F.3d 829, 831–32 (Fed. Cir. 1999) (describing the "government contacts exception"). The Supreme Court has never previously addressed the "government contacts exemption," which was developed by the courts of the District of Columbia. *See* Envtl. Research Int'l, Inc. v. Lockwood Greene Eng'rs, Inc., 355 A.2d 808 (D.C. 1976) (en banc); Naartex Consulting Corp. v. Watt, 722 F.2d 779 (D.C. Cir. 1983).

IV. PERSONAL JURISDICTION AND SITUS OF INJURY AFTER *ZENECA*

Since *Zeneca* has effectively eliminated the place of ANDA infringement as a forum for a claim of patent infringement, the question remains: "where can patent holders bring actions against an ANDA applicant?" Filing suit where general personal jurisdiction can be established presents no novel difficulties. However, establishing personal jurisdiction based on the specific act of ANDA patent infringement is anything but straightforward after *Zeneca*. As the district court in *Zeneca* noted, "it is unclear what effect, if any, Congress intended [that] section 271(e)(2) would have on the personal jurisdiction of a defendant."[50]

Establishing jurisdiction over an ANDA applicant turns on whether the "Due Process Clause of the Federal Constitution or specific limiting provisions in [a state's] long-arm statute preclude the exercise of jurisdiction . . . ."[51] The constitutional requirement for personal jurisdiction is purposeful minimum contacts with the forum state.[52] The minimum contacts requirement helps ensure that non-residents have fair warning that a particular activity may subject them to litigation within the forum.[53] State "long-arm" statutes usually further require the "transaction of business," the "commission of a tortious act," or the occurrence of "tortious injury" within the forum state.[54] In the post-*Zeneca* world the two most likely locations in which these constitutional and statutory requirements can be met with respect to an entity filing an ANDA paragraph IV certification are the plaintiff's place of residence and the defendant's place of residence or business.

A. Personal Jurisdiction at the Plaintiff's Place of Residence

1. Minimum Contacts

To determine whether personal jurisdiction may be exercised over an ANDA applicant in a patent holder's place of residence, we must examine whether the defendant has minimum contacts, whether exercising jurisdiction comports with traditional notions of fair play and

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50. Zeneca Ltd. v. Mylan Pharms., Inc., 968 F. Supp. 268, 273 (W.D. Pa. 1997).
51. Beverly Hills Fan v. Royal Sovereign Corp., 21 F.3d 1558, 1564 (Fed. Cir. 1994).
52. *See* Burger King Corp. v. Rudzewicz, 471 U.S. 462, 472 (1985).
53. *See id.*
54. *See, e.g.*, 735 ILL. COMP. STAT. 5/2-209 (West 1994); VA. CODE ANN. § 8.01–328.1 (Michie 1992).

substantial justice,[55] and for states with long-arm statutes, whether tortious injury has occurred within the forum state. An act of the defendant, purposefully directed toward the forum state, is sufficient to establish minimum contacts.[56] (At the time an ANDA infringement suit is filed, the applicant has not yet marketed or sold its products, so the "stream of commerce" theory cannot be used to find minimum contacts.[57]) "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."[58] If a defendant is aware that it may be committing an act of infringement, it is knowingly causing harm to the patent holder's intellectual property rights.[59] While some courts find constructive notice sufficient,[60] others require that the defendant have actual knowledge of the existence of the patent and of the patent holder's residence in order "to establish the requisite minimum contacts necessary for the exercise of personal jurisdiction . . . ."[61] This standard is readily met in the case of an ANDA paragraph IV certification. The ANDA application requires that the applicant identify patents that might be infringed and assert that the patent is "invalid or will not be infringed."[62] Moreover, the applicant must give notice of this certification to the patent holder.[63] Thus, since the applicant has actual knowledge of both the existence of the patent and of the patent holder's residence, the

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55. *See* Int'l Shoe Co. v. Washington, 326 U.S. 310, 316 (1945).

56. *See* Asahi Metal Indus. Co. v. Superior Court of California, 480 U.S. 102, 112 (1987).

57. *See* World-Wide Volkswagen v. Woodson, 444 U.S. 286 (1990).

58. Nichols v. G.D. Searle & Co., 783 F. Supp. 233, 237 (D. Md. 1992) (citing Burger King Corp. v. Rudzewicz, 471 U.S. 462, 477–78 (1985)). In contrast, some district courts have held that the filing of an ANDA paragraph IV certification is not purposefully directed toward the patent holder's forum of residence, but rather toward Maryland (the forum where the FDA is located). *See* Zeneca Ltd. v. Mylan Pharms., Inc., 968 F. Supp. 268, 274 (W.D. Pa. 1997); Glaxo Inc. v. Genpharm Pharms., Inc., 796 F. Supp. 872 (E.D.N.C. 1992). However, at the Federal Circuit, Judge Rader concluded that an ANDA applicant "has not purposefully availed itself of the benefits of the laws of Maryland or purposefully directed its activities at Maryland residents" merely by filing with the FDA. Zeneca Ltd. v. Mylan Pharms., Inc., 173 F.3d 829, 835 (Fed. Cir. 1999) (Rader, J., concurring).

59. *See* Horne v. Adolph Coors Co., 684 F.2d 255, 259–60 (3d Cir. 1982).

60. *See id.*

61. Laitram Corp. v. OKI Elec. Indus. Co., Ltd., 30 U.S.P.Q.2d 1527, 1531 (E.D. La. 1994).

62. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (1994).

63. *See* 21 U.S.C. § 355(j)(2)(B) (1994).

minimum contacts necessary to satisfy the constitutional inquiry can be met.

2. Fair Play and Substantial Justice

The fact that the ANDA applicant is on actual notice of the plaintiff's patent and residence means that it could reasonably anticipate being haled into court in the plaintiff's forum of residence. Further, as a patent is "property created by federal law, and the cause of action for patent infringement, by virtue of the exclusivity provision in 28 U.S.C. § 1338(a), is one over which no state could assert adjudicatory competence,"[64] there is no issue of conflicting state sovereignties in asserting personal jurisdiction. Finally, the burden on the ANDA applicant to mount its defense in a forum other than where it resides is not overwhelming:

> The legal issues of validity and infringement are not such as will be likely to require witnesses from any particular locality. In these circumstances it cannot be said that requiring the alleged infringer to defend in the forum chosen by the patent owner, which also happens to be the patent owner's residence, so offends traditional notions of fairness as to be a violation of due process and therefore unconstitutional.[65]

Moreover, "public policy . . . favors providing a forum for an injured resident to bring an action against a nonresident manufacturer."[66] The interests of the forum state must be weighed in determining whether exercising jurisdiction would be "fair."[67] Circuit courts have found that states have "a significant interest in redressing injuries that occur within [their] borders at the hands of nonresidents."[68] Therefore, asserting personal jurisdiction over the ANDA applicant in the patent holder's forum of residence arguably comports with notions of fair play and substantial justice if the plaintiff can show infringement would cause it injury in the forum.

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64. *Horne*, 684 F.2d at 259.
65. *Id.* at 260.
66. *Laitram*, 30 U.S.P.Q.2d at 1531.
67. *See* Asahi Metal Indus. Co. v. Superior Court of California, 480 U.S. 102, 115 (1987); World-Wide Volkswagen Corp. v. Woodson, 444 U.S. 286, 292 (1980).
68. WNS, Inc. v. Farrow, 884 F.2d 200, 204 (5th Cir. 1989).

3. Situs of Injury

At this point the constitutional inquiry and the statutory long-arm inquiry collapse into a single question: is the plaintiff's residence a situs of injury in patent infringement? As discussed in Section I of this Note, *Beverly Hills Fan* and its progeny answer this question in the negative. However, it is noteworthy that in both *Beverly Hills Fan* and *North American Philips*, it was the *defendant* arguing that the plaintiff could only sue in its home district and not the plaintiff asserting that it had been harmed in its home forum. Further, both *Beverly Hills Fan* and *North American Philips* involved the "making, using, or selling of an infringing article."[69] In these cases the injury to the patent holder occurred "at the place where the infringing sale [was] made because the patent owner los[t] business there."[70] However, unlike the situation in *Beverly Hills Fan* and *North American Philips*, there is not any product to be marketed or sold when an ANDA is filed. Nonetheless, these cases do provide some guidance.

4. Place of Economic Loss and Construing the Defining Statute

Beverly Hills Fan instructs courts to consider where "economic loss" occurs to the patent holder and "assess realistically" the legal situs of injury.[71] While the filing arguably does not "cause a tangible injury to the patent holder,"[72] harm may occur to the patent holder's reputation and business goodwill.[73] Such harm is likely to be centered in the patent

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69. North Am. Philips Corp. v. American Vending Sales, Inc., 35 F.3d 1576, 1579 (Fed. Cir. 1999).

70. Beverly Hills Fan Co. v. Royal Sovereign Corp, 21 F.3d 1558, 1571 (Fed. Cir. 1999).

71. *Beverly Hills Fan*, 21 F.3d at 1570–71.

72. Zeneca Ltd. v. Mylan Pharms., Inc., 173 F.3d 829, 836 (Fed. Cir. 1999) (Rader, J., concurring).

73. One court has analogized patent infringement to tortious injuries to personality: "[Patent infringement] is somewhat related, though the analogy is of course not a perfect one, to . . . libel, slander or invasion of privacy." Acrison, Inc. v. Control & Metering Ltd., 730 F. Supp. 1445, 1448 n.7 (N.D. Ill. 1990). Thus, it is relevant that in *Calder v. Jones*, a case involving libel, the Supreme Court "unanimously held that personal jurisdiction over Florida defendants was proper in California courts because the defendants had engaged in intentional, tortious actions 'expressly aimed' at the forum and because the defendants 'knew that the brunt of the injury would be felt' in the forum.'" Joseph William Singer, *Publicity Rights and the Conflict of Laws: Tribal Court Jurisdiction in the Crazy Horse Case*, 41 S.D. L. REV. 1, 35 (1996) (quoting Calder v. Jones, 465 U.S. 783, 789–90 (1984)). The *Calder* court concluded: "Under the circumstances, the petitioners must 'reasonably anticipate being haled into court [in the forum]' . . . . An individual injured in California need not go to Florida to seek redress

holder's principal place of business.[74] By filing an ANDA paragraph IV certification, the applicant effectively asserts that it believes the patent holder has an invalid patent or that it will be able to compete with the patent holder.[75] The patent holder's stock price and business opportunities may suffer as a result of such assertions. So at the most basic level, the realistic situs of injury is where the patent holder resides.[76] Although the Federal Circuit effectively defined injury under 35 U.S.C. § 271(a) as occurring at the situs of the act,[77] the cause of action for ANDA infringement comes from a different statutory provision. The court has not spoken on where injury occurs under § 271(e), which defines infringement in the ANDA setting without mention of § 271(a). Since Hatch-Waxman made the manufacture or use of a patented invention in conjunction with an FDA application a non-tortious act,[78] suing under § 271(e) is the only way a patent holder can continue to protect its interests. If injury is to be found from the filing of an ANDA, arguably it must be where the patent holder suffers economically: at its residence.

5. Analogy to Declaratory Judgment

Unlike many lawsuits in which patent infringement is alleged, the timing of an ANDA infringement case is largely controlled by the defendant rather than the plaintiff. As such, it is akin to a suit for declaratory judgment of patent invalidity. The defendant, the ANDA applicant, chooses when to file the ANDA with the FDA. In certifying

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from persons who, though remaining in Florida, knowingly cause the injury in California." 465 U.S. at 790 (citations omitted).

74. *Cf.* Singer, *supra* note 73, at 38 ("In the case of defamation, the harm to the plaintiff's reputation is likely to be centered at home.").

75. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (1994).

76. *See, e.g.*, Horne v. Adolph Coors Co., 684 F.2d 255, 260 (3d Cir. 1982) (noting the infringer "was aware that if the products it placed in the stream of interstate commerce infringed a valid patent it would cause injury to the owner thereof, in whatever state he resided.").

77. In *North American Philips*, the Court noted that "the cause of action for patent infringement is created and defined by statute" and specifically cited 35 U.S.C. § 271(a) (1988). It was in referring to § 271(a) that the Court held, "[t]he statute does not speak generally of the 'tort of patent infringement,' but specifically of a liability that arises upon the making, using, or selling of an infringing article. Thus, the statute on its face clearly suggests the conception that the 'tort' of patent infringement occurs where the offending act is committed and not where the injury is felt." 35 F.3d at 1579. Clearly the court was not addressing infringement under § 271(e)(2).

78. *See* Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 678 (1990) ("Quite obviously, the purpose of subsections (e)(2) and (e)(4) is to enable the judicial adjudication upon which the ANDA . . . schemes depend.").

that a patent is invalid or will not be infringed by the defendant's activities, the defendant triggers a forty-five day window in which the patent holder *must* sue the defendant for infringement, otherwise the "approval [of the ANDA by the FDA] shall be made effective immediately."[79] Upon expiration of the forty-five day window, the ANDA applicant can sue for declaratory judgment; however, it must sue where the patent holder "has its principle place of business or a regular and established place of business."[80] Since the ANDA applicant determines when the patent holder must sue and must effectively waive personal jurisdiction in a suit for declaratory judgment and sue in the patent holder's place of residence, it may be reasonable to allow the exercise of jurisdiction over the ANDA applicant in the patent holder's forum of residence.[81] It may not be contrary to notions of "fair play and substantial justice" to force the applicant to defend itself within the patent holder's forum since it would be required by statute to take its case to the patent holder's forum of residence to seek declaratory judgment.

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79. 21 U.S.C. § 355(j)(5)(B)(iii).

80. *Id.*

81. In contrast, the district court in Glaxo Inc. v. Genpharm Pharms., Inc., 796 F. Supp. 872 (E.D.N.C. 1992), held that the defendant's "mailing of its certification of invalidity of the . . . patent to [the patent holder] in North Carolina was not a purposeful act directed at North Carolina such that litigation in this forum could have been reasonably foreseen . . . . [N]othing in the statute or case law suggests that the defendant would be subject to an infringement suit wherever the notice to the approved-NDA holder is mailed." *Id.* at 876. As the mailing was to the patent holder's residence, *Glaxo* would seem to suggest that the patent holder's forum of residence has no special claim of personal jurisdiction to assert over the ANDA applicant. However, the *Glaxo* court also found that it was "immaterial . . . that Genpharm knew when it filed its ANDA that it would cause apprehension and possibly economic harm in North Carolina" because the "act of infringement took place in Maryland . . . ." *Id.* at 876–77. The court granted a motion to transfer the case to the District of Maryland. *See id.* at 877. The *Glaxo* court was focused singularly on whether the mailing of the certification letter, in and of itself, was sufficient to result in an exercise of personal jurisdiction and failed to consider fully the underlying implications of tortious injury. Moreover, there were questions about whether to apply the "national contacts theory" for finding minimum contacts over alien defendants, which have since been superseded by the enactment of Federal Rule of Civil Procedure 4(k)(2). Finally, since the *Glaxo* court's resolution of the personal jurisdiction issue resulted in a transfer to Maryland — an option since eliminated in *Zeneca* by the Federal Circuit — *Zeneca* calls into question *Glaxo*'s analysis of personal jurisdiction.

6. Judicial Economy, Public Policy, and Burden on the Plaintiff

As several courts have observed, "the potential saving of judicial resources that could be realized by an action against all allegedly infringing defendants in a single forum" is significant.[82] This is particularly true in ANDA litigation where the act of infringement by every ANDA applicant is the same — the filing of an ANDA paragraph IV certification — and the underlying questions in manufacturing generic versions of the patent holder's drug are often similar. In addition, the inconvenience to a single ANDA applicant forced to defend itself in a forum other than its principle place of business is relatively small as "[t]he legal issues of validity and infringement are not such as will be likely to require witnesses from any particular locality."[83] By contrast, the choice of forum is highly significant to a patent holder who may be defending multiple ANDA certifications against a single patent at once. Hence, public policy and judicial economy suggest the better rule is to allow patent holders in ANDA cases to defend against all ANDA certifications in a single forum.

A number of procedural innovations, such as the motion to transfer under 28 U.S.C. § 1404(a) and the procedures under 28 U.S.C. § 1407 for multidistrict litigation, are based on the premises of "prevent[ing] the waste of 'time, energy, and money' and 'protect[ing] litigants, witnesses and the public against unnecessary inconvenience and expense.'"[84] However the Supreme Court has observed that it is not necessary to resort to these procedures to streamline multiple ANDA cases involving the same patents:

> The relationship between the defendant and the forum must be such that it is "reasonable . . . to require the corporation to defend the particular suit which is brought there." Implicit in this emphasis on reasonableness is the understanding that the burden on the defendant, while always a primary concern, will in an appropriate case be considered in light of other

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82. Laitram Corp. v. OKI Elec. Indus. Co., 30 U.S.P.Q.2d 1527, 1531 (E.D. La. 1994). *See also* Smithkline Corp. v. Sterling Drug, Inc., 406 F. Supp. 52, 55–56 (D. Del. 1975) (noting the benefit of having only one judge learn the intricacies of the patents involved); Ginsey Indus., Inc. v. I.T.K. Plastics, Inc., 545 F. Supp. 78, 81 (E.D. Pa. 1982) ("[I]t is clearly more convenient to conduct related litigation in a single district rather than in two separate forums.").

83. Horne v. Adolph Coors Co., 684 F.2d 255, 260 (3d Cir. 1982).

84. Van Dusen v. Barrack, 376 U.S. 612, 616 (1964) (quoting Continental Grain Co. v. Barge FBL-585, 364 U.S. 19, 26–27 (1960)).

> relevant factors, including the forum State's interest in adjudicating the dispute; the plaintiff's interest in obtaining convenient and effective relief, at least when that interest is not adequately protected by the plaintiff's power to choose the forum; the interstate judicial system's interest in obtaining the most efficient resolution of controversies; and the shared interest of the several States in furthering fundamental substantive social policies . . . .[85]

Thus, the burden on the plaintiff, the interests of judicial economy, and the interests of the courts in furthering substantive policies of uniformity and clarity in the United States patent system[86] all point toward allowing the plaintiff to file against all ANDA infringers in a single forum — the patent holder's forum of residence. The defendants would all have a common tie to this single forum — they have injured the patent holder in this forum. Proceeding in a single forum would lead to consolidated discovery as well as ensure that pre-trial rulings are internally consistent and made within the context of a single judicial view as to how the litigation should proceed. Not only would it be more convenient for the parties and the witnesses and avoid duplication of testimony, but it would also prevent inconsistent outcomes in the verdicts and avoid the ad hoc consolidation that can result from transfers and the multidistrict litigation process. Finally, the appellate process would be greatly simplified as there would be only one set of claim constructions to consider, as well as a single, unified case history.

B. Personal Jurisdiction Only at the Defendant's Place of Business

In the wake of *Zeneca*, a competing theory for determining the forum in which ANDA infringement suits can be filed is that they can only be brought at the applicant/defendant's place of business. Establishing personal jurisdiction over the ANDA applicant in its place of business is straightforward, since general personal jurisdiction can be asserted. Therefore this Section will address arguments against the exercise of personal jurisdiction over the ANDA applicant in the patent holder's forum of residence based solely on the act of infringement in filing an ANDA paragraph IV certification. In addition, it will consider

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85. World-Wide Volkswagen Corp. v. Woodson, 444 U.S. 286, 292 (1980) (citations omitted).

86. *Cf.* Panduit Corp. v. All States Plastic Mfg. Co., 744 F.2d 1564, 1573–74 (Fed. Cir. 1984).

multiple places of business in which jurisdiction over the ANDA applicant might be obtained.

1. Due Process Issues

Allowing the forum of the patent holder's place of residence to assert personal jurisdiction over an ANDA applicant — merely because it has filed a certificate asserting the invalidity or non-infringement of that patent holder's patent — may not conform to traditional notions of due process. The defendant's conduct and connection with the forum state should be such that "he should reasonably anticipate being haled into court there."[87] "Only the fortuitous circumstance of the plaintiff's residence would connect the forum with the tort; a result which likely violates the defendant's due process rights and could lead to forum shopping."[88] A corporate patent holder could potentially have an arbitrary choice between two forum states in which to file suit against an ANDA infringer — that of its incorporation and that of its principal place of business. Taken to the extreme, a defendant in any patent case might

> find itself subject to personal jurisdiction in any forum in which the patent holder chooses to reside, regardless of any other contact with that forum. Such unilateral control of the personal jurisdiction analysis would essentially result in a type of nationwide service for patent cases, and does not comport with due process.[89]

Moreover, asserting jurisdiction under such an approach is legally questionable, since it would substitute the plaintiff's contacts (residence) with the forum for the required minimum contacts of the defendant. Effectively, such assertions of personal jurisdiction would be based solely on the purported economic loss of the plaintiff, wherever it is, as opposed to the actions of the defendant.[90] Such a "subtle shift in focus from the defendant to the plaintiff . . . is forbidden by *International Shoe* and its progeny."[91] For, while the parties' relationships with each other may be significant in evaluating their ties to the forum, the plaintiff's

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87. *World-Wide Volkswagen*, 444 U.S. at 297.
88. Wille, *supra* note 9, at 675.
89. Laitram Corp. v. OKI Elec. Indus. Co., 30 U.S.P.Q.2d 1527, 1530 (E.D. La 1994).
90. *See* Wille, *supra* note 9, at 675.
91. Rush v. Savchuk, 444 U.S. 320, 332 (1980).

contacts with the forum cannot be "decisive in determining whether the defendant's due process rights are violated."[92] By focusing on where the patent holder, and thus the patent, is located, the "injury at the patent holder's residence" approach arguably makes this prohibited mistake.

The defendant's relationship to the forum is a theoretical one based only on the hypothetical harm caused by what the Supreme Court has called a "highly artificial act of infringement."[93] The foreseeability of causing a hypothetical injury within a forum, without more, is insufficient to assert personal jurisdiction.[94] As Judge Rader noted in *Zeneca*, "the mere filing of an ANDA does not at that point even cause a tangible injury to the patent holder."[95] This would be an "exalt[ing] of form over substance in an area where the Supreme Court generally has cautioned against such an approach."[96] "The Court long ago rejected the notion that personal jurisdiction might turn on 'mechanical' tests, or on 'conceptualistic . . . theories. . . .'[, instead emphasizing] the need for a 'highly realistic' approach . . . ."[97] Thus the court in *Glaxo* specifically refused to exercise jurisdiction over an ANDA defendant in the patent holder's state of residence when the defendant's other contacts with the forum state were "virtually non-existent."[98]

2. Legislative Intent: Interpreting What Hatch-Waxman Did Not Change

The assertion that *Beverly Hills Fan* and *North American Philips* do not apply to ANDA infringement assumes that Congress intended the Hatch-Waxman Act to eliminate all previous reference to § 271(a) in creating a new "artificial" act of patent infringement in § 271(e). However, "it is unclear what effect, if any, Congress intended § 271(e)(2) would have on the personal jurisdiction of a defendant."[99] Actions now held exempt from infringement under § 271(e)(1) were held

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92. *Id.*
93. Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 678 (1990).
94. *See* World-Wide Volkswagen Corp. v. Woodson, 444 U.S. 286, 295–96 (1980) ("If foreseeability were the criterion, [e]very seller of chattels would in effect appoint the chattel his agent for service of process. His amenability to suit would travel with the chattel." (citations omitted)).
95. Zeneca Ltd. v. Mylan Pharms., Inc., 173 F.3d 829, 836 (Fed. Cir. 1999) (Rader, J., concurring).
96. North Am. Philips Corp. v. American Vending Sales, Inc., 35 F.3d 1576, 1579 (Fed. Cir. 1994).
97. Burger King Corp. v. Rudzewicz, 471 U.S. 462, 478–79 (1985) (citations omitted).
98. Glaxo Inc. v. Genpharm Pharms., Inc., 796 F. Supp. 872, 875 (E.D.N.C. 1992).
99. Zeneca Ltd. v. Mylan Pharms., Inc., 968 F. Supp. 268, 273 (W.D. Pa. 1997).

to have infringed a valid patent under § 271(a) prior to Hatch-Waxman.[100] Thus, Congress was not writing on a clean slate. The key is to determine what § 271(e) modified and what it left unchanged.

In examining the House Report accompanying the passage of the Hatch-Waxman Act, it appears that the bill did not intend to change many aspects of patent infringement and litigation. For example, the Report states that:

> The provisions of this bill relating to the litigation of disputes involving patent validity and infringement are not intended to modify existing patent law with respect to the burden of proof and the nature of the proof to be considered by the courts in determining whether a patent is valid or infringed.[101]

Further, the changes that are acknowledged in the House Report are largely ones of timing — when the patent holder can or must sue the infringer to obtain an injunction stopping FDA approval. The Report notes that "under current law, if the generic obtains approval and goes on the market before the patent expires, then the patent holder can sue for patent infringement."[102] In contrast:

> The provisions of the bill . . . modify this rule by providing that if a generic files for approval and requested marketing authority during the life of the patent that the FDA cannot act immediately.... The generic must also notify the patent holder. The patent holder must then commence litigation within 45 days to assert the validity of the patent [in order to obtain a 30-month injunction against FDA approval].[103]

Thus, the modification addressed by the Report is when, not where, suit can be brought. The Act "safeguards patent owners from premature defenses of their patent rights that would create needless litigation and divert and drain resources. Patent litigation would not be permitted until after the generic manufacturer has at least demonstrated a legitimate

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100. *See* Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858 (Fed. Cir. 1984).
101. H.R. Rep. No. 98-857, pt. 1, at 27–28 (1984).
102. *Id.*, pt. 2, at 9.
103. *Id.*

interest in a drug by investment in preparing a complete ANDA."[104] The bill created a moratorium on suits for experimental use that could have been brought under *Roche* pursuant to § 271(a), until after the competitor files an ANDA. Therefore, to determine where the newly created ANDA infringement action can be brought, one may analogize by considering where a suit for conducting activities related to obtaining FDA approval might have been brought before *Roche*.

Beverly Hills Fan and *North American Philips* are instructive in determining where suit can be brought since they point to the forum where the "*making*, *using*, or selling of an infringing article" occurs.[105] In conducting experiments while preparing an ANDA for the FDA, the applicant makes or uses the patent holder's invention. Therefore the patent holder could file suit wherever general personal jurisdiction over the applicant can be found or, "in the absence of any experimental use exception[,] . . . in a district where only an experimental use has occurred."[106] Since *Roche* effectively eliminated the experimental use exception, specific jurisdiction arguably could be found in the forum state in which the ANDA applicant conducted experiments with the patent holder's invention.

While Congress's intent with respect to personal jurisdiction in section 271(e)(2) may be unclear,[107] the House Report does not seem to contemplate patent holders necessarily asserting personal jurisdiction over all ANDA applicants within a single district — be it the patent holder's residence or elsewhere. The Report specifically makes provision for multidistrict litigation: "In the event of multiple ANDA's certifying patent invalidity or non-infringement, the courts should employ the existing rules for multidistrict litigation, when appropriate, to avoid hardship on the parties and witnesses and to promote the just and efficient conduct of the patent infringement actions."[108] If Congress intended to empower a patent holder to sue all of the ANDA applicants in a single district, there presumably would be no need for this comment on the use of multidistrict litigation.[109] Legislative history thus

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104. *Id.* at 61.

105. North Am. Philips Corp. v. American Vending Sales, Inc., 35 F.3d 1576, 1579 (Fed. Cir. 1994) (emphasis added).

106. Richard E. Bee, *Experimental Use as an Act of Patent Infringement*, 39 J. PAT. OFF. SOC'Y 357, 360 (1957).

107. *See* Zeneca Ltd. v. Mylan Pharms., Inc., 968 F. Supp. 268, 273 (W.D. Pa. 1997).

108. H.R. Rep. No. 98-857, pt. 1, at 28 (1984) (footnote omitted).

109. However, recognizing the need for multidistrict litigation is equally consistent with providing another option to patentees that do not want to sue in their home states. Therefore, the discussion of multidistrict litigation in the House Report does not necessarily indicate Congressional disapproval of having patentees suing all ANDA applicants in a single district.

demonstrates no clear intent to allow the exercise of jurisdiction over ANDA applicants in the patent holder's forum of residence merely because the defendant has filed with the FDA.

3. Alien Plaintiffs and Defendants

To extend personal jurisdiction over an ANDA applicant in the place of residence of the patent holder may leave a gap with respect to alien and non-resident American patent holders.[110] If injury occurs at the patent holder's residence, then a person or corporation not resident in the United States either would be able to sue the ANDA applicant in the patent holder's home country or else would be left without any remedy other than suing the defendant wherever general personal jurisdiction can be found.[111] There is no suggestion in the Hatch-Waxman Act that Congress intended to subject ANDA applicants to foreign adjudication. Further, nothing in the patent laws designates a domestic residence for alien or non-resident patent holders. While 35 U.S.C. § 293 defines the process for obtaining jurisdiction over a non-resident patent holder, it does not purport to assign a "residence" to that non-resident. Thus if the patent holder is a non-resident, a finding that injury occurs where the patent holder resides leaves no forum in which specific jurisdiction can be asserted over an ANDA applicant. Section 293 provides for jurisdiction over non-resident defendants, specifying that a non-resident may appoint a designee, resident in the United States, to accept service of process or notice, or in the alternative, that the U.S. District Court for the District of Columbia have jurisdiction over the non-resident.[112] However, there is no statutory analog for the non-resident plaintiff seeking to show harm at its place of residence or at the "place of the patent." If such an analog existed, it could lead to either of two unacceptable results. Allowing non-resident patent holders to pick a forum of residence merely by designating a resident representative could give them unconstitutional discretion to sue anywhere. Alternatively, giving the D.C. District Court jurisdiction would create a "supercourt" for non-resident ANDA litigation, an implication rejected by Judge Gajarsa in *Zeneca*.[113]

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110. For the procedure for non-residents to file in the Patent and Trademark Office, see 35 U.S.C. § 293 (1994).

111. For a discussion of the complications and legal fictions that can arise from determining domicile when an alien is involved, see Mas v. Perry, 489 F.2d 1396 (5th Cir. 1974).

112. *See* 35 U.S.C. § 293.

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

In contrast, alien defendants in ANDA litigation will not be immunized from service of process merely because they are non-resident.[114] Thus, an alien can be sued in any district in which it can be found. Furthermore, if an alien is not subject to general personal jurisdiction in any state or to a state's long-arm statute, Federal Rule of Civil Procedure 4(k)(2), enacted in 1993, allows for the alien to be sued in any federal court based on a theory of aggregate national contacts.[115] Thus a non-resident ANDA applicant does not escape jurisdiction merely because its only contact with the United States is filing with the FDA. Rule 4(k)(2) in conjunction with Rule 4(f), which allows for service upon individuals in a foreign country, prevents non-residents from slipping through the cracks if personal jurisdiction is only allowed at the ANDA applicant's residence or place of business. In contrast, allowing personal jurisdiction at the patent holder's place of residence may create unforeseen complications when an alien patent holder is involved.

4. Applying the Venue Statute

The single most compelling reason to reject the patent holder's forum of residence as a proper venue is that it is contrary to the patent venue statute. The statute provides that "[a]ny civil action for patent infringement may be brought in the judicial district where the defendant resides, or where the defendant has committed acts of infringement and has a regular and established place of business."[116] The venue statute is an expression of Congressional preference for where patent litigation is to occur — the defendant's residence. A corporate defendant is deemed to reside wherever it is subject to personal jurisdiction.[117] However, one might argue that in filing an ANDA, the defendant neither enters the patent holder's forum of residence nor causes any "tangible injury" to the patent holder.[118] Under traditional personal jurisdiction analysis, no

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114. *See* 28 U.S.C. § 1391(d) (1994) (providing that "[a]n alien may be sued in any district.").

115. FED. R. CIV. P. 4(k)(2) provides:

> If the exercise of jurisdiction is consistent with the Constitution and laws of the United States, serving a summons or filing a waiver of service is also effective, with respect to claims arising under federal law, to establish personal jurisdiction over the person of any defendant who is not subject to the jurisdiction of the courts of general jurisdiction of any state.

116. 28 U.S.C. § 1400(b) (1994).

117. *See* VE Holding Corp. v. Johnson Gas Appliance Co., 917 F.2d 1574 (Fed. Cir. 1990) (holding that 28 U.S.C. § 1391(c) applies to corporate defendants in patent cases).

118. *Zeneca*, 173 F.3d at 836 (Rader, J., concurring).

defendant would be found to have purposeful contacts with a patent holder's state under such circumstances. It seems unlikely that an ANDA applicant could be deemed a resident of a patent holder's state merely by filing a form with the FDA in Maryland. If the act of filing an ANDA subjects the applicant to personal jurisdiction, Congress could have specified the patent holder's residence as the proper venue for filing suit. However, Congress made no mention of venue or personal jurisdiction over the ANDA applicant. By contrast, the House Report contemplated that courts could "employ *the existing rules* for multidistrict litigation" if multiple ANDA's paragraph IV certifications were filed.[119] Had Congress intended to subject ANDA applicants to venue in the patent holder's state of residence, such a comment on multidistrict litigation would have arguably been unnecessary.

By contrast, 21 U.S.C. § 355(j)(5)(B)(iii) specifies that any suit for declaratory judgment brought by the ANDA applicant after the expiration of the forty-five day window in which the patent holder may sue for infringement must be brought where the patent holder has its "principal place of business or a regular and established place of business."[120] Congress specifically defined the venue for an ANDA declaratory judgment suit more narrowly than 28 U.S.C. § 1391(c) permits. If Congress had intended the venue for ANDA infringement suits to be the residence of the patent holder, it presumably could have specified that venue as well.[121] The fact that it did not may show a lack of Congressional intent to establish the patent holder's forum of residence as a venue for ANDA infringement cases.

V. Conclusion

Even before *Zeneca*, it was unclear where specific personal jurisdiction could be asserted over ANDA applicants. Neither Congress

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119. H.R. Rep. No. 98-857, pt. 1, at 28 (1984) (emphasis added).
120. 21 U.S.C. § 355(j)(5)(B)(iii) (1994).
121. However, prior to the creation of the Federal Circuit, the Third Circuit noted that 28 U.S.C. § 1400(b) cannot specify the limits of due process. "In restricting venue in patent infringement actions Congress did not and indeed could not assume the authority to make a constitutional law pronouncement about the due process limits of in personam jurisdiction." Horne v. Adolph Coors Co., 684 F.2d 255, 260 (3d Cir. 1982). Congress cannot, through a venue statute, limit the scope of personal jurisdiction. The fact that Congress did not specify the patent holder's state as a venue for ANDA litigation does not mean that personal jurisdiction cannot be exercised over the ANDA applicant in that state. Congressional silence on the choice of venue for ANDA infringement litigation does not support a negative inference. "Congress' intention is simply not known. Ordinarily, Congress' silence is just that—silence." *VE Holding Corp.*, 917 F.2d at 1581 (citations and internal quotes omitted).

nor the courts have defined where the injury occurs from this "highly artificial" statutory act of infringement. If not overruled by the Supreme Court, *Zeneca* eliminates one potential forum for ANDA infringement litigation. Although the act of infringement occurs in Maryland when the applicant files with the FDA, *Zeneca* prohibits an exercise of jurisdiction unless the defendant has other contacts with the state. Thus *Zeneca* parts company with the *Beverly Hills Fan* line of cases in which the Federal Circuit held that jurisdiction could be asserted where the act of infringement, a federal tort, was purposefully committed. Certainly personal jurisdiction can be asserted at the applicant's places of business. Such an approach is consistent with the patent venue statute as well as the House Report accompanying the Hatch-Waxman Act. It also presents no constitutional challenges to due process.

However, a pre-*Beverly Hills Fan* approach to determining the situs of injury may provide another forum for patent holders to assert jurisdiction over ANDA applicants. While the Federal Circuit has held that the situs of a tangible injury, such as use or sale of a patented invention under 35 U.S.C. § 271(a), is where the act occurred,[122] it has not addressed the situs of "artificial" acts of infringement under § 271(e). Arguably the only place the patent holder feels injury when an ANDA paragraph IV certification is filed is at the patent holder's place of residence. Thus, although the due process issues are complicated, it is reasonable that a patent holder could be able to take action against all ANDA infringers in the patent holder's state of residence. Such an approach may be desirable from a public policy perspective. Not only would it be less burdensome on an inventor defending itself from multiple ANDA attacks, it would also be in the interest of judicial economy and the interest of the courts in furthering substantive policies of uniformity and clarity in the United States patent system. Inconsistency in pre-trial rulings, claim construction, and verdicts would be prevented, while discovery, trials, and appeals could be streamlined or consolidated. While it might be desirable for Congress to take the lead in encouraging the use of a single venue in ANDA litigation, this is not necessary. Following *Zeneca*, courts have the freedom to explore a new approach to determining the situs of injury and hence, personal jurisdiction, in ANDA cases.

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122. *See* Beverly Hills Fan Co. V. Royal Sovereign Corp., 21 F.3d 1558 (Fed. Cir. 1994); North Am. Philips Corp. v. American Vending Sales, Inc., 35 F.3d 1576 (Fed. Cir. 1994).