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Patent Venue, and How It Works in Abbreviated New Drug Application Litigation

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In litigation, where the case should be litigated poses an important procedural question. Though federal courts must have both personal and subject matter jurisdiction over a case in order to adjudicate it, cases arise where more than one court has jurisdiction. In such cases, the rules on venue help determine which court should hear the case.¹

Special rules apply in patent litigation. The federal district courts have both original and exclusive jurisdiction over patent cases.2 Further, the patent venue statute, 28 U.S.C. § 1400(b) – which is separate from the general venue statute – provides: "Any 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."3 A firm grasp of patent venue, therefore, requires understanding what the statute means by "resides," "has committed acts of infringement," and has "a regular and established place of business." It is also important to establish which party bears the burden of proof on patent venue. Finally, unique considerations arise in the context of cases involving "artificial" acts of infringement

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under the Hatch-Waxman Act. Hatch-Waxman litigators should be aware of the interplay between venue and "protective ANDA suits."

This article reviews the case law interpreting § 1400(b) and the current law on which party bears the burden of proof on patent venue, and discusses how protective ANDA suits and venue are interrelated.

"RESIDES"

The case of TC Heartland LLC v. Kraft Foods Group Brands LLC began as follows. 4TC Heartland was headquartered in and organized under the laws of Indiana.⁵ Kraft was organized under Delaware law and headquartered in Illinois.6 Kraft sued TC Heartland for patent infringement in the U.S. District Court for the District of Delaware. TC Heartland, which had "no meaningful local presence" in Delaware, moved to dismiss the case or transfer venue to the U.S. District Court for the Southern District of Indiana on the basis of improper venue.7 The district court denied TC Heartland's motion and TC Heartland petitioned the U.S. Court of Appeals for the Federal Circuit for a writ of mandamus to direct the district court to either dismiss or transfer the case.8

The panel, led by Judge Moore, applied the Federal Circuit's quarter-century-old approach to patent venue from *VE Holding*, and denied TC

Heartland's petition.¹⁰ The panel summarized the rationale in *VE Holding* as follows:

In VE Holding, we found that the Supreme Court's decision in Fourco with regard to the appropriate definition of corporate residence for patent cases in the absence of an applicable statute to be no longer the law because in the 1988 amendments Congress had made the definition of corporate residence applicable to patent cases. 28 U.S.C. § 1391(c) (1988) ("For the purposes of venue under this chapter"). In 1988, the common law definition of corporate residence for patent cases was superseded by a Congressional one. Thus, in 2011, there was no established governing Supreme Court common law ruling which Congress could even arguably have been codifying in the language "except otherwise provided by law."11

The Supreme Court granted certiorari.

Writing for a unanimous 8-membered Court, Justice Thomas rejected the Federal Circuit's interpretation of "resides" in § 1400(b). The Court reaffirmed its 60-year-old holding in *Fourco* "that for purposes of § 1400(b) a domestic corporation "resides" only in its State of incorporation."

Almost a year after *TC Heartland*, the Federal Circuit addressed a follow-on issue specific to states with multiple judicial districts. ¹⁴ Writing for a unanimous panel, Judge Linn clarified that:

[A] domestic corporation incorporated in a state having multiple judicial districts "resides" for purposes of the patent-specific venue statute, 28 U.S.C. § 1400(b), only in the single judicial district within that state where it maintains a principle place of business, or failing that, the judicial district in which its registered office is located....¹⁵

"REGULAR AND ESTABLISHED PLACE OF BUSINESS"

In the aftermath of *TC Heartland*, as one district court observed, "the long-dormant "regular and established place of business" prong of § 1400(b) has made a comeback." While *TC Heartland* clarified what "resides" means in § 1400(b), *Cray* clarified

the statute's phrase "a regular and established place of business." ¹⁷

Like the facts in TC Heartland, the facts in Cray are simple. Cray was a Washington corporation with a principal place of business in Washington.¹⁸ Cray had no physical offices or property in the Eastern District of Texas, but Cray did have two employees work remotely from their homes in the district.¹⁹ Raytheon sued Cray for patent infringement in the U.S. District Court for the Eastern District of Texas.²⁰ Cray filed motions to dismiss and transfer for improper venue.²¹ After applying a four-factor test, the district court determined that Cray maintained "a regular and established place of business" in the Eastern District of Texas.²² Cray petitioned the Federal Circuit for a writ of mandamus vacating the district court's order denying Cray's motion to transfer.²³

Writing for a unanimous panel, Judge Lourie rejected the district court's four-factor test. Instead, the Federal Circuit explained, district courts must consider three general requirements. ²⁴ In determining whether a place constitutes "a regular and established place of business," the district court must find that the place is: (1) "a physical place in the district"; "a regular and established place of business"; and "the place of the defendant." ²⁵ Applying this test to the facts of *Cray*, and emphasizing that no one factor controls, the Federal Circuit found that Cray did not have a regular and established place of business in the Eastern District of Texas and directed the district court to transfer the case to an appropriate venue. ²⁶

Although the Federal Circuit in *Cray* found the presence of remote workers in a district insufficient to meet the "regular and established place of business" prong of § 1400(b), it did not categorically exclude a finding that remote workers might be sufficient to establish venue in some instances. *In re Monolithic Power Systems* demonstrates the open questions remaining in the context of remote workers.²⁷

In *Monolithic*, Bel Power sued Monolithic for patent infringement in the U.S. District Court for the Western District of Texas.²⁸ Monolithic moved to dismiss or transfer for lack of venue, arguing that the homes of four fulltime remote employees in the Western District of Texas did not constitute a "regular and established place of business."²⁹ The district court distinguished *Cray* in finding that

Monolithic had a "regular and established place of business" in the Western District of Texas, citing Monolothic's history of soliciting employment in the Western District to support local customers and provision of lab equipment or products to be used in or distributed from their homes to certain employees in the Western District.³⁰ Monolithic petitioned the Federal Circuit for a writ of mandamus directing the district court to dismiss or transfer the case.³¹

The Federal Circuit denied the petition. The per curium majority of Judges Chen and Stark found the district court's ruling did not warrant mandamus, noting that the case "may present an idiosyncratic set of facts."32 The court highlighted the amount of specialized equipment present in the home of one of Monolithic's employees in the Western District, which is not typically found in a home office.³³ The court noted, however, that denial of mandamus did not mean the district court's venue decision was correct.³⁴ Judge Lourie dissented, arguing that the facts clearly failed to meet the requirements for a "regular and established place of business" in the Western District and finding mandamus particularly warranted in view of "the increased prevalence of remote work."35

Following *Monolithic*, how the "regular and established place of business" prong will be applied to remote workers remains an open question.

"HAS COMMITTED ACTS OF INFRINGEMENT"

The statutory phrase "has committed acts of infringement" has received surprisingly little judicial interpretation given its longevity. This is largely the result of the pre-*TC Heartland* treatment of "resides," which made "resides" a much lower bar to, and thus a more attractive means of, establishing venue.

One area where this statutory phrase has received judicial attention has been litigation under the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act). Until the last few years, two district courts – in *Bristol-Myers* and *Galderma*, ³⁶ respectively – had been split on which acts are relevant to determining where an Abbreviated New Drug Application (ANDA) defendant "has committed acts of infringement." The ANDA is a filing that a drug manufacturer submits to the U.S. Food and Drug Administration

(FDA) to obtain FDA approval to enter the market with a generic version of a FDA-approved drug. The mere submission of the ANDA to the FDA constitutes an artificial act of infringement.³⁷ The artificial nature of the drug manufacturer's infringement was the main source of disagreement between the *Bristol-Myers* and *Galderma* courts.

In *Bristol-Myers*, Judge Stark – now a judge on the Federal Circuit – wrote that "*planned*, *future acts* that the ANDA filer *will take* in this District *must be considered now* in determining whether venue is proper here." Judge Stark reasoned that "ANDA litigation is prospective in nature." In his opinion, Judge Stark also explicitly rejected the notion that the act of infringement occurs where the ANDA submission is made (or the place where the filing is mailed from), writing:

But MPI offers no persuasive reason for why the Court should expand the scope of the "acts of infringement" inquiry to include preparatory activities that are explicitly *not* infringing acts under § 271(e)(1)'s safe harbor. Nor does MPI offer a persuasive reason for why, if the "acts of infringement" are something more than just the submission of an ANDA, the pertinent "acts of infringement" should not be understood as something broader than what MPI seems to have arbitrarily selected. 40

The Galderma court, in contrast, considered the preparation and submission of the ANDA filing as the only acts relevant to determining whether the defendant "has committed acts of infringement." Chief Judge Lynn emphasized that the patent venue statute provides that venue is proper "where the defendant has committed acts of infringement." The only act that has occurred, she explained, is the drug manufacturer's filing of the ANDA. Chief Judge Lynn noted that "the Court is not relying on research or activities other than the preparation and actual submission of the ANDA itself."

In Valeant Pharms., the Federal Circuit resolved this split and held that in Hatch-Waxman suits the "acts of infringement" occur "only in districts where actions related to the submission of an Abbreviated New Drug Application (ANDA) occur, not in all locations where future distribution of the generic products specified in the ANDA is contemplated." Venue in Hatch-Waxman suits, the Federal Circuit

held, "must be predicated on *past acts* of infringement. . ." In so holding, the Federal Circuit rejected Judge Stark's reasoning in *Bristol-Myers*, stating that Valeant raised "strong policy reasons for adopting its [broad] reading of the statutes" but leaving it to Congress to revise the statutes to the extent it finds such policy considerations persuasive.

More recently, in Celgene Corp., the Federal Circuit reaffirmed that venue in Hatch-Waxman suits must be predicated on past acts of infringement and expanded on Valeant Pharms.'s statement that "acts of infringement" must be related to submission of the ANDA. 47 The Federal Circuit clarified that "the relevant infringing acts must, at a minimum, fairly be part of the submission – not merely "related to" it in some broader sense."48 With that narrower interpretation in hand, the Federal Circuit rejected Celgene's argument that the receipt of the notice letter is an infringement act, because the statute treats the notice letter and the ANDA submission as different things.49 In fact, the ANDA applicant cannot send the notice letter to the brand-patentee drug company until the FDA has confirmed receipt of the ANDA.⁵⁰ While the notice letter has, thus, been ruled out, what other acts are considered to be "part of the submission" remains to be seen.

BURDEN OF PROOF ON PATENT VENUE

Which party bears the burden of proof on patent venue has, until very recently, remained a somewhat murky area of patent law. The weight of district court cases has favored placing the burden on the plaintiff to prove patent venue is proper. Likewise, the federal courts of appeals that have addressed the issue – before the Federal Circuit was established in 1982 and obtained exclusive jurisdiction over patent appeals (other than those arising from patent claims brought as permissive counterclaims) – placed the burden on the plaintiff. Some district courts, however, including some with patent-heavy dockets, have placed the burden of proving patent venue is improper on the party opposing venue. Some

Almost one year after *TC Heartland*, the Federal Circuit squarely addressed this issue for the first time. In *In re ZTE*, ZTE petitioned the Federal Circuit for a writ of mandamus seeking an order reversing the lower court's denial of its motion to dismiss for improper venue.⁵⁴ The Federal Circuit directed the parties to provide supplemental

briefing on two issues: (1) "Does the Federal Circuit or regional circuit law apply to the question of who bears the burden of proof on a challenge to venue under 28 U.S.C. § 1406 in a patent case?"; and (2) "On this question, which party bears the burden of proof?"55 In its supplemental brief, ZTE stressed, in response to the first question, that the issue of burden in the patent venue context is "unique to patent law." This is, in part, because § 1400(b) requires proof of "where the defendant has committed acts of infringement."57 American GNC Corporation, the respondent, argued in its supplemental brief that because § 1406 – the statute that governs the consequence of improper venue – is not specific to patent law, regional circuit law applies.⁵⁸ The parties, of course, made several other arguments too numerous to summarize here.

A unanimous panel, led by Judge Linn, announced the following two black letter rules: (1) "Federal Circuit law governs the placement of the burden of persuasion on the propriety of venue under § 1400(b)"; and (2) "the [p]laintiff bears the burden of establishing proper venue." ⁵⁹

PROTECTIVE ANDA SUITS

The unanswered questions about patent venue addressed elsewhere in this article have added importance in ANDA litigation. The following discussion explains why.

The phrase "protective ANDA suits" refers to the common ANDA litigation practice of filing a second and nearly (or completely) identical complaint in a second district court after filing a first complaint in a first district court. 60 The filing of the second complaint, which is the "protective ANDA suit," is a litigation strategy developed in response to a latent ambiguity in the Hatch-Waxman Act. The Act states that, once an ANDA applicant (and soon-to-be defendant) files its Paragraph IV certification, the FDA shall approve the ANDA "effective immediately." 61 If, however, the plaintiff brings a patent infringement action against the ANDA applicant within 45 days of its receipt of the notice letter, then the FDA is automatically precluded from approving the ANDA for 30 months from the date the plaintiff received the applicant's notice letter. 62 The statute is silent as to how a jurisdiction-based dismissal would affect the 30-month-long injunction.⁶³ Therefore, plaintiffs concerned about personal jurisdiction or venue challenges often bring protective ANDA suits to try to preserve the injunction.

Typically, the plaintiff moves to stay the second suit - to keep it as a back-up without incurring significant expenses – and the defendant moves to dismiss. The court can stay the case while the other litigation proceeds, grant the defendant's motion to dismiss, transfer venue to the other district, or let the litigation proceed normally if the first case is, in the interim, terminated or transferred. Courts' analysis ordinarily begins by addressing the "first-to-file rule," which states that "when actions involving nearly identical parties and issues have been filed in two different district courts, the court in which the first suit was filed should generally proceed to judgment."64 Factors that weigh against applying the first-to-file rule include "extraordinary circumstances, inequitable conduct, bad faith, anticipatory suits, and forum shopping."65 ANDA defendants may try to argue that these exceptions apply in an effort to force the litigation in the second district, but, as one court put it, in view of the "unusual nature of ANDA claims . . . and absen[ce] [of] any guidance in the statute or case law regarding the handling of such "protective" suits, courts generally grant such stays.⁶⁶ One court has, however, denied plaintiff's motion for a stay, reasoning:

If the [first] forum is in any way questionable in order to necessitate a "protective filing" as Plaintiffs maintain, then *this Court* is clearly the better forum, as all of the parties agree that both jurisdiction and venue lie here."

Accordingly, ANDA litigants should be especially mindful of any uncertainties as to what constitutes improper venue.

FOREIGN CORPORATIONS

A last, but quite important, wrinkle in patent venue jurisprudence is the distinction between domestic and foreign corporations. In *TC Heartland*, the Supreme Court reaffirmed its *Fourco* holding "that for purposes of § 1400(b) a *domestic* corporation 'resides' only in its State of incorporation." Since the Court expressly declined to address the impact of its decision on foreign corporations, ⁶⁹ patent venue over foreign corporations remained somewhat of an open question in the months following the Court's decision. The consensus among courts that addressed the issue in the wake of *TC Heartland* was that foreign corporations may be sued

in any judicial district in the United States.⁷⁰ For example, one district court explained:

In *Brunette*, the Supreme Court held that when a foreign defendant is the subject of a patent infringement action, venue is governed by the general venue provision, rather than by § 1400(b). *Brunette*, 406 U.S. at 714, 92 S. Ct. 1936. The general venue provision states that "a defendant not resident in the United States may be sued in *any* judicial district."

In a recent Federal Circuit decision,⁷² then-Chief Judge Prost reaffirmed the rule that foreign corporations may be sued in any judicial district in the United States. As to the reasoning, the Federal Circuit clarified that "aliens are wholly outside the operation of all the federal venue laws, general and special."⁷³ Accordingly, foreign corporations, unlike domestic corporations, which benefit from the venue protections listed above, cannot successfully move to dismiss based on improper venue.

CONCLUSION

In the aftermath of *TC Heartland*, patent venue remains a hot topic in patent litigation. While the Supreme Court resolved, once and for all, the meaning of "resides" in § 1400(b), several other issues have bubbled to the surface. The Federal Circuit has actively been trying to bring clarity to these once murky areas of patent law. Whether these decisions survive Supreme Court scrutiny has yet to be seen. Further, where a party "has committed acts of infringement" and the contours of a "regular and established place of business" remain open questions.

Notes

- 1. See 28 U.S.C. § 1400.
- 2. 28 U.S.C. § 1338.
- 3. 28 U.S.C. § 1400(b); cf. 28 U.S.C. § 1391.
- 4. TC Heartland LLC v. Kraft Foods Group Brands LLC, 137 S. Ct. 1514 (2017).
- 5. Id. at 1517.
- 6. Id.
- 7. Id.
- 8. In re TC Heartland LLC, 821 F.3d 1338 (Fed. Cir. 2016), rev'd, 137 S. Ct. 1514 (2017).

- 9. Id. at 1340 (citing VE Holding Corp. v. Johnson Gas Appliance Co., 917 F.2d 1574 (Fed. Cir. 1990)).
- 10. Id. at 1341.
- Id. at 1342 (discussing Fourco Glass Co. v. Transmirra Prods. Corp., 353 U.S. 222 (1957)).
- 12. See generally TC Heartland, 137 S. Ct. 1514.
- 13. Id. at 1516-17 (citing Fourco Glass Co. v. Transmirra Prods. Corp., 353 U.S. 222).
- 14. In re: BigCommerce, Inc., No. 2018-122 (Fed. Cir. May 15, 2018).
- 15. Id. at 2.
- Peerless Network, Inc. v. Blitz Telecom Consulting, LLC, 2018 WL 1478047, 17-CV-1725, at *2 (JPO) (S.D.N.Y. Mar. 26, 2018).
- 17. In re: Cray Inc., 871 F.3d 1355 (Fed. Cir. 2017).
- 18. Id. at 1357.
- 19. Id.
- 20. Id.
- 21. Id.
- See Raytheon Company v. Cray, Inc., 258 F.Supp.3d
 (E.D. Tex. June 29, 2017).
- 23. In re: Cray Inc., 871 F.3d at 1357.
- 24. Id. at 1360.
- 25. Id.
- 26. Id. at 1364-67.
- 27. See In re Monolithic Power Systems, Inc., 50 F. 4th 157 (Fed. Cir. 2022).
- 28. Id. at 158.
- 29. Id. at 158-59.
- 30. Id. at 159.
- 31. Id.
- 32. Id. at 160-61.
- 33. Id. at 160.
- 34. Id. at 161.
- 35. Id. at 162-63.
- Bristol-Myers Squibb Co. v. Mylan Pharm. Inc., 2017
 WL 3980155, C.A. No. 17-379-LPS (D. Del. Sep. 11, 2017);
 Galderma Labs., LP v. Teva Pharm. USA, Inc., 2017
 WL 6505793, Case No. 17-cv-01076 (N.D. Tex. Nov. 17, 2017).
- 37. 35 U.S.C. § 271(e)(2)(A).
- 38. Bristol-Myers Squibb Co., 2017 WL 3980155 at *9.
- 39. Id. at *10.
- 40. Id. at *****11.
- 41. Galderma Labs., 2017 WL 6505793 at 6.
- 42. Id. at *5 (internal citation omitted).
- 43. Id.
- 44. Id. at *6.
- 45. Valeant Pharms. N. Am. LLC v. Mylan Pharms. Inc., 978 F.3d 1374, 1375 (Fed. Cir. 2020).
- 46. Id. at 1381.
- 47. Celgene Corp. v. Mylan Pharms. Inc., 17 F.4th 1111, 1120 (Fed. Cir. 2021).

- 48. Id. at 1121.
- 49. Id.
- 50. See 21 U.S.C. § 314.95(b)(2).
- 51. See, e.g., Personal Audio, LLC v. Google, Inc., 280 ESupp.3d 922, 928 (E.D. Tex. Dec. 1, 2017); Flexible Technologies, Inc. v. SharkNinja Operating LLC, 2018 WL 1175043, C.A. No. 8:17-cv-00117-DCC (D. S.C. Feb. 14, 2018); Tower Labs., Ltd. v. Lush Cosmetics Ltd., 285 ESupp.3d 321 (D. D.C. Jan. 24, 2018).
- See, e.g., Cordis Corp. v. Cardiac Pacemakers, 599 F.2d
 1085, 1086 (1st Cir. 1979); Grantham v. Cook Bros., Inc.,
 420 F.2d 1182, 1184 (7th Cir. 1969).
- 53. See, e.g., Soverain IP, LLC v. Apple, Inc., Nos. 2:17-cv-00204-RWS-RSP, 2:17-cv-00207-RWS-RSP, 2017 U.S. Dist. LEXIS 140039 at *3 (E.D.Tex. July 25, 2017) (characterizing venue as a personal privilege and shield from inconvenience); Bristol-Myers Squibb Co., 2017 WL 3980155 at *1 (stating that the defendant to the ANDA litigation bore the burden of proving that it did not satisfy the requirements of the second prong of § 1400).
- 54. Petition for Writ of Mandamus, In re ZTE (USA) Inc., No. 2018-113 (Fed. Cir. Nov. 30, 2017).
- Order, In re ZTE (USA) Inc., No. 2018-113 (Fed. Cir. Feb. 20, 2018).
- 56. Petitioner's Supplemental Brief, In re ZTE (USA) Inc., No. 2018-113 at 5 (Fed. Cir. Mar. 2, 2018).
- 57. Id. at 7.
- 58. Respondent's Supplemental Brief, In re ZTE (USA) Inc., No. 2018–113 at 5 (Fed. Cir. Mar. 2, 2018).
- In re ZTE (USA) Inc., No. 2018–113 at 8 (Fed. Cir. May 14, 2018).
- 60. See, e.g., Pfizer Inc. v. Apotex, Inc., 2009 WL 2843288, C.A. No. 08-cv-00948 (D. Del. Aug. 13, 2009); Pfizer Inc. v. Sandoz Inc., 2010 WL 256548, C.A. No. 09-742-JJF (D. Del. Jan. 20, 2010); Pfizer Inc. v. Sandoz, Inc., 2010 WL 502726, C.A. No. 09-cv-02392-CMA-MJW (D. Colo. Feb. 8, 2010); Sandoz, Inc. v. Pfizer, Inc., 2010 WL 502727, C.A. No. 09-cv-02457-CMA-MJW (D. Colo. Feb. 8, 2010); Purdue Pharma L.P. v. Collegium Pharmaceutical, Inc., 2015 WL 4653164, Civ. No. 15-260-SLR (D. Del. Aug. 6, 2015); Pfizer, Inc. v. Mylan, Inc., 2009 WL 10270101, C.A. No. 1:09-CV-79 (N.D. W.Va. Nov. 20, 2009); Novartis AG v. Ezra Ventures, LLC, 2015 WL 4197692, No. 4:15-cv-00095 KGB (E.D. Ark. July 10, 2015); Schering Corp. v. Caraco Pharmaceutical Labs., Ltd., 2007 WL 1648908, No. 06-14386 (E.D. Mich. June 6, 2007); Takeda Pharmaceutical Co. Ltd. v. Mylan, Inc., 2012 WL 932147, No. 12cv0026 (W.D. Pa. Mar. 19, 2012).
- 61. 21 U.S.C. § 355(j)(5)(B)(iii).
- 62. Id.

- 63. See 21 U.S.C. § 355(j)(5)(B).
- 64. Zide Sport Shop of Ohio, Inc. v. Ed Tobergte Associates, Inc., 16 F. App'x 433, 437 (6th Cir. 2001) (internal quotation marks omitted).
- 65. Id.
- PDL Biopharma, Inc. v. Sun Pharmaceutical Industries, Ltd., 2007 WL 2261386, C.A. No. 07-11709, *2 (E.D. Mich. Aug. 6, 2007).
- 67. Aventis Pharma Deutschland GMBH v. Lupin Ltd., 403 F.Supp.2d 484, 490 (E.D.Va. Dec. 2, 2005).
- 68. TC Heartland LLC, 137 S. Ct. at 1517 (emphasis added).

- 69. Id. at 1520 n. 2.
- 70. See, e.g., Infogation Corp. v. HTC Corporation, 2017 WL 2869717, No. 16-cv-01902-H-JLB at *4 n.2 (S.D. Cal. July 5, 2017); 3G Licensing, S.A. v. HTC Corp., 2017 WL 6442101, No. 17-83-LPS-CJB at *2 (D. Del. Dec. 18, 2017).
- 71. Mya Saray, LLC v. Dabes, 2018 WL 1161145, C.A. No. 3:17CV00016 (W.D.Va. Mar. 5, 2018).
- 72. In re: HTC Corp., 889 F.3d 1349 (Fed. Cir. 2018). 73. Id. at 7.

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