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# Tightening the Gilstrap: How "TC Heartland" Limited the Pharmaceutical Industry When it Reined in the Federal Circuit

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## **TIGHTENING THE GILSTRAP: HOW *TC HEARTLAND* LIMITED THE PHARMACEUTICAL INDUSTRY WHEN IT REINED IN THE FEDERAL CIRCUIT**

*Amanda Walton Newton\**

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“At bottom, [TC HEARTLAND] is nothing more than a request for an ill-conceived, one-size-fits-all judicial end-run around existing legislative policy decisions.”<sup>1</sup>

— Amicus Curiae, The Pharmaceutical Research and Manufacturers of America (PhRMA)

## I. INTRODUCTION

On February 4, 2016, Martin Shkreli visited Capitol Hill.<sup>2</sup> As CEO of Turing Pharmaceuticals, Shkreli faced Congressional pressure for Turing’s purchase of an old drug, Daraprim, and the company’s decision to hike the price from \$13.50 to \$750 per dose.<sup>3</sup> Though headlines focused on Shkreli’s newfound infamy as “PhRMA Bro,” the underlying issue “ha[d] as much to do with the Food and Drug Administration as Shkreli: although the drug’s patent expired in the nineteen-fifties, the F.D.A. certification process for generic drugs is grueling enough that, for the moment, whoever owns Daraprim has a virtual monopoly in America.”<sup>4</sup> In short, Shkreli’s company could increase Daraprim’s price as high as they wished because the FDA approval process for a generic was so onerous to initiate that, even though Daraprim’s patent expired years ago, the drug faced no competition.<sup>5</sup>

The Daraprim saga is far from unique. As of October 30, 2017, the FDA announced that at least 319 pharmaceutical drugs in the United States had expired patents but no generic competitor.<sup>6</sup> Lomustine, a forty-year-old drug used to treat multiple types of cancer, was purchased by NextSource

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<sup>1</sup> Brief of the Pharmaceutical Research and Manufacturers of America (PhRMA) as *Amicus Curiae* in Support of Respondent at 4, *TC Heartland LLC v. Kraft Food Groups Brands LLC*, 137 S. Ct. 1514 (2017) (No. 16-341).

<sup>2</sup> Haley Sweetland Edwards, *Pharma ‘Bad Boy’ Martin Shkreli Mocks Congress*, TIME (Feb. 4, 2016), [time.com/4207931/martin-shkreli-congress-turning-pharmaceutical-hearing/](http://time.com/4207931/martin-shkreli-congress-turning-pharmaceutical-hearing/).

<sup>3</sup> Jordan Weissmann, *How the Government Could Punish That Hedge Fund Bro Who Wanted to Raise a Drug’s Price 5,000 Percent*, SLATE: MONEYBOX (Sept. 23, 2015, 8:48 AM), [http://www.slate.com/blogs/moneybox/2015/09/23/martin\\_shkreli\\_and\\_daraprim\\_how\\_the\\_government\\_could\\_stop\\_his\\_drug\\_price.html](http://www.slate.com/blogs/moneybox/2015/09/23/martin_shkreli_and_daraprim_how_the_government_could_stop_his_drug_price.html).

<sup>4</sup> Kelefa Sanneh, *Everyone Hates Martin Shkreli. Everyone Is Missing the Point*, NEW YORKER (Feb. 5, 2016), <https://www.newyorker.com/culture/cultural-comment/everyone-hates-martin-shkreli-everyone-is-missing-the-point>.

<sup>5</sup> Weissmann, *supra* note 3.

<sup>6</sup> U.S. FOOD & DRUG ADMIN., LIST OF OFF-PATENT, OFF-EXCLUSIVITY DRUGS WITHOUT AN APPROVED GENERIC (2017).

Biotechnology in 2013; between 2013 and 2017, the price increased 1,400 percent.<sup>7</sup> The company justified the pricing increase based on “product-development costs, regulatory-agency fees, and the benefit the treatment delivers to patients.”<sup>8</sup> Normally, massive price increases for an off-patent drug (regardless of their justification) would encourage generic competition, but generic drug manufacturers have been deterred by “big entry costs and time commitments associated with obtaining regulatory approval” by the FDA.<sup>9</sup>

The Drug Price Competition and Patent Term Restoration Act, or Hatch-Waxman Act,<sup>10</sup> was designed in order to ensure healthy competition between branded and generic pharmaceuticals and prevent companies like Turing and NextSource from engaging in price gouging.<sup>11</sup> Signed into law in 1984, the Hatch-Waxman Act was drafted with two “competing goals in mind: to spur new pharmaceutical development and to encourage greater public access to generic drugs.”<sup>12</sup> Periods of market exclusivity were given to brand-name pharmaceutical manufacturers,<sup>13</sup> while their generic competitors were given expedited review of their FDA application for approval to enter the market.<sup>14</sup> Although the Hatch-Waxman Act was at first successful in balancing the interests of these two groups, in recent years, the FDA’s slow approval process has deterred generic pharmaceutical corporations from entering the market to compete with brand-name companies.<sup>15</sup>

In March 2017, the U.S. Supreme Court unwittingly backed into a solution that mitigates the impact of the FDA’s problematic approval process. In *TC Heartland LLC v. Kraft Foods Group Brands LLC*,<sup>16</sup> the Supreme Court turned a

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<sup>7</sup> Peter Loftus, *Cancer Drug Price Rises 1,400% With No Generic to Challenge It*, WALL ST. J. (Dec. 25, 2017, 7:00 AM), <https://www.wsj.com/articles/cancer-drug-price-rises-1400-with-no-generic-to-challenge-it-1514203201>.

<sup>8</sup> *Id.*

<sup>9</sup> *Id.*

<sup>10</sup> Pub. L. No. 98-417, 98 Stat. 1585 (1984). The Act’s common name, the Hatch-Waxman Act, is derived from the original sponsors of the bill as introduced in Congress, Senator Orrin Hatch and Representative Henry Waxman.

<sup>11</sup> David Crow, *Waxman bits out at Allergan patent deal with Mohawk tribe*, FIN. TIMES (Oct. 8, 2017), <https://www.ft.com/content/81bd8930-abb8-11e7-aab9-abaa44b1e130> (quoting Henry Waxman as saying that “[w]hen drafting the Hatch-Waxman Act, Senator Hatch and I worked hard to find a balance that would promote price competition while providing at the same time incentives for manufacturers”).

<sup>12</sup> Allen M. Sokal & Bart A. Gerstenblith, *The Hatch-Waxman Act: Encouraging Innovation and Generic Drug Competition*, 10 CURRENT TOPICS ON MEDICINAL CHEMISTRY 1950 (2010).

<sup>13</sup> *Id.*

<sup>14</sup> *Id.*

<sup>15</sup> Currently, 80% of American prescriptions are for generic drugs. However, drug prices have increased massively in recent years. Weissmann, *supra* note 3.

<sup>16</sup> 137 S. Ct. 1514 (2017).

long-standing interpretation of the patent venue statute, 28 U.S.C. § 1400, on its head. Part (b) of the statute provides that a patent suit “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.”<sup>17</sup> For the twenty-seven years prior to *TC Heartland*, U.S. courts had followed the Federal Circuit’s interpretation of § 1400(b), thereby gifting the court the moniker “de facto supreme court of patents.”<sup>18</sup> The Federal Circuit interpreted the statute’s reference to a defendant’s residence expansively, finding venue proper anywhere the defendant was subject to personal jurisdiction.<sup>19</sup> Doing so gave extensive “flexibility to pharmaceutical companies . . . bringing Hatch-Waxman cases,”<sup>20</sup> so Hatch-Waxman suits were filed almost exclusively in Delaware and New Jersey, where most branded pharmaceutical companies were incorporated.<sup>21</sup>

Though plaintiffs’ “forum-selection flexibility”<sup>22</sup> lasted nearly thirty years, in *TC Heartland*, the Supreme Court reversed the Federal Circuit and limited a corporation’s residence to “the state of incorporation only”<sup>23</sup> by relying on a narrower 1957 interpretation of § 1400(b) in *Fourco Glass Co. v. Transmirra Products Corp.*<sup>24</sup> As a result, the *TC Heartland* decision led patent plaintiffs to rely on the second prong of § 1400(b), where a defendant commits “acts of infringement”

<sup>17</sup> 28 U.S.C. § 1400(b) (2016).

<sup>18</sup> Mark D. Janis, *Patent Law in the Age of the Invisible Supreme Court*, 2001 U. ILL. L. REV. 387, 387 (2001).

<sup>19</sup> *VE Holding Corp. v. Johnson Gas Appliance Co.*, 917 F.2d 1574, 1584 (Fed. Cir. 1990), *abrogated by TC Heartland LLC v. Kraft Foods Group Brands LLC*, 137 S. Ct. 1514 (2017); *see also Toombs v. Goss*, 768 F. Supp. 62, 63 (W.D.N.Y. 1991) (“[A] corporation now is a resident of a district if it is subject to personal jurisdiction in that district.”); *Braden Shielding Sys. v. Shielding Dynamics*, 812 F. Supp. 819, 821 (N.D. Ill. 1992) (“To the extent that *Fourco* and *VE Holding* conflict, we must favor *VE Holding* . . .”); *Hester Industries Inc. v. Stein Inc.*, No. 96-719-A, 1996 WL 710835, at \*1–2 (E.D. Va. Oct. 3, 1996) (“[T]he standards for personal jurisdiction and venue involve weighing the same elements . . .”); *Pfizer Inc. v. Synthon Holding, B.V.*, 386 F. Supp. 2d 666, 679 (M.D.N.C. 2005) (“The Federal Circuit holds that a defendant ‘resides’ in a district if it is subject to personal jurisdiction there.”).

<sup>20</sup> Paul A. Ainsworth & Joshua I. Miller, *Practical Issues for the Pharmaceutical and Biopharmaceutical Industry in the Wake of TC Heartland*, NAT’L L. REV. 1, 1 (May 23, 2017), <https://www.natlawreview.com/article/practical-issues-pharmaceutical-and-biopharmaceutical-industry-wake-tc-heartland> (citing *VE Holding Corp.*, 917 F.2d at 1574).

<sup>21</sup> *The Supreme Court’s TC Heartland Decision: Implications for Hatch-Waxman Litigation*, ARENT FOX LLP (May 25, 2017), <https://www.arentfox.com/newsroom/alerts/supreme-court%E2%80%99s-tc-heartland-decision-implications-hatch-waxman-litigation>.

<sup>22</sup> Ainsworth, *supra* note 20, at 2.

<sup>23</sup> 137 S. Ct. 1514, 1519 (2017).

<sup>24</sup> 353 U.S. 222, 226 (1957).

and has a “regular and established place of business,”<sup>25</sup> in order to find a proper venue. For Hatch-Waxman litigants, relying on the second prong of § 1400(b) created an “impenetrable problem”<sup>26</sup> because “the unique [forward-looking] posture of pharmaceutical litigation”<sup>27</sup> contradicts the “backward-looking, historical conduct”<sup>28</sup> of § 1400(b)’s second prong. District courts since *TC Heartland* have split when considering how to resolve this issue and apply the second prong of § 1400(b) in the Hatch-Waxman context,<sup>29</sup> leaving brand-name pharmaceutical plaintiffs uncertain as to where they can sue their generic competitors.<sup>30</sup> Thus, though “venue decisions . . . can be essential for both plaintiffs and defendants,”<sup>31</sup> litigation since *TC Heartland* “bodes well for defendants (accused infringers) seeking to defend patent cases on their home turf or otherwise seeking a more favorable forum”<sup>32</sup> because of the newfound difficulty for pharmaceutical plaintiffs in finding a proper venue.

Branded pharmaceutical companies urge that *TC Heartland* disrupts the “carefully crafted balance[ ]” in the Hatch-Waxman Act and “serves no purpose except to invite harassment, enable and encourage inconsistent results, and waste the innovator’s time and resources.”<sup>33</sup> Nevertheless, this Note argues that the newfound difficulty *TC Heartland* imposes on branded pharmaceutical companies reinforces the goal of the Hatch-Waxman Act by restoring market

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<sup>25</sup> See *OptoLum, Inc. v. Cree, Inc.*, No. CV-16-03828-PHX-DLR, 2017 WL 3130642, at \*1 (D. Ariz. July 24, 2017) (finding that *TC Heartland* “made clear that a corporation ‘resides’ only in its State of incorporation for purposes of the patent venue statute”); see also *Boston Sci. Corp. v. Cook Grp., Inc.*, 269 F. Supp. 3d 229, 244 (D. Del. 2017) (Noting that after *TC Heartland*, “the issue of how to determine what is and is not a regular and established place of business is arising before courts with increased frequency.”).

<sup>26</sup> *Bristol-Myers Squibb Co. v. Mylan Pharm., Inc.*, No. 17-397-LPS, 2017 WL 3980155, at \*6 (D. Del. Sept. 11, 2017).

<sup>27</sup> Christina A. Ondrick et al., *U.S. Supreme Court Limits Venue Under the Patent Statute in TC Heartland*, PAUL HASTINGS LLP (May 23, 2017), <https://www.paulhastings.com/publications-items/details/?id=9a75ec69-2334-6428-811c-ff00004cbded>.

<sup>28</sup> *Bristol-Myers*, No. 17-397-LPS, 2017 WL 3980155, at \*7.

<sup>29</sup> Compare *Bristol-Myers*, 2017 WL 3980155, at \*7, with *Galderma Labs., L.P. v. Teva Pharm. USA, Inc.*, No. 3:17-cv-01076-M, 2017 WL 6505793, at \*1, \*5 (N.D. Tex. Nov. 17, 2017).

<sup>30</sup> Scott W. Doyle et al., *What is a ‘Regular and Established Place of Business?’*, FRIED FRANK LLP (July 10, 2017), <http://www.friedfrank.com/index.cfm?pageID=25&itemID=7812>.

<sup>31</sup> Jake Holdreith et al., *New Strategies for Venue in Hatch-Waxman Litigation*, 13 PLIR 372, 374, Mar. 13, 2015 (arguing that delays in the disposition of venue suits are harmful to generic manufacturers: “even when a generic ultimately wins on the merits, if the resolution takes too long, it can effectively be a win for the brand”).

<sup>32</sup> Franklin D. Kang & Lyle D. Kossis, *Federal Circuit Issues First Published Decision Applying High Court’s T.C. Heartland Decision Regarding Patent Venue*, MCGUIREWOODS: LEGAL ALERT (Sept. 26, 2017), <https://www.mcguirewoods.com/Client-Resources/Alerts/2017/9/Federal-Circuit-Published-Decision-TC-Heartland-Patent-Venue.aspx>.

<sup>33</sup> Brief of PhRMA *supra* note 1, at \*2–4.

competition. To do so, Part Two of this Note will examine the maturity of the patent venue provision, § 1400(b) and the development of the Supreme Court's decision in *TC Heartland*. In Part Three, this Note will analyze the options available to pharmaceutical plaintiffs to clarify confusion in patent infringement suits, including filing a protective suit, requesting consolidation through multidistrict litigation, and encouraging Congressional action. This Note finds the first two solutions untenable due to their high cost, and ultimately argues that Congress's failure to act is beneficial in the pharmaceutical context because, by making it more difficult for pharmaceutical plaintiffs to file suit, generic manufacturers are once again able to enter the market and compete with brand-name manufacturers.

## II. BACKGROUND

### A. NARROW BEGINNINGS

1. *Creation of the Patent Venue Statute.* As the Supreme Court notes at the beginning of *TC Heartland*,<sup>34</sup> the continually-changing, century-long history of patent venue provisions is crucial to parse the language of the present statute. Congress first enacted a venue statute specific to patents in 1897<sup>35</sup> and put patent infringement cases "in a class by themselves, outside the scope of general venue legislation."<sup>36</sup> For the next forty-five years, courts interpreted the patent-specific venue statute to be the exclusive provision governing venue for patent infringement suits,<sup>37</sup> whereby suits could be filed in the district where the defendant was an "inhabitant" or in the district where the defendant "committed acts of infringement" and had a "regular and established place of business."<sup>38</sup> In 1942, the Supreme Court justified its continued adherence to the exclusivity of the patent venue provision by arguing that its purpose in defining the exact jurisdictional parameters would be undermined if the provision was interpreted to "dovetail with the general [venue] provisions."<sup>39</sup>

In 1948, Congress "re-codified" the statute as § 1400(b) and replaced the word "inhabit[s]" with the word "resides."<sup>40</sup> Separately, the 1948 Act also

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<sup>34</sup> *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514, 1518 (2017) ("The history of the relevant statutes provides important context for the issue in this case.").

<sup>35</sup> Act of Mar. 3, 1897, ch. 395, 29 Stat. 695.

<sup>36</sup> *Brunette Mach. Works, Ltd. v. Kockum Indus., Inc.*, 406 U.S. 706, 713 (1972).

<sup>37</sup> *See Stonite Prods. Co. v. Melvin Lloyd Co.*, 315 U.S. 561, 563 (1942) (determining that § 1400 "is the exclusive provision controlling venue in patent infringement proceedings").

<sup>38</sup> Act of Mar. 3, 1897, ch. 395, 29 Stat. 695.

<sup>39</sup> 315 U.S. at 566.

<sup>40</sup> *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514, 1518–19 (2017) (citing Act of June 25, 1948, 62 Stat. 936).



established § 1391, the general venue statute,<sup>41</sup> which defines corporate residence “for venue purposes” broadly as “any judicial district in which [the corporation] is incorporated or licensed to do business or is doing business . . .”<sup>42</sup>

Although intended to eliminate confusion about venue in patent infringement suits, re-codification only muddied the waters and created a circuit split<sup>43</sup> because courts were unclear whether the new use of “resides” in § 1400(b) fell under the definition of “residence” in § 1391(c).<sup>44</sup> To resolve the split, the Supreme Court granted certiorari in 1957 in *Fourco Glass Co. v. Transmirra Products Corp.* and examined whether § 1400(b) was the “sole and exclusive provision controlling venue in patent infringement actions.”<sup>45</sup>

2. *The Supreme Court’s Ruling in Fourco.* In *Fourco*, the Supreme Court considered whether 28 U.S.C. § 1400(b), the patent venue provision, was “supplemented” by 28 U.S.C. § 1391(c), the general patent statute.<sup>46</sup> Transmirra sued Fourco, a West Virginia corporation, in the Southern District of New York for patent infringement.<sup>47</sup> Transmirra alleged that Fourco resided in the Southern District of New York for venue purposes because it was “actively inducing infringement” of Transmirra’s patented invention by “making, selling or using television receivers, television cathode ray receiving tubes or other devices . . . within the Southern District of New York.”<sup>48</sup> In finding that Fourco had not demonstrated the requisite acts of infringement in S.D.N.Y., the Supreme Court rejected the argument that the general venue provision supplemented § 1400(b) and found that patent infringement suits could be brought *exclusively* in either “the judicial district where the defendant resides, or where the defendant has committed acts of infringement and has a regular and

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<sup>41</sup> See *id.* at 1519 (noting that when Congress “recodified the patent venue statute . . . [it] also enacted the general venue statute”).

<sup>42</sup> 28 U.S.C. § 1391(c) (1952).

<sup>43</sup> See *Fourco Glass Co. v. Transmirra Products Corp.*, 353 U.S. 222, 224 n.3 (1957) (finding that “[t]he Third Circuit, in *Ackerman v. Hook*, 183 F.2d 11, the Seventh Circuit in *C-O-Two Fire Equipment Co. v. Barnes*, 194 F.2d 410, and the Tenth Circuit, in *Ruth v. Eagle-Picher Company*, 225 F.2d 572, as well as numerous District Courts, have held that 28 U.S.C. § 1400(b) alone controls venue in patent infringement cases, while, on the other hand, the Fifth Circuit, in *Dalton v. Shakespeare Co.*, 196 F.2d 469, and in *Guiberson Corp. v. Garrett Oil Tools, Inc.*, 205 F.2d 660, and several District Courts, have held that the provisions of 28 U.S.C. § 1391(c) are to be read into, and as supplementing, § 1400(b), as the Second Circuit held in this case, and that, hence, a corporation may be sued for patent infringement in any district where it merely ‘is doing business’”).

<sup>44</sup> *TC Heartland*, 137 S. Ct. at 1519.

<sup>45</sup> *Fourco*, 353 U.S. at 229.

<sup>46</sup> *Id.* at 222.

<sup>47</sup> *Id.* at 223.

<sup>48</sup> *Transmirra Prods. Corp. v. Fourco Glass Co.*, 133 F. Supp. 531, 532 (S.D.N.Y. 1955), *rev’d* 353 U.S. 222 (1957)).

established place of business.”<sup>49</sup> In other words, patent venue under § 1400(b) is more restrictive than the general § 1391 venue provision. Crucially, the *Fourco* Court based its argument on its interpretation of Congressional intent: the Court relied on the distinction between the “general language” of § 1391(c) and the “specific terms” of § 1400(b)<sup>50</sup> to decide that § 1391(c) did not control because “nothing in the 1948 recodification evidenced [congressional] intent to alter that status.”<sup>51</sup>

#### B. PATENT VENUE EXPANSION

In 1988, Congress amended § 1391 and altered the statutory language relied on by the Supreme Court in *Fourco*.<sup>52</sup>

1. *The 1988 Amendment.* At the time *Fourco* was decided, § 1391(c) ended with the qualifier “for venue purposes.”<sup>53</sup> The 1988 amendment split the statute into two sentences<sup>54</sup> and established new “exact and classic language.”<sup>55</sup> The new language made it clear that “for purposes of venue under this chapter, a defendant that is a corporation shall be deemed to reside in any judicial district in which it is subject to personal jurisdiction . . .”<sup>56</sup> Though the Supreme Court was silent on the issue, the Federal Circuit in 1990 found that the 1988 amendment broadened the scope of § 1391(c) to incorporate the definition of residence in § 1400(b), thus rendering § 1400(b) meaningless.<sup>57</sup>

2. *The Federal Circuit’s Ruling in VE Holding.* In 1990, the Federal Circuit in *VE Holding Corp. v. Johnson Gas Appliance Co.* found that a corporate defendant resided anywhere it was subject to personal jurisdiction.<sup>58</sup> The Federal Circuit seized what they viewed to be an open door to reformulate case law on patent infringement<sup>59</sup> and justified its departure from *Fourco* by relying on the 1988

<sup>49</sup> *Fourco*, 353 U.S. at 228–29.

<sup>50</sup> *Id.* (“Specific terms prevail over the general in the same or another statute which otherwise might be controlling.” (citing *Clifford F. MacEvoy Co. v. United States ex rel. Calvin Tomkins Co.*, 322 U.S. 102, 107 (1944))).

<sup>51</sup> *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514, 1519 (2017). The *Heartland* Court also noted that in *Fourco*, the Court also determined that “‘resides’ in the recodified version . . . bore the same meaning as ‘inhabits.’” *Id.* (citing *Fourco*, 353 U.S. at 226).

<sup>52</sup> *VE Holding Corp. v. Johnson Gas Appliance Co.*, 912 F.2d 1574, 1578 (Fed. Cir. 1990).

<sup>53</sup> *Id.*

<sup>54</sup> 28 U.S.C. § 1391(c) (1988).

<sup>55</sup> *VE Holding*, 917 F.2d at 1579.

<sup>56</sup> Judicial Improvements and Access to Justice Act, Pub. L. No. 100-702, § 1013(a), 102 Stat. 4669 (emphasis added).

<sup>57</sup> *See VE Holding*, 917 F.2d 1574.

<sup>58</sup> *Id.* at 1579 (“Section 1391(c) as it was in *Fourco* is no longer.”).

<sup>59</sup> *Id.* at 1575 (“This is a case of first impression.”).

amendment to the general venue provision.<sup>60</sup> *VE Holding* arose from a dispute between two competitors about the patentability of agricultural tools.<sup>61</sup> Plaintiff VE Holding Corporation filed suit against California Pellet Mill Company and Johnson Gas Appliance Company<sup>62</sup> in the Northern District of California, alleging patent infringement and inducement to infringe. Defendant Johnson moved to dismiss, arguing that, as an Iowa corporation with no regular and established place of business in the Northern District of California, venue was improper there.<sup>63</sup> While the district court in California rejected defendant's arguments, the Federal Circuit found that Congress would have made its intentions explicit if it had intended § 1400(b) to be excepted from the 1988 amendment.<sup>64</sup> The Federal Circuit found instead that § 1391(c) now indicated "a clear intention" that the general statute "expressly read[] itself into the specific statute" of § 1400(b) in order to "define a term," rather than supplant the specific patent statute entirely.<sup>65</sup> Thus, the Federal Circuit found that "the precedential status of *Fourco* was no more."<sup>66</sup> With the freedom to establish the parameters of this "matter of first impression,"<sup>67</sup> the Federal Circuit in *VE Holding* ultimately determined that the test for venue in patent infringement suits "is whether the defendant was subject to personal jurisdiction" under § 1391, as is the case in any other civil litigation.<sup>68</sup>

3. *The Venue Act.* Courts generally applied *VE Holding* in patent infringement suits until the Supreme Court decided *TC Heartland*.<sup>69</sup> Importantly, this trend continued even after a second amendment to the general venue provision. In 2011, Congress passed the Venue Act, which added a preface to § 1391(a) stating

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<sup>60</sup> *Id.*

<sup>61</sup> *Id.* at 1576.

<sup>62</sup> Plaintiff ultimately filed two suits. In *VE Holding I*, plaintiff sued both California Pellet Mill and Johnson Gas Appliance. In *VE Holding II*, plaintiff filed suit against Johnson alone. *Id.*

<sup>63</sup> *Id.*

<sup>64</sup> *Id.* at 1579 ("Congress could readily have added 'except for section 1400(b),' if that exception, which we can presume was well known to the Congress, was intended to be maintained. Certainly it would not be sensible to require Congress to say, 'For purposes of this chapter, and we mean everything in this chapter.'") (emphasis in original).

<sup>65</sup> *Id.* at 1580.

<sup>66</sup> *Id.* at 1579.

<sup>67</sup> *Id.*

<sup>68</sup> *Id.* at 1584.

<sup>69</sup> See, e.g., *Price v. Code-Alarm, Inc.*, No. 91 C 699, 1991 WL 134188 (N.D. Ill. July 16, 1991); *Meteoro Amusement Corp. v. Six Flags*, 267 F. Supp. 2d 263 (N.D.N.Y. 2003); *Sanofi-Aventis v. Synthon Holding BV*, No. 1:07cv86, 2008 WL 819295, at \*3 (M.D.N.C. Mar. 20, 2008); *Imageware Sys., Inc. v. WCC Servs. US, Inc.*, No. 13cv309 DMS (JMA), 2013 WL 12097556 (S.D. Cal. June 17, 2013).

that the section only applied “[e]xcept as otherwise provided by law.”<sup>70</sup> Nevertheless, district courts found that this so-called “saving clause”<sup>71</sup> did not “undermine the conclusion”<sup>72</sup> in *VE Holding*. Instead, courts interpreted the altered language to be “even *broader* than the language it replaced” because the updated language was applicable to all venue statutes, not just venue statutes under title twenty-eight of the U.S. Code.<sup>73</sup>

### C. AT THE HEART OF IT

Six years after Congress passed the Venue Act, the Supreme Court heard oral arguments regarding § 1400(b) and § 1391(c) for the first time since its 1957 *Fourco* decision,<sup>74</sup> and on May 22, 2017, the Court published its decision in *TC Heartland LLC v. Kraft Foods Group Brands LLC*.<sup>75</sup>

1. *The Supreme Court in TC Heartland.* *TC Heartland* arose in the context of a dispute between competitors who both manufacture flavored drink mixes.<sup>76</sup> *TC Heartland* is an Indiana company headquartered in Indiana; although it “is not registered to conduct business in Delaware and has no meaningful local presence there,” *TC Heartland* was sued by Kraft in a Delaware district court because of its shipment of the alleged infringing products into the state.<sup>77</sup> The district court rejected *TC Heartland*’s argument that it neither resided in Delaware nor had a regular and established place of business there, and the Federal Circuit denied *TC Heartland*’s petition for writ of mandamus, both courts citing the flexible

<sup>70</sup> 28 U.S.C. § 1391(a) (2016).

<sup>71</sup> *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514, 1516 (2017).

<sup>72</sup> *Script Sec. Sols. L.L.C. v. Amazon.com, Inc.*, 170 F. Supp. 3d 928, 933 (E.D. Tex. 2016) (“[T]he analysis in *VE Holding* is just as applicable to the post-2011 version of the venue statute as it was to the pre-2011 version.”) *Id.* at 934; *see also* *TeleSign Corp. v. Twilio, Inc.*, No. CV 15-3240 PSG (Ssx), 2015 WL 12765482, at \*5 (C.D. Cal. Oct. 16, 2015) (“The Court . . . declines to hold that *VE Holdings* is no longer good law.”).

<sup>73</sup> *Script Sec. Sols.*, 170 F. Supp. 3d at \*934 (“The 1988 version of section 1391(c) made its provisions applicable ‘[f]or purposes of venue under this chapter,’ while the 2011 version of section 1391 makes its provisions applicable ‘[f]or all venue purposes.’”) (emphasis added).

<sup>74</sup> Keith Grady & Karen Morris, *Denying TC Heartland Changed the Law on Venue Ignores Reality*, IPWATCHDOG (Oct. 8, 2017), <http://www.ipwatchdog.com/2017/10/08/denying-tc-heartland-changed-law-venue-ignores-reality/id=88227/>.

<sup>75</sup> 137 S. Ct. 1514 (2017).

<sup>76</sup> *Id.* at 1517. Note that although neither entity is incorporated, respondent alleged the competitors were corporations in its complaint and petitioner admitted this allegation in its answer. As a result, this Note, like the Court, does not address the question of whether § 1400(b) applies to unincorporated entities.

<sup>77</sup> *Id.*

venue landscape from *VE Holding*.<sup>78</sup> The Federal Circuit found that *VE Holding* “firmly resolved” any confusion regarding patent venue and refused to reconsider this “settled precedent for over 25 years.”<sup>79</sup> The Federal Circuit also rejected TC Heartland’s claim that the 2011 amendments overruled *VE Holding* and re-codified *Fourco* by arguing that “there was no established governing Supreme Court common law” to codify after the 1988 amendment to § 1391.<sup>80</sup> TC Heartland petitioned the Supreme Court for certiorari to determine whether the 2011 amendments meant that § 1391(c) supplemented § 1400(b).<sup>81</sup>

The Supreme Court found that the Venue Act did not alter the scope of the patent venue statute for two reasons. First, the Court relied on a 1966 case, *Pure Oil Co. v. Suarez*,<sup>82</sup> to find that the shift in § 1391’s language from “for venue purposes” to encompass “all venue purposes” made no material difference “to the already comprehensive provision.”<sup>83</sup> Second, the Court found that the addition of the savings clause to § 1391 solidified the Court’s position as to Congressional intent.<sup>84</sup> Contrary to the Federal Circuit’s belief that the savings clause made the general venue statute “even broader,”<sup>85</sup> the Supreme Court found that the clause “expressly state[d]” that some venue provisions are exempt from the default definition of residence if they provide their own distinct definition.<sup>86</sup> Because the Court had found that § 1391 did not govern in *Fourco*, even when the statute contained no exceptions, the Court reasoned that the savings clause meant the *Fourco* holding “rest[ed] on even firmer footing now . . .”<sup>87</sup>

In the short, eight-page opinion, the Court makes one final observation: it dismisses TC Heartland’s argument that the 2011 amendment ratified the Federal Circuit’s *VE Holding* opinion.<sup>88</sup> Instead, the Court directly contradicts the Federal Circuit, noting that the lower court relied “heavily” on the 1988

<sup>78</sup> Kraft Foods Grp. Brands LLC v. TC Heartland, LLC, No. 14-28-LPS, 2015 WL 5613160, at \*1–2 (D. Del. Sept. 24, 2015); *In re TC Heartland LLC*, 821 F.3d 1338, 1341 (Fed. Cir. 2016), *rev’d sub nom*, TC Heartland, LLC v. Kraft Foods Grp. Brands LLC, 137 S. Ct. 1514 (2017).

<sup>79</sup> *In re TC Heartland*, 821 F.3d at 1341

<sup>80</sup> *Id.* at 1341–42.

<sup>81</sup> *TC Heartland*, 137 S. Ct. at 1521.

<sup>82</sup> *Pure Oil Co. v. Suarez*, 384 U.S. 202 (1966).

<sup>83</sup> *TC Heartland*, 137 S.Ct. at 1520 (citing *Pure Oil Co. v. Suarez*, 384 U.S. 202, 204–05 (1966)) (In *Pure Oil*, the Court found that the phrase “for venue purposes” cover[ed] “all venue statutes.”).

<sup>84</sup> *Id.* at 1521 (“This particular argument is even weaker . . . because the current provision includes a saving clause expressly stating that it does not apply when ‘otherwise provided by law.’”).

<sup>85</sup> *Script Sec. Sols. L.L.C. v. Amazon.com, Inc.*, 170 F. Supp. 3d 928, 934 (2016).

<sup>86</sup> *TC Heartland*, 137 S. Ct. at 1521.

<sup>87</sup> *Id.*

<sup>88</sup> *Id.*

amendment that specified that the general venue statute applied to provisions “under this chapter.”<sup>89</sup> Congress eliminated this language in 2011, which the Supreme Court found indicative of Congressional intent to distance the statute from its 1988 formulation and realign its interpretation with the *Fourco*-era text.<sup>90</sup> In short, the *TC Heartland* Court determined that because “nothing in the text” indicates Congress intended to approve *VE Holding*, the sixty-five-year-old decision in *Fourco* remained binding precedent and venue was improper for TC Heartland in Delaware.<sup>91</sup>

2. *Judge Gilstrap’s ‘Rocket Docket.’* Following the Court’s *TC Heartland* decision, patent case filings shifted dramatically. Prior to the ruling, thirty-six percent of patent cases filed in the U.S. in 2016 were brought in the Eastern District of Texas,<sup>92</sup> where Judge Rodney Gilstrap of the Eastern District heard almost one out of every four patent venue suits filed *nationwide*.<sup>93</sup> Known as the “Rocket Docket,” Texas’ Eastern District “actively cultivate[d], or at least tolerate[d], an image as the go-to jurisdiction”<sup>94</sup> for patent trolls.<sup>95</sup> In the first six weeks after *TC Heartland*, however, just fourteen percent of cases were filed there;<sup>96</sup> instead, the District of Delaware (where, as of 2016, almost sixty-seven percent of U.S. Fortune 500 companies are incorporated<sup>97</sup>) saw a nearly sixteen-percent jump in case filings, followed by an increase in case filings in Silicon Valley’s Central and Northern Districts of California.<sup>98</sup> For patent trolls, filing in the district of Delaware under the first prong of § 1400(b) presented an “obvious workaround” to the uncertainty created by *TC Heartland* because “patent suits there typically rule in favor of” those entities.<sup>99</sup>

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<sup>89</sup> *Id.* (quoting § 1391(c) (1988 ed.)).

<sup>90</sup> *Id.*

<sup>91</sup> *Id.*

<sup>92</sup> Benjamin Anger & Boris Zelkind, *Where Plaintiffs Are Filing Suit Post-TC Heartland*, LAW360 (July 7, 2017, 12:20 PM), <https://www.law360.com/articles/942115/where-plaintiffs-are-filing-suit-post-tc-heartland>.

<sup>93</sup> Brian J. Love & James Yoon, *Predictably Expensive: A Critical Look at Patent Litigation in the Eastern District of Texas*, 20 STAN. TECH. L. REV. 1, 6 (2017).

<sup>94</sup> *Id.* at 3–4.

<sup>95</sup> *Id.* Patent trolls are “companies formed solely for the purpose of monetizing patent rights through litigation, often using methods that seem to leverage the costs and burdens of litigation more so than the value of the patented technology.” *Id.* at 3.

<sup>96</sup> Anger & Zelkind, *supra* note 92.

<sup>97</sup> Delaware Division of Corporations, 2016 Annual Report, <https://corp.delaware.gov/2016AnnualReport.pdf>.

<sup>98</sup> Anger & Zelkind, *supra* note 92. The leap in California filings can be attributed to the high volume of technology companies headquartered in Silicon Valley. *Id.*

<sup>99</sup> Robert Stoll, *What Changes Result from the Supreme Court Decision in TC Heartland?*, IPWATCHDOG (Sept. 6, 2017), <http://www.ipwatchdog.com/2017/09/06/changes-result-supreme-court-decision-tc-heartland/id=87612/>.

Nevertheless, high “court congestion” in Delaware led to additional difficulty for patent infringement litigants.<sup>100</sup> Down to only two active judges, Delaware courts resorted to “lobbing cases to other courts, mean[ing that] patent holders who want to keep their infringement lawsuits in that court are facing new uncertainty.”<sup>101</sup> As an alternative, patent plaintiffs began filing suit under the previously under-utilized second prong of § 1400 (b), which permits an assertion of venue anywhere the defendant has committed “acts of infringement and has a regular and established place of business.”<sup>102</sup> It is under the second prong of § 1400 that Judge Rodney Gilstrap reasserted the Eastern District of Texas’s relevance as a haven for patent infringement plaintiffs.<sup>103</sup>

3. *The Federal Circuit in Raytheon v. Cray.* On June 29, 2017, the Eastern District of Texas considered residency for venue purposes in *Raytheon Co. v. Cray, Inc.*<sup>104</sup> Raytheon alleged that Cray infringed on its four computer-related patents by selling computers to customers in Texas and inducing others to use the products.<sup>105</sup> Because Cray is incorporated in the State of Washington, the Eastern District quickly dismissed venue under the first prong of § 1400(b)<sup>106</sup> before considering whether Cray had committed “acts of infringement” in the district and whether Cray had a regular and established place of business there.<sup>107</sup>

The court determined that Cray had committed acts of infringement based on two allegations by Raytheon: (1) Cray induced patent infringement by supercomputer users in the Eastern District; and (2) Cray infringed on Raytheon’s patent when a Cray employee offered to sell a supercomputer while working in the Eastern District.<sup>108</sup> Finding these allegations sufficient to constitute acts of infringement for the purposes of establishing proper venue, the Eastern District then considered whether Cray had a regular and established place of business in the district.<sup>109</sup> The district court lamented the Supreme Court’s failure in *TC Heartland* to clear up a circuit split regarding what constitutes a regular and established place of business:<sup>110</sup> While some courts have traditionally required a “physical presence in the district” for the place of

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<sup>100</sup> Malathi Nayak, *Swelling Docket Pushing Delaware Judges to Transfer Patent Cases*, 86 USLW (BNA) No. 11 (Sept. 28, 2017).

<sup>101</sup> *Id.*

<sup>102</sup> 28 U.S.C. § 1400(b) (2016).

<sup>103</sup> See Stoll, *supra* note 99.

<sup>104</sup> 258 F. Supp. 3d 781 (E.D. Tex. 2017), *mandamus granted, order vacated, sub nom, In Re Cray Inc.*, 871 F.3d 1355 (Fed. Cir. 2017).

<sup>105</sup> *Id.* at 784

<sup>106</sup> *Id.* at 788.

<sup>107</sup> *Id.* at 788–99.

<sup>108</sup> *Id.* at 789–90.

<sup>109</sup> *Id.* at 792.

<sup>110</sup> *Id.*

business to be regular and established,<sup>111</sup> others have historically been less strict.<sup>112</sup> Without Supreme Court precedent to rely on, the Eastern District relied on a 1985 Federal Circuit opinion, *In re Cordis Corp.*<sup>113</sup> to find that a single employee in the Eastern District was sufficient to constitute a regular and established place of business.<sup>114</sup>

In *Cordis*, a Minnesota corporation filed a patent infringement suit in Minnesota against a Florida corporation.<sup>115</sup> The defendant had two full-time sales representatives based in Minnesota and hired a Minnesota secretarial service to receive Cordis's goods and messages, but alleged that it did not have a regular and established place of business because it was not registered to do business in Minnesota, did not have a bank account there, and did not lease or own any property in the state.<sup>116</sup> The Federal Circuit found those contacts were insufficient to warrant granting petitioner's writ of mandamus, declaring that "the appropriate inquiry" is whether Cordis has a "permanent and continuous presence," not whether the corporation has a "fixed *physical* presence."<sup>117</sup> Because the Eastern District in *Cray* viewed the Cray employee's activities as "factually similar" to those in *In re Cordis*, the Eastern District applied the permanent-and-continuous analysis and found that the employee's exclusive contract as a sales executive working full-time within the Eastern District with the "administrative support" from Cray satisfied the "regular and established place of business" condition.<sup>118</sup>

To clarify *Cordis* and "adapt[ ] . . . to the modern era," the court in *Raytheon v. Cray* also enumerated four factors intended to act as "guideposts" in a "tailored 'totality of the circumstances' approach": (1) defendant's physical presence (for instance through a retail store or warehouse); (2) defendant's representations (that it has a presence, whether internally or externally); (3) benefits received by defendant from its presence in the district (with sales revenue being relevant but

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<sup>111</sup> *Id.* (citing *Holub Indus., Inc. v. Wyche*, 290 F.2d 852, 854 (4th Cir. 1961); *Gen Radio Co. v. Superior Elec. Co.*, 293 F.2d 949, 951 (1st Cir. 1961); *Phillips v. Baker*, 121 F.2d 752, 756 (9th Cir. 1941); *Warner-Lambert Co. v. C.B. Fleet Co.*, 583 F. Supp. 519, 522 (D.N.J. 1984); *Coleco Indus., Inc. v. Kransco Mfg., Inc.* 247 F. Supp. 571, 574 (S.D.N.Y. 1965)).

<sup>112</sup> *Id.* (citing various degrees of austerity in *Mastantuono v. Jacobsen Manufacturing Co.*, 184 F. Supp. 178 (S.D.N.Y. 1960); *Brunswick Corp. v. Suzuki Motor Co.*, 575 F. Supp. 1412, 1424 (E.D. Wis. 1983); *Instrumentation Specialties Co. v. Waters Assocs., Inc.*, No. 76 C 4340, 1977 WL 22810, at \*6 (N.D. Ill. Oct. 12, 1977); *Shelter-Lite, Inc. v. Reeves Bros.*, 356 F. Supp. 189, 195 (N.D. Ohio 1973)).

<sup>113</sup> *In re Cordis Corp.*, 769 F.2d 733 (Fed. Cir. 1985).

<sup>114</sup> *Raytheon*, 258 F. Supp. 3d at 794.

<sup>115</sup> *Cordis*, 769 F.2d at 734.

<sup>116</sup> *Id.* at 735.

<sup>117</sup> *Id.* at 737 (emphasis added).

<sup>118</sup> *Id.* at 793–794.



not essential); and (4) defendant's targeted interactions with the district.<sup>119</sup> These factors, enumerated by Judge Randy Gilstrap in the Eastern District, became known as the "Gilstrap test" and temporarily "grant[ed] patent plaintiffs] a lifeline"<sup>120</sup> by making it easier to predict and litigate suits against generic patent infringers.

Relief was short-lived, however, for the Federal Circuit granted Cray's petition for a writ of mandamus in *In re Cray Inc.* and ordered Judge Gilstrap to transfer the case to the Western District of Wisconsin.<sup>121</sup> The Federal Circuit found that the Eastern District "misunderstood the scope and effect" of *Cordis*<sup>122</sup> and determined that the four-factor Gilstrap test was "[in]sufficiently tethered" to the statute's language because it (1) inappropriately expanded the physical location requirement, (2) overlooked the requisite regularity for a place of business, and (3) mistakenly relied on an employee's place of business rather than a place established by the business itself.<sup>123</sup> Instead, the Federal Circuit found that three requirements are necessary to find that a defendant had a "regular and established place of business" in the district: "(1) there must be a physical place in the district; (2) it must be a regular and established place of business; and (3) it must be the place of the defendant. If any statutory requirement is not satisfied, venue is improper . . ." <sup>124</sup> In doing so, the Federal Circuit created a third requirement for venue in patent infringement suits: "the 'place' . . . must be that of the defendant," not their employee.<sup>125</sup> The Federal Circuit justified this more narrow interpretation of § 1400(b) by arguing that the statute was designed to be a "restrictive measure"<sup>126</sup> that "[g]ave] original jurisdiction to the court where [only] a *permanent* agency transacting the business is located"<sup>127</sup> in order to "eliminate the 'abuses engendered' " by other venue statutes.<sup>128</sup> The Federal Circuit concluded its opinion by noting that "no one fact is controlling,"<sup>129</sup> but most industry experts have proffered that "the Federal Circuit put a 'nail in the

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<sup>119</sup> *Id.* at 796–99.

<sup>120</sup> Stoll, *supra* note 99.

<sup>121</sup> 871 F.3d 1355, 1367 (Fed. Cir. 2017).

<sup>122</sup> *Id.* at 1359 (citing *In re Cordis Corp.*, 769 F.2d 733 (Fed. Cir. 1985)).

<sup>123</sup> *Id.* at 1362–63.

<sup>124</sup> *Id.* at 1360. Contrast this approach with that of Judge Gilstrap, who applied a totality of the circumstances analysis that required consideration of "other realities present in individual cases," in order to avoid "the siren call of bright line rules." *Raytheon*, 258 F. Supp. 3d at 799. See also Doyle, *supra* note 30.

<sup>125</sup> *In re Cray*, 871 F.3d at 1362.

<sup>126</sup> *Id.* (quoting *Stonite Prods. Co. v. Melvin Lloyd Co.*, 315 U.S. 561, 66 (1942)).

<sup>127</sup> *Id.* at 1361 (quoting 29 CONG. REC. 1900 (1897) (statement of Rep. Lacey) (emphasis added)).

<sup>128</sup> *Id.* (quoting *Schnell v. Peter Eckrich & Sons, Inc.*, 365 U.S. 260, 262 (1961)).

<sup>129</sup> *Id.* at 1366.

coffin on forum shopping in patent cases' "when it overturned the Gilstrap test."<sup>130</sup>

Ultimately, Cray did not help its employee select a location for his home and Cray did not store materials at the home; as a result, the Federal Circuit refused to find that Cray's employee's home satisfied the third "place of the defendant" element.<sup>131</sup> The Federal Circuit's more narrow interpretation of the statute mimics the Supreme Court's "textualist interpretation"<sup>132</sup> in *TC Heartland*, eliminating much of the uncertainty that abounded after the Supreme Court's May *Heartland* ruling<sup>133</sup> and aligning the approaches to patent venue suits in the two courts.<sup>134</sup>

#### D. IN THE PHARMACEUTICAL CONTEXT

Through *Cray*, the Federal Circuit clarified confusion for district courts caught in the back-and-forth between the Supreme Court and the Federal Circuit over the scope of the patent venue provision.<sup>135</sup> Nevertheless, because the Hatch-Waxman Act creates a "unique posture"<sup>136</sup> for litigants, application of *TC Heartland* in pharmaceutical patent suits remains uncertain.

1. *The Hatch-Waxman Act*. Passed in 1984, the Hatch-Waxman Act<sup>137</sup> was adopted in order to address a "pharmaceutical marketplace dominated by

<sup>130</sup> Patrick H.J. Hughes, *Attorneys weigh in on impact of Federal Circuit patent venue ruling*, WL INTELL. PROP. DAILY BRIEFING, 2017 WL 4295782 (Sept. 28, 2017) (quoting interview with Jeremy Elman, Attorney, Dorsey & Whitney).

<sup>131</sup> *Id.* at 1363.

<sup>132</sup> Robert G. Bone, *Forum Shopping & Patent Law—A Comment on TC Heartland*, 96 TEX. L. REV. 141, 141 (2017).

<sup>133</sup> See Bart Rankin & Yoon Chae, *Federal Circuit Provides Standard for Interpreting 'Regular and Established Place of Business' for Patent Venue*, BAKER MCKENZIE (Sept. 26, 2017), <http://www.bakermckenzie.com/en/insight/publications/2017/09/standard-patent-venue/> ("The Federal Circuit's Cray decision . . . provides needed guidance.").

<sup>134</sup> See Jonathan D.J. Loeb et al., *Federal Circuit Brings More Clarity to Rules Governing Proper Venue for Patent Cases*, DECHERT LLP (Sept. 2017), <https://info.dechert.com/10/9377/september-2017/federal-circuit-court-brings-more-clarity-to-rules-governing-proper-venue-for-patent-cases.aspx?sid=1a6e94cf-966c-490e-b720-7359884fc294#> (finding that "recent rulings from the Supreme Court (*TC Heartland LLC v. Kraft Food Group Brands LLC*, 137 S. Ct. 1514 (2017)) and the Federal Circuit (*In re Cray Inc.*, No. 2017-129) are making it easier for defendants to escape the Eastern District for friendlier venues").

<sup>135</sup> The *Cray* decision is binding on district courts because, "in matters unique to patent law, [the Federal Circuit] applies its own law . . . [t]hus, Federal Circuit law, rather than regional circuit law, governs [the] analysis of what § 1400(b) requires." *In re Cray Inc.*, 871 F.3d 1355, 1360 (Fed. Cir. 2017).

<sup>136</sup> Ondrick, *supra* note 27.

<sup>137</sup> Pub. L. No. 98-417, 98 Stat. 1585 (1984). Its common name, the Hatch-Waxman Act, is derived from the original sponsors of the bill as introduced in Congress, Senator Orrin Hatch and Representative Henry Waxman.

expensive brand-name drugs despite their patent protection having lapsed.”<sup>138</sup> The goal of the Act during implementation was two-fold:<sup>139</sup> it aimed to incentivize branded pharmaceutical manufacturers to create new drugs *and* expedite the Food and Drug Administration’s (FDA) approval of generic drugs, which are “therapeutically equivalent to brand-name products” but are also far less expensive to produce and to purchase.<sup>140</sup>

For brand-name manufacturers, the Hatch-Waxman Act grants innovative products five years of exclusive market control following FDA approval.<sup>141</sup> For generics, the Hatch-Waxman Act established the Abbreviated New Drug Application (ANDA) process, under which generic manufacturers can make one of four claims about the patented drug at issue.<sup>142</sup> The last of these claims, known as a “Paragraph IV” certification,<sup>143</sup> allows generic drug manufacturers to request expedited approval of the generic drug by asserting that the branded drug either has an “invalid” patent or its patent “will not be infringed by the manufacture, use, or sale of the new drug.”<sup>144</sup> The first generic drug manufacturer to successfully challenge a brand-name manufacturer’s patent receives a six-month period of market exclusivity.<sup>145</sup> However, generic challengers must notify the branded manufacturer of their ANDA upon making a Paragraph IV certification, and brand-name pharmaceutical companies are then given forty-five days to file a patent infringement suit.<sup>146</sup> If the branded manufacturer files suit, the FDA will wait thirty months before granting final approval of the ANDA filer’s application.<sup>147</sup>

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<sup>138</sup> Aaron S. Kesselheim & Jonathan J. Darrow, *Hatch-Waxman Turns 30: Do We Need a Re-Designed Approach for the Modern Era?*, 15 YALE J. HEALTH POL’Y, L. & ETHICS 293, 295 (2015).

<sup>139</sup> Mylan Pharms., Inc. v. FDA, 454 F.3d 270, 272 (4th Cir. 2006) (finding that Hatch-Waxman “aimed to strike a balance between . . . induc[ing] name-brand pharmaceutical[s] . . . to develop new drug products, while simultaneously enabling competitors to [make] cheaper, generic copies” (quoting *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 230 (4th Cir. 2002))).

<sup>140</sup> Kesselheim, *supra* note 138, at 295.

<sup>141</sup> *Id.* at 305.

<sup>142</sup> Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585, 1586 (1984) (codified as amended at 35 U.S.C. § 271 (1984)).

<sup>143</sup> Kesselheim, *supra* note 138, at 305.

<sup>144</sup> Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585, 1586 (1984) (codified as amended at 35 U.S.C. § 271 (1984)).

<sup>145</sup> *See* Kesselheim, *supra* note 138, at 304 (“The Act afforded a six-month period of market exclusivity to the first generic manufacturer to certify that the . . . brand-name manufacturer’s patents were invalid or not infringed.”).

<sup>146</sup> Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585, 1589 (1984) (codified as amended at 35 U.S.C. § 271 (1984)). For this reason, brand-name manufacturers are generally the plaintiffs in patent infringement suits.

<sup>147</sup> *Id.* at 1594.

Prior to *TC Heartland*, branded manufacturers who filed suit within the forty-five-day deadline were able to do so in a number of different jurisdictions, including filing multiple Hatch-Waxman claims against separate ANDA filers in a single jurisdiction.<sup>148</sup> This flexibility was made possible by a 2016 Federal Circuit opinion, *Acorda Therapeutics, Inc. v. Mylan Pharmaceuticals, Inc.*,<sup>149</sup> where the court found that a generic drug company in a Hatch-Waxman suit was subject to personal jurisdiction anywhere the company intended to market its product.<sup>150</sup>

2. *The Federal Circuit in Acorda Therapeutics.* In *Acorda*, plaintiff Acorda Therapeutics filed suit in the District of Delaware alleging that generic manufacturer Mylan infringed on its patents when Mylan applied for FDA approval to market its generic versions of drugs Ampyra®, Onglyza®, and Kombiglyze.<sup>TM</sup><sup>151</sup> Though Mylan is incorporated in West Virginia and prepared and submitted its ANDA filings in West Virginia, Mylan also made the “costly, significant step of applying to the FDA for approval to engage in future activities . . . that will be purposefully directed at Delaware.”<sup>152</sup> Because of the “close connection” between an ANDA filing and *future* minimum contacts, the *Acorda* court determined Mylan’s ANDA filing to be a “concrete, non-artificial act[] of infringement” because it was “tightly tied, in purpose and planned effect, to the deliberate making of sales in Delaware.”<sup>153</sup> Thus, the court found Mylan was subject to personal jurisdiction in Delaware.<sup>154</sup>

The *Acorda* court’s personal jurisdiction analysis is “intimately related to” the § 1400(b) patent venue analysis because, prior to *TC Heartland*, venue was proper anywhere the defendant was subject to personal jurisdiction.<sup>155</sup> With venue proper wherever the generic manufacturer had minimum contacts, and minimum contacts satisfied by “planned, non-speculative harmful conduct before it occurs,”<sup>156</sup> branded pharmaceuticals after *Acorda* could file a patent infringement suit essentially “nationwide.”<sup>157</sup> Doing so disadvantaged generic drug

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<sup>148</sup> Ainsworth, *supra* note 20.

<sup>149</sup> 817 F.3d 755, 757 (Fed. Cir. 2016), *cert. denied*, 137 S. Ct. 625 (2017).

<sup>150</sup> Bristol-Myers Squibb Co. v. Mylan Pharm., Inc., No. 17-397-LPS, 2017 WL 3980155, at \*8 (D. Del. Sept. 11, 2017).

<sup>151</sup> *Acorda*, 817 F.3d at 757. (Acorda markets Ampyra®, and AstraZeneca markets Onglyza® and Kombiglyze<sup>TM</sup>; AstraZeneca also sued Mylan separately. *Id.* at 757–58.)

<sup>152</sup> *Id.* at 759.

<sup>153</sup> *Id.* at 760.

<sup>154</sup> *Id.* at 764.

<sup>155</sup> *Bristol-Myers*, 2017 WL 3980155, at n.6 (citing *Beverly Hills Fan Co. v. Royal Sovereign Corp.*, 21 F.3d 1558, 1564 (Fed. Cir. 1994)).

<sup>156</sup> *Acorda*, 817 F.3d at 762 (citing *United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953)).

<sup>157</sup> Colleen Tracy James & Manuel J. Velez, *TC Heartland May Cause Protective Suits In ANDA Cases*, LAW360 (Mar. 24, 2017, 12:27 PM), <https://www.law360.com/articles/903700/tc-heartland-may-cause-protective-suits-in-anda-cases>.

manufacturers who made a “conscious decision not to have a presence”<sup>158</sup> in a particular jurisdiction like Delaware, which is historically patentee-friendly.<sup>159</sup> In “burden[ing] unnecessarily”<sup>160</sup> these generic manufacturers, the Federal Circuit’s 2016 decision in *Acorda* disturbed the balance between the interests of brand-name and generic drug manufacturers in the Hatch-Waxman Act.

*TC Heartland* re-jiggered the Hatch-Waxman balancing act once again. Though the Federal Circuit later provided some clarity for patent litigants in *Cray*, application of the statute in the context of a Hatch-Waxman suit requires additional analysis. Part III of this Note considers the implications for both brand-name pharmaceutical companies and their generic manufacturers of the 2017 changes in the statutory interpretation of the patent venue statute.

### III. ANALYSIS

#### A. CRAY-ZINESS FOR THE PHARMACEUTICAL INDUSTRY

While the *Cray* decision generally calmed the waters of patent infringement suits after the Federal Circuit made the decision to bend the knee<sup>161</sup> to the Supreme Court’s textual interpretation, in the pharmaceutical industry, no higher court has yet resolved the confusion among district courts in how to interpret prong two of § 1400(b) for Hatch-Waxman litigants. In the first suit to consider the issue, *Bristol-Myers Squibb Co. v. Mylan Pharm. Inc.*,<sup>162</sup> the District of Delaware considered what constituted a future act of infringement and a regular and established place of business for a Hatch-Waxman litigant.<sup>163</sup>

1. *Bristol-Myers Squibb v. Mylan*. In *Bristol-Myers*, plaintiffs Bristol-Myers Squibb Co. and Pfizer Co. brought suit in Delaware alleging that Mylan [MPI], a West Virginia company, infringed upon its patented drug when it submitted an ANDA to the FDA.<sup>164</sup> While MPI was registered with the Delaware Board of Pharmacy, the corporation did not have any real property, addresses, or employees in Delaware.<sup>165</sup> Bristol-Myers Squibb nevertheless argued MPI’s

<sup>158</sup> Ainsworth, *supra* note 20.

<sup>159</sup> Love, *supra* note 93, at 1.

<sup>160</sup> See Brief for The Generic Pharmaceutical Association as *Amicus Curiae* in Support of Mylan’s Petition for Rehearing En Banc at 10, *Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755 (2016) (No. 15-1456, 15-1460).

<sup>161</sup> “[W]hen your enemies defy you, you must serve them steel and fire. When they go to their knees, however, you must help them back to their feet. Elsewise no man will ever bend the knee to you.” GEORGE R.R. MARTIN, *A STORM OF SWORDS* 122 (Bantam 2013).

<sup>162</sup> No. 17-397-LPS, 2017 WL 3980155, at \*1 (D. Del. Sept. 11, 2017).

<sup>163</sup> *Id.*

<sup>164</sup> *Id.* at \*1–2.

<sup>165</sup> *Id.* at \*2.

ANDA filing constituted an act of infringement and argued the corporation had a regular and established place of business in the district.<sup>166</sup>

The *Bristol-Myers* court, like the *VE Holding* court, began its analysis by noting that the issue is one of “first impression”; no court prior to *Bristol-Myers* has been forced to interpret the second prong of § 1400(b) in the Hatch-Waxman context.<sup>167</sup> The court then addressed the first half of the second prong of § 1400(b): what constitutes an act of infringement in Hatch-Waxman suits.<sup>168</sup> Looking to the text of the statute, the court found it dispositive that Congress chose to use the present perfect tense in § 1400(b) when referring to acts of infringement by asking where the defendant “has committed” these acts.<sup>169</sup> For Hatch-Waxman patent litigants, this choice of language creates “an almost impenetrable problem” because a Hatch-Waxman suit is focused on acts where the defendant “will” manufacture, sell, or offer to sell a product “in the future,”<sup>170</sup> while § 1400(b) is focused on acts that have already been committed.<sup>171</sup> In other words, it is problematic that “the temporal focus of the Hatch-Waxman infringement analysis is in the future, *not*—as is true in essentially all other patent infringement suits—the past, or even the present.<sup>172</sup>

One particularly complicated facet of this “temporal mismatch” is the safe harbor provision of § 271(e), under which a generic drug manufacturer that might otherwise have committed patent infringement is saved from litigation if the act(s) of infringement are “reasonably related” to an ANDA filing.<sup>173</sup> In doing so, the safe harbor provision protects generic drug companies from patent infringement suits if they have submitted, or plan to submit, an ANDA filing.<sup>174</sup> As a result, “historical conduct that constitutes patent infringement in a typical patent lawsuit is expressly and statutorily deemed non-infringing in the context of Hatch-Waxman litigation.”<sup>175</sup>

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<sup>166</sup> *Id.*

<sup>167</sup> *Id.* at \*6.

<sup>168</sup> *Id.*

<sup>169</sup> “The Supreme Court has emphasized the importance of analyzing ‘Congress’ choice of verb tense to ascertain a statute’s temporal reach.” *Id.* at \*6 (quoting *Carr v. United States*, 560 U.S. 438, 448 (2010)).

<sup>170</sup> *Id.* See *Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 760 (Fed. Cir. 2016) (finding that the defendant’s “ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drug”).

<sup>171</sup> *Bristol-Myers*, 2017 WL 3980155, at \*6.

<sup>172</sup> *Id.* (citing *Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 760 (Fed. Cir. 2016)) (emphasis in original).

<sup>173</sup> *Id.* at \*7 (citing 353 U.S.C. § 271(e)(i) and *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005)).

<sup>174</sup> *Id.*

<sup>175</sup> *Id.*

Though Hatch-Waxman litigants are expressly protected from backward-looking litigation, § 271(e) allows for the creation of a “‘highly artificial act of infringement’ [to] precipitate[] litigation . . . for the express purpose of resolving patent disputes *before* a generic drug product is launched.”<sup>176</sup> Under § 271(e)(2), generic drug companies commit an act of infringement if they file an ANDA that “seeks approval [of a generic bioequivalent drug] before the expiration of a patent covering the branded drug.”<sup>177</sup> This “particularized framework” acts as a “stand-in” in order to “move [the infringement] forward in time” and in doing so resolves the “complete mismatch” between § 1400(b) and § 271(e).<sup>178</sup>

In *Bristol-Myers*, the court found that the “acts of infringement” requirement in § 1400(b) was satisfied by MPI’s submission of an ANDA filing because “MPI’s ‘ANDA filings are tightly tied, in purpose and planned effect, to the deliberate making of sales in Delaware.’”<sup>179</sup> In other words, although MPI had not yet infringed on the Bristol-Myers Squibb patent, the *Bristol-Myers* court found the ANDA filing sufficient as an artificial act of infringement, and if the FDA approved the generic drug product, it would do so.

After establishing that § 271(e)(2) created a run-around to satisfy the act of infringement requirement in § 1400(b), the *Bristol-Myers* court considered whether MPI had a “regular and established place of business” in Delaware.<sup>180</sup> To start, the Delaware district court analyzed the “regular and established place of business” language in § 1400(b) using “‘clear and specific’ “ guidance provided by the Supreme Court over fifty years ago.”<sup>181</sup> Under that interpretation, the *Bristol-Myers* court found that “[t]he words of the statute . . . require[]: a (i) place of business that is (ii) regular and (iii) established.”<sup>182</sup> Aiding in the court’s understanding of the statute’s text was “the Federal Circuit’s 1985 decision in *In re Cordis*, 769 F.2d at 733, which mark[ed] the most recent, precedential case applying the ‘regular and established place of business’ prong of § 1400(b).”<sup>183</sup> The *Bristol-Myers* court found that the reasoning in *In re Cordis* applied to the facts at bar and maintained that a “place of business” must have a “meaningful physical manifestation” like “a place authorized by the defendant where some part of the defendant’s business is done.”<sup>184</sup>

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<sup>176</sup> *Id.* at \*7–8 (quoting *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990)) (emphasis in original).

<sup>177</sup> *Id.* at 7.

<sup>178</sup> *Id.* at 6–8.

<sup>179</sup> *Id.* at \*9 (quoting *Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 763 (Fed. Cir. 2016)).

<sup>180</sup> *Id.* at \*1

<sup>181</sup> *Id.* at \*14 (quoting *Schnell v. Peter Eckrich & Sons, Inc.*, 365 U.S. 262, 62 (1961)).

<sup>182</sup> *Id.*

<sup>183</sup> *Bristol-Myers*, 2017 WL 3980155, at \*14.

<sup>184</sup> *Id.* at \*14–15.

Ultimately, however, Judge Stark found that Mylan's unique status as a generic manufacturer meant that additional venue-related discovery was required in order to determine whether MPI satisfied the *Cordis* test, leaving district courts uncertain as to what would satisfy the "regular and established" prong of § 1400(b).<sup>185</sup> Ten days later, the Federal Circuit would distinguish *Cordis* in its *Cray* decision, creating new appellate court guidance based on three similar, but not identical, statutory elements: whether there is "(1) a physical place in the district; (2) . . . a regular and established place of business; and (3) . . . [a] place of the defendant."<sup>186</sup> Nevertheless, Judge Stark's comment that a company's "constant involvement in Hatch-Waxman litigation . . . must weigh into the assessment of whether [a company] has a . . . regular and established place of business"<sup>187</sup> demonstrates that "there remains some uncertainty as to how the district courts will specifically adopt the Cray standard"<sup>188</sup> in Hatch-Waxman suits.

2. Galderma Labs. The Northern District of Texas created further confusion when, following *Cray*, Judge Barbara Lynn discussed *Bristol-Myers* in *Galderma Laboratories, L.P. v. Teva Pharmaceuticals USA, Inc.*<sup>189</sup> and found "several issues with the decision."<sup>190</sup> The *Bristol-Myers* court had utilized an ANDA filing as a "stand-in"<sup>191</sup> for an act of infringement in a Hatch-Waxman suit, but Judge Lynn criticized the *Bristol-Myers* rationale as "inconsistent with the plain language" in Hatch-Waxman, which "does not identify any act of infringement other than the ANDA submission."<sup>192</sup> Referencing the Federal Circuit's decision in *Cray* to reject Judge Gilstrap's test as "'not sufficiently tethered' to the statutory language,"<sup>193</sup> the *Galderma* court found it more appropriate to find venue proper where the ANDA submission was prepared and submitted.<sup>194</sup> As to the "regular and established place of business" prong, the *Galderma* court applied the three part test from *Cray*, requiring: "(1) a physical place in the district; (2) a regular

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<sup>185</sup> *Id.* at \*18 (noting that "Mylan's business model is in large part predicated upon participating in a large amount of litigation, since almost all of the generic drugs Mylan seeks to market in the U.S. are [generic] bioequivalent[s]").

<sup>186</sup> *In re Cray Inc.*, 871 F.3d 1355, 1360 (Fed. Cir. 2017).

<sup>187</sup> *Bristol-Myers*, 2017 3980155, at \*18.

<sup>188</sup> Rankin, *supra* note 133.

<sup>189</sup> No. 3:17-cv-01076-M, 2017 WL 6505793 (N.D. Tex. Nov. 17, 2017).

<sup>190</sup> *Id.* at \*5.

<sup>191</sup> *Bristol-Myers*, 2017 WL 3980155, at \*8.

<sup>192</sup> *Galderma*, 2017 WL 6505793, at \*5.

<sup>193</sup> *Id.* (quoting *In re Cray, Inc.*, 871 F.3d 1355, 1362 (Fed. Cir. 2017)).

<sup>194</sup> *Id.* at \*6 (citing *Pfizer Inc. v. Apotex, Inc.*, No. 08-cv-00948-LDD, 2009 WL 2843288, at \*3 n.5 (D. Del. Aug. 13, 2009) ("'[L]ocation of the preparation and submission of the ANDA' is 'the location of the injury' for venue purposes in Hatch-Waxman Act cases.")).



and established place of business; and (3) it must be the place of the defendant.’<sup>195</sup>

3. *Mallinckrodt and Javelin*. The District of Delaware decided *Bristol-Myers* just before the Federal Circuit’s *Cray* decision, while the Northern District of Texas published *Galderma* two months later and cites the *Cray* decision directly when criticizing the reasoning in *Bristol-Myers*.<sup>196</sup> While it would appear that the interpretation of § 1400(b) is converging around *Cray*, since *Galderma* and *Cray*, the District of Delaware has issued multiple decisions further complicating the analysis. In *Javelin Pharmaceuticals Inc. v. Mylan Laboratories Ltd.*,<sup>197</sup> Judge Stark refused to follow *Galderma* in ruling that a corporate subsidiary could satisfy the “place of the defendant” element of § 1400(b)’s second prong.<sup>198</sup> Two weeks later, however, Judge Stark contradicted his *Bristol-Myers* analysis in *Mallinckrodt IP v. B. Braud Medical Inc.*,<sup>199</sup> finding that “a courthouse is not a place ‘of the defendant.’”<sup>200</sup> In short, application of *TC Heartland* in the pharmaceutical industry, even after *Cray*, remains highly fluid.

#### B. MOVING BEYOND BRISTOL-MYERS AND GALDERMA LAB

As *TC Heartland* continues to cause confusion for pharmaceutical litigants, branded pharmaceuticals are left wondering how best to proceed. Some industry experts have advised pharmaceutical plaintiffs to file protective suits in order to ensure that the company’s statutory thirty-month stay from generic competition is protected.<sup>201</sup> Others have advised brand-name drug manufacturers to apply

<sup>195</sup> *Id.* at \*7 (quoting *In re Cray Inc.*, 871 F.3d 1355, 1360 (Fed. Cir. 2017)).

<sup>196</sup> *Id.* at \*5 (arguing that “the Delaware court’s approach to venue in ANDA cases” is a “liberal interpretation” that is “inconsistent with the Federal Circuit’s guidance”).

<sup>197</sup> C.A. No. 16-224-LPS, 2017 WL 5953296, at \*1 (D. Del. Dec. 1, 2017).

<sup>198</sup> *Compare Javelin*, 2017 WL 5953296, at \*4 (“In the Court’s view, it follows from *Cray* that the ‘place’ of a corporate affiliate or subsidiary of a named defendant may, in some circumstances, and similar to the place of a defendant’s employee, be treated as a ‘place of the defendant’ (‘), with *Galderma*, 2017 WL 6505793, at \*8 (“A subsidiary’s presence in the district cannot be imputed to the parent for venue purposes.”); *See also* Scott W. Doyle et al., *December 11, 2017 – TC Heartland Weekly Update*, FRIED FRANK LLP (Dec. 11, 2017), <http://www.friedfrank.com/index.cfm?pageID=25&itemID=7955>.

<sup>199</sup> No. 17-cv-0365, 2017 WL 6383610, at \*1 (D. Del. Dec. 14, 2017).

<sup>200</sup> *Id.* at \*7 (quoting *In re Cray Inc.*, 871 F.3d 1355, 1363 (Fed. Cir. 2017)). By contrast, in *Bristol-Myers*, Judge Stark cited MPI’s appearance “in more than 100 cases in the District of Delaware” and “constant involvement in Hatch-Waxman litigation” as a factor in the regular and established place of business analysis. *Bristol-Myers*, 2017 WL 3980155, at \*18. *See also* Doyle et al., *December 26, 2017 – TC Heartland Weekly Update*, FRIED FRANK LLP (Dec. 26, 2017), <http://www.friedfrank.com/index.cfm?pageID=25&itemID=7966>.

<sup>201</sup> James, *supra* note 157.

for consolidation of multiple suits against different ANDA filers through multidistrict litigation.<sup>202</sup>

1. *The Habit of Filing Protective Suits.* Until the *Acorda* decision in 2016, many Hatch-Waxman litigants filed “protective suits,” or suits filed “in the forum where jurisdiction over the generic manufacturer is certain,” in order to continue litigating the case “even if the first-filed action in the preferred forum is dismissed on jurisdictional grounds.”<sup>203</sup> Doing so was “protective” of a brand-name plaintiff because it ensured that the thirty-month stay preventing an ANDA filer from receiving FDA approval and competing against the branded manufacturer remained in place.<sup>204</sup>

In construing personal jurisdiction as broadly as it did, the court in *Acorda* “reduce[d] or eliminate[d] the need for protective suits”<sup>205</sup> because branded pharmaceutical companies were no longer concerned about the court dismissing their first-filed action. When *TC Heartland* was decided, however, it reinvigorated these companies’ concern that their suit would be dismissed and their drug no longer assured thirty months of protection from generic competition.

Although filing protective suits would ensure that pharmaceutical plaintiffs’ exclusivity will be preserved for thirty months, the procedural mechanism would “increase the costs of litigating ANDA cases.”<sup>206</sup> Furthermore, many U.S. companies are incorporated in Delaware.<sup>207</sup> Delaware courts are already overloaded—the district is currently making do with only two active judges, two vacancies, and a number of visiting judges, yet is faced with the onslaught of patent infringement suits ferreted away from the Rocket Docket.<sup>208</sup> Already, Delaware courts have had to resort to punting cases outside of the district.<sup>209</sup> Filing protective suits in Delaware would overload Delaware courts even more and could exacerbate issues of cost and uncertainty if the case was transferred because of a lack of judicial resources.

2. *Reliance on the Joint Panel for Multidistrict Litigation.* A second solution to the uncertainty of pharmaceutical patent venue was floated by the *Bristol-Myers* court

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<sup>202</sup> Patrick M. Arenz et al., *Another Prediction About Patent Cases After TC Heartland: More Multidistrict Litigation*, 94 PAT., TRADEMARK & COPYRIGHT J. (BNA) 2325 (Sept. 1, 2017).

<sup>203</sup> James, *supra* note 157.

<sup>204</sup> As part of its ANDA approval process, the FDA will stay approval of a generic bioequivalent for thirty months while litigation ensues. A protective suit ensures that this thirty-month stay will continue, even if the action filed in plaintiff’s preferred forum is dismissed. *Id.*

<sup>205</sup> *Id.*

<sup>206</sup> *Id.*

<sup>207</sup> See Delaware Division of Corporations, *supra* note 97.

<sup>208</sup> Nayak, *supra* note 100.

<sup>209</sup> *Id.* (finding that Delaware patent infringement complaints more than doubled between May and August).

itself: relying on the Joint Panel on Multidistrict Litigation to “create more Hatch-Waxman multidistrict litigations.”<sup>210</sup> The *Bristol-Myers* court hinted at the possibility of consolidating multiple cases against a single ANDA filer into multidistrict litigations (“MDLs”) in response to concern about “the time and expense that is required to resolve these cases.”<sup>211</sup>

Although MDLs were not commonly used for patent infringement suits prior to *TC Heartland*,<sup>212</sup> consolidation could lessen the burden on over-flooded Delaware court dockets because “there will be at least some common issues of discovery . . . similar claim construction issues, and likely related infringement theories and invalidity defenses.”<sup>213</sup>

Nevertheless, the *Bristol-Myers* court found that relying on MDLs is not a perfect solution because “the process of creating an MDL often involves litigation (adding time and expense) and, even once created, cases are transferred to an MDL only for pretrial purposes. They must be transferred back to the transferor districts for trial, unless a party waives its right to be transferred back.”<sup>214</sup> In other words, the ease of consolidating patent infringement suits based on common discovery issues may not warrant the time and expense of MDLs. Furthermore, there are additional uncertainties associated with using MDLs because: (1) “it is unclear exactly how many jurisdictions need to be implicated to lead to an MDL transfer”; (2) “it is not clear where cases will go”; (3) “there is a lack of clarity as to how similar the accused products must be to warrant transfer”; and (4) “it remains to be seen which court is best suited and most likely to preside over trials after the conclusion of MDL pretrial proceedings.”<sup>215</sup>

Ultimately, MDLs, like protective suits, do not represent a particularly appealing option for pharmaceutical plaintiffs in patent infringement suits because they would increase the time and expense associated with litigation.

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<sup>210</sup> *Bristol-Myers Squibb Co. v. Mylan Pharm. Inc.*, No. 17-379-LPS, 2017 WL 3980155, \*1, \*12, n.17 (D. Del. Sept. 11, 2017).

<sup>211</sup> *Id.*

<sup>212</sup> See Arenz, *supra* note 202 (“To date, this tool has not been used extensively in patent cases.”).

<sup>213</sup> *Id.*

<sup>214</sup> *Bristol-Myers*, 2017 WL 3980155, at \*12, n.17 (citations omitted).

<sup>215</sup> Arenz, *supra* note 202.

Instead, judges<sup>216</sup> and industry experts<sup>217</sup> have argued that Congressional action is needed to update § 1400(b) for the modern era.

### C. THE EFFICACY OF RELYING ON CONGRESSIONAL ACTION

Members of Congress and others<sup>218</sup> assert that legislative action is necessary in order to resolve the uncertainty and inefficiency created by *TC Heartland*. For instance, Representative Darrell Issa, House of Representatives Judiciary Committee member and Chairman of the Subcommittee on Courts, Intellectual Property, and the Internet, said in a July 13, 2017 Committee hearing that Judge Gilstrap's attempt to circumvent *TC Heartland* in *Raytheon v. Cray* was "reprehensible"<sup>219</sup> and that his Subcommittee would consider new legislation following the creation of the four-part test.<sup>220</sup> The Federal Circuit's later decision to reject the Gilstrap test means that legislation on that particular issue is unnecessary, but Chairman Issa's comments are nonetheless indicative of the general view that "patent reform is now a staple of Congress's agenda."<sup>221</sup> Similarly, Senator Orrin Hatch, Chairman of the Senate Finance Committee and the Senate Republican High-Tech Task Force, indicated that patent venue

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<sup>216</sup> The Federal Circuit impliedly suggested Congressional action was needed when it noted that the current patent venue language had not been updated for the modern era. Scott Graham, *Federal Circuit: No More Loosey-Goosey Rules on Patent Venue*, LAW.COM (Sept. 21, 2017, 7:43 PM), <https://www.law.com/sites/almstaff/2017/09/21/federal-circuit-no-more-loosey-goosey-rules-on-patent-venue/?slreturn=20180008085957> (citing *In re Cray Inc.*, 871 F.3d 1355, 1359 (Fed. Cir. 2017) (the court "recognize[s] that the world has changed . . . [b]ut, notwithstanding these changes, in the wake of the Supreme Court's holding in *TC Heartland* . . . we must focus on the full and unchanged language of the statute")).

<sup>217</sup> Matthew Bultman, *Pharma Groups Urge Justices to Avoid Patent Venue Changes*, LAW360 (Mar. 9, 2017, 8:41 PM), <https://www.law360.com/articles/900202/pharma-groups-urge-justices-to-avoid-patent-venue-changes>.

<sup>218</sup> See Alexander Poonai, Note, *Hatch-Waxman in the Heartland: Achieving Fair Venue Reform in Pharmaceutical Litigation*, 27 FED. CIRCUIT B.J. 103, 113 (2017) (noting that *TC Heartland* caused a "pendulum [swing] in the opposite direction" away from the "broad discretion to sue" that was previously afforded to "pioneer" (or branded) drug manufacturers). Poonai argues that new legislation is necessary in order to "centralize the location of Paragraph IV disputes in two locations: the Patent Trials and Appeals Board ("PTAB") and the District of Maryland." *Id.* at 108.

<sup>219</sup> *The Impact of Bad Patents on American Businesses: Hearing Before the Subcomm. On Courts, Intell. Prop., & the Internet of the H. Comm. On the Judiciary*, 115th Cong. (July 3, 2017) (statement of Rep. Darrell Issa, Member, H. Comm. On the Judiciary), <https://judiciary.house.gov/hearing/impact-bad-patents-american-business/>.

<sup>220</sup> Stoll, *supra* note 99.

<sup>221</sup> Paul R. Gugliuzza, *How Much Has the Supreme Court Changed Patent Law?*, 16 CHI.-KENT J. INTELL. PROP. 330, 332-33 (2017).

reform is a priority for the 115th Congress.<sup>222</sup> While some argue that it is crucial to “preserve the balance of power between pioneer and generic manufacturers,”<sup>223</sup> for the reasons discussed below, this Note argues that Congressional reform of the patent system is neither a realistic nor a necessary solution.

1. *Congress’s First Attempt at Reform.* The Federal Circuit anticipated Congressional action in *In re Cray*, when Judge Lourie “recognize[d] that the world has changed since 1985,” but felt bound by the “unchanged language of the statute.”<sup>224</sup> In doing so, the *Cray* court implicitly suggested that Congressional action was needed in order to update the statutory language to fit the modern era.<sup>225</sup>

In 2011, Congress attempted to adapt to the modern era by passing the Leahy-Smith America Invents Act (AIA), which has since been viewed as the “most significant change to the U.S. patent system since” *Fourco*.<sup>226</sup> Through the AIA, Congress established Inter Partes Review (IPR), a mechanism for fast-tracking patent litigation by limiting discovery in order to “improve patent quality and limit unnecessary and counterproductive litigation costs.”<sup>227</sup> In an IPR procedure, any party can petition the U.S. Patent and Trademark Office (USPTO) to review a patent; if that petition is granted, then the Patent Trial and Appeal Board within the USPTO will determine whether the patent claim is valid.<sup>228</sup>

Although the more efficient two-step IPR procedure provides a quicker mechanism for contesting patent claims than cumbersome district court litigation, IPR proceedings unwittingly created further uncertainty in the patent litigation world because claims have historically been invalidated at a far higher

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<sup>222</sup> Orrin Hatch, Chairman, United States Senate Republican High-Tech Task Force, Innovation Agenda for the 115th Congress (Feb. 16, 2017) (transcript available at <https://www.hatch.senate.gov/public/index.cfm/2017/2/hatch-unveils-innovation-agenda-for-the-115th-congress>).

<sup>223</sup> Poonai, *supra* note 218, at 108.

<sup>224</sup> *In re Cray, Inc.*, 871 F.3d 1355, 1359 (Fed. Cir. 2017); *see also* Matthew J. Rizzolo et al., *Federal Circuit Provides Guidance on Patent Venue Post TC Heartland*, ROPES & GRAY LLP (Sept. 25, 2017), <https://www.ropesgray.com/newsroom/alerts/2017/09/Federal-Circuit-Provides-Guidance-on-Patent-Venue-Post-TC-Heartland.aspx> (“[T]he court’s ruling appears to imply that any efforts by infringement plaintiffs to extend the patent venue statute to cover virtual business locations are better addressed in Congress as opposed to the courts.”).

<sup>225</sup> *In re Cray*, 871 F.3d at 1359. *See also* Graham, *supra* note 216.

<sup>226</sup> Renoj Zachariah, *Fighting the Troll Toll: The Case for Judicial Review of the U.S.P.T.O. Director’s Denial of a Petition to Institute an Inter Partes Review*, 38 CARDOZO L. REV. 2273, 2275 (2017).

<sup>227</sup> H.R. REP. NO. 112-98, at 40 (2011).

<sup>228</sup> *See* Zachariah, *supra* note 226, at 2276–77 (explaining that “[i]f the petition is granted, then, in the second step, the USPTO[] . . . will conduct an IPR proceeding and render a patentability decision”).

rate than in federal district courts.<sup>229</sup> Thus, a claimant that files an IPR proceeding is not guaranteed, or even reasonably reassured, that his or her claim would pass muster in district court litigation. As a result, IPR proceedings, although less expensive and more efficient, have not stemmed the influx of litigants filing patent infringement suits. This begs the question: is another attempt at reform necessary?

Some members of Congress believe so. Representative Issa has advanced “the possibility of broad IPR reform, not to bring uncertainty, but to further empower a system which is considered . . . to be good, but . . . not good enough.”<sup>230</sup>

Even so, no reform attempt has yet been signed into law, though legislation was introduced in both Houses of Congress.<sup>231</sup> In February 2017, Senator Hatch indicated that reform was imminent “this year,”<sup>232</sup> but to patent infringement plaintiffs, “it is becoming clear that protection from . . . Congress is not coming any time soon.”<sup>233</sup> On January 2, 2018, Senator Hatch announced his retirement from the United States Senate.<sup>234</sup>

Legislative reforms of pharmaceutical industry have been particularly lackluster. Lawmakers “have been resistant to making market-specific exclusions or changes to patent law” despite any “increase[d] efficiency” because reforms would be “politically challenging.”<sup>235</sup> Redrafting the Hatch-Waxman Act to “embrace the speculative, artificial, and delocalized nature of the current law,” for instance, would require Congress to “take a second look at one of the best legislative compromises it has produced in recent memory . . .”<sup>236</sup> Compromise in the current political climate is unlikely given the “contention, polarization and antipathy that exists between the two major parties . . .”<sup>237</sup> In short, Congress

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<sup>229</sup> Joanna Shepherd, *Disrupting the Balance: The Conflict Between Hatch-Waxman and Inter Partes Review*, 6:1 N.Y.U. J. INTELL. PROP. & ENT. L. 14, 17 (2016).

<sup>230</sup> Issa, *supra* note 219.

<sup>231</sup> On June 21, 2017, Senator Christopher Coons introduced the STRONGER Patents Act of 2017 to amend the patent infringement provisions in Section 271 and the Inter Partes Review provisions in Section 316(a), but the bill has only three co-sponsors and has not been considered by the Senate Committee on the Judiciary, where it was referred following introduction. The STRONGER Patents Act of 2017, S. 1390, 115th Cong (2017).

<sup>232</sup> Hatch, *supra* note 222.

<sup>233</sup> Stoll, *supra* note 99.

<sup>234</sup> Lisa Hagen, *Hatch announces retirement from Senate*, THE HILL (Jan. 2, 2018, 2:09 PM), <http://thehill.com/homenews/campaign/367082-hatch-to-retire>.

<sup>235</sup> Kesselheim, *supra* note 138, at 325–26.

<sup>236</sup> Poonai, *supra* note 218, at 114, 122.

<sup>237</sup> Ed Rendell, Opinion, *Congress damaged its reputation, but it's not too late for compromise*, THE HILL (Dec. 26, 2017, 6:00 AM), <http://thehill.com/opinion/civil-rights/366435-congress-damaged-its-reputation-but-its-not-too-late-for-compromise>. While Rendell, the former Pennsylvania Governor, proposed how progress toward a legislative compromise might be

needed “some help figuring out how to fix th[e] broken market”<sup>238</sup> for pharmaceutical litigants.

2. *Is Another Attempt at Congressional Reform Needed?* Should legislative reform be attempted, proposals to amend Hatch-Waxman vary greatly. Some medical professionals have posited that the FDA should fast-track approval of a single generic bioequivalent drug when the price of its branded counterpart increases quickly.<sup>239</sup> By lowering regulation of the bioequivalent alternative, the fast-track process would encourage competition in order to lower prices. Alternatively, other experts argue that heightened government regulation is needed in order to combat the rising costs of prescription drugs.<sup>240</sup>

Even if reform were politically and technically tenable, the question would remain: *should* the patent venue statute be updated in order to make it easier for branded pharmaceutical companies to sue their generic competitors? During oral arguments prior to its *TC Heartland* ruling, the Supreme Court expressed concern about the impact of its decision on the pharmaceutical industry: “What do we do . . . about the — all of the cases, like the pharmaceutical cases that will be upended and made completely impractical by ignoring 1391?”<sup>241</sup>

This Note nevertheless argues that although pharmaceutical patent infringement cases were upended by *TC Heartland*, the result was not impractical. The pharmaceutical industry is plagued by high drug prices, driven in large part by a lack of competition from generic manufacturers. The *TC Heartland* decision inadvertently provides an effective, albeit messy, fix to the problem of high drug prices. Namely, the decision impacts drug manufacturers in two major ways: first, it “spe[ ]d up . . . market entry for the generic”; second, it “provide[d] generic companies with the ability to think strategically about their jurisdictional choices.”<sup>242</sup>

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reached, he lamented “the inability of Congress to work together in a bipartisan fashion to get things done.” *Id.*

<sup>238</sup> Matthew Herper, *After the Martin Shkreli Circus, How Can We Fix Drug Pricing?*, FORBES (Feb. 4, 2016, 4:44 PM), <https://www.forbes.com/sites/matthewherper/2016/02/04/here-are-some-solutions-to-the-martin-shkreli-problem/#78c6083bf799>.

<sup>239</sup> Jonathan D. Alpern et al., *High-Cost Generic Drugs – Implications for Patients and Policymakers*, 371 N. ENGL. J. MED. 1859–62 (2014). *See also* Herper, *supra* note 238 (arguing that “when a dramatic price increase happens,” one possible solution would be to “allow the FDA to fast-track any generic that comes along”).

<sup>240</sup> *See* Weissmann, *supra* note 3 (“Some experts have suggested . . . [that] the only solution to the rising cost of generics, especially for specialty drugs, is more direct government regulation.”).

<sup>241</sup> Tr. Of Oral Arg. at 54, *In re TC Heartland LLC*, 137 S. Ct. 1514 (2017) (No. 16-341).

<sup>242</sup> *The Supreme Court’s TC Heartland Decision: Implications for Hatch-Waxman Litigation*, ARENT FOX LLP (May 25, 2017), <https://www.arentfox.com/newsroom/alerts/supreme-court’s-tc-heartland-decision-implications-hatch-waxman-litigation>.

These changes alleviate one of the “fundamental flaws of American oversight of the pharmaceutical industry,” which is the belief that “once [a drug company’s] patents expire, competition from generics will drive down costs.”<sup>243</sup> In theory, this belief is sound.<sup>244</sup> The FDA’s approval process has historically been so slow, however, that it acts as a “barrier to market entry for new generic drug manufacturers.”<sup>245</sup>

Thus, by imposing a new burden on plaintiffs filing patent infringement suits, the Supreme Court did by accident what Congress had been attempting for years—re-balance the competition between generic drug manufacturers and branded pharmaceutical companies. The *TC Heartland* decision *did* disadvantage branded pharmaceuticals, but it did so in a way that counteracted the habit of those companies to “play the role of the ‘boy scout,’ [i.e.] agreeing to behave well but doing it in a way that prevents further competition in the market.”<sup>246</sup> In short, *TC Heartland* eliminated the market advantage previously afforded to branded pharmaceuticals by “drastically narrow[ing] the plaintiff’s choice of forum”<sup>247</sup> and helping generic drug companies reassert some control over the venue where they might be subject to suit.

To be sure, the solution provided by *TC Heartland* is imperfect. It is an unorganized run-around to the complex Hatch-Waxman Act that fails to “create a . . . centralized solution to the problem at hand.”<sup>248</sup> The Supreme Court’s decision does not ensure, for example, that generic drug companies will be sufficiently incentivized to enter the market, nor does it help lower prices for drugs where competition is already in place.<sup>249</sup> In the absence of other viable solutions, however, *TC Heartland* provides relief by encouraging, or at least hampering the prevention of, generic entry into the market.

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<sup>243</sup> Weissmann, *supra* note 3.

<sup>244</sup> See Jeremy A. Greene, *Can the Government Stop the Next Martin Shkreli?*, SLATE (Mar. 22, 2016, 5:45 AM), [http://www.slate.com/articles/business/moneybox/2016/03/the\\_fda\\_wants\\_to\\_stop\\_the\\_next\\_martin\\_shkreli\\_by\\_speeding\\_up\\_the\\_approval.html](http://www.slate.com/articles/business/moneybox/2016/03/the_fda_wants_to_stop_the_next_martin_shkreli_by_speeding_up_the_approval.html) (“If the invisible hand was doing its job balancing supply and demand, any increase in price would be met by a flood of new competitors entering the market.”).

<sup>245</sup> U.S. GOV’T ACCOUNTABILITY OFF., GAO-16-706, GENERIC DRUGS UNDER MEDICARE: PART D GENERIC DRUG PRICES DECLINED OVERALL, BUT SOME HAD EXTRAORDINARY PRICE INCREASES 1 (2016). The GAO report found that “competition could be increased if FDA would approve more abbreviated new drug applications (ANDA), which would allow generic drug manufacturers to market a drug, but there is a backlog at FDA.” *Id.* at 26.

<sup>246</sup> ROBIN FELDMAN & EVAN FRONDORF, DRUG WARS: HOW BIG PHARMA RAISES PRICES AND KEEPS GENERICS OFF THE MARKET 25 (Cambridge University Press 2017).

<sup>247</sup> Poonai, *supra* note 218, at 113.

<sup>248</sup> Poonai, *supra* note 218, at 114.

<sup>249</sup> For a general discussion of the continued challenges faced after a barrier to competition in the pharmaceutical industry is removed, see Greene, *supra* note 244.



## IV. CONCLUSION

Until *TC Heartland*, plaintiffs in patent infringement suits had ample flexibility in deciding where to file suit against a generic competitor. *TC Heartland* vastly limited this flexibility. But does it matter? The scope of *TC Heartland* itself is an admittedly narrow “technical issue of statutory interpretation.”<sup>250</sup> Nevertheless, *TC Heartland* “attracted widespread public attention”<sup>251</sup> for “implicat[ing] substantial questions of patent policy and promis[ing] serious real-world consequences affecting the future of patent litigation.”<sup>252</sup> Though *Cray* provided clarity, the pharmaceutical industry remains plagued by real-world uncertainty.

This Note argues that the confusion caused by the Supreme Court in *TC Heartland* was a necessary chaos. By narrowing the number of jurisdictions where a pharmaceutical company can file suit against a generic manufacturer, the Supreme Court’s decision made it more difficult for patent infringement plaintiffs to file suit against their generic competition. The ruling pushed back against brand-name pharmaceutical companies attempting to exploit their control of the market to raise drug prices and inadvertently re-balanced the seesaw between branded pharmaceutical companies and generic drug manufacturers that is at the “heart” of the Hatch-Waxman Act.

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<sup>250</sup> See Bone, *supra* note 132 at 141.

<sup>251</sup> *Id.* More than thirty amicus briefs were filed by corporations, states, and individuals, including one retired Chief Judge from the Federal Circuit and the state of Texas. *Id.*

<sup>252</sup> *Id.* at 141.