RESOLVED, That the American Bar Association supports an interpretation of the phrase “where the defendant has committed acts of infringement” in the patent venue statute, 28 U.S.C. § 1400(b), for cases involving infringement under 35 U.S.C. § 271(e)(2) by submitting Abbreviated New Drug Applications (“ANDA”), that includes all of the acts (i.e., makes, uses, offers to sell, sells or imports) that would constitute patent infringement under 35 U.S.C. § 271(a); and

FURTHER RESOLVED, That the American Bar Association supports an interpretation of the phrase “where the defendant has committed acts of infringement” in 28 U.S.C. §1400(b) such that venue in a patent infringement case involving an ANDA submission under 35 U.S.C. § 271(e)(2) is proper in a district in which the defendant who filed the ANDA submission is anticipated to commit acts of infringement.
REPORT

I. Introduction

This Resolution urges federal courts to interpret the clause “where the defendant has committed acts of infringement,” in 28 U.S.C. § 1400(b) when applied to Abbreviated New Drug Application (ANDA) litigation under 35 U.S.C. § 271(e)(2) to mean “districts in which the defendant who filed the ANDA submission is anticipated to commit acts of infringement.”

In patent infringement lawsuits, venue must be established according to the patent venue statute, 28 U.S.C. § 1400(b), rather than the general venue statute, 28 U.S.C. § 1391. The patent venue statute provides that venue is appropriate “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.” Until recently, a domestic corporation was considered to “reside[,]” for purposes of § 1400(b), anywhere it was subject to personal jurisdiction. In 2017, the Supreme Court of the United States held that for purposes of § 1400(b), a corporation “resides” only in the State where it is incorporated. TC Heartland LLC v. Kraft Foods Group Brands LLC, 137 S.Ct. at 1520. TC Heartland’s narrow interpretation of corporate residence has placed added emphasis on the portion of § 1400(b) which allows venue to be laid in any jurisdiction “where the defendant has committed acts of infringement and has a regular and established place of business.”

The meaning of “where the defendant has committed acts of infringement” in § 1400(b) is uniquely important in Abbreviated New Drug Application (“ANDA”) litigation because of the disparity between the requirement for a defendant to have “committed acts of infringement” under Section 1400(b) and the artificial act of infringement during ANDA litigation.¹ Pursuant to 35 U.S.C. § 271(e)(2), the “act of infringement to submit” certain drug applications for approval is the cause of action in ANDA litigation. This artificial act of infringement allows brand drug manufacturers to institute patent litigation against the filer of the ANDA while the application is pending with the U.S. Food and Drug Administration (FDA), to allow the brand manufacturer and generic manufacturers to mete out any patent infringement disputes before the generic is approved for marketing by the FDA.

Following TC Heartland, federal courts are divided regarding the meaning of “committed acts of infringement” in § 1400(b) in ANDA litigation. Some courts have held that venue is appropriate in districts where the defendant is anticipated to commit acts of infringement. Other courts have read the statute more narrowly and held that venue is satisfied only where the ANDA application was prepared and submitted by the ANDA filer. The broader interpretation of “committed acts of infringement” interprets “infringement” consistent with the term’s meaning in other statutes and in a way that is sensible and foreseeable to practitioners and members of the public. It allows prospective defendants to predict where they might be subject to suit and to tailor their actions accordingly, while

¹ To establish venue under Section 1400(b), the defendant must also have a regular and established place of business in the district.
also preserving the broadest choice of forum selection for prospective plaintiffs. This Resolution therefore urges federal courts to interpret the clause “where the defendant has committed acts of infringement,” in §1400(b) to a district where the defendant who filed the ANDA submission is anticipated to commit acts of infringement.

II. Statutory and Historical Background

In patent infringement lawsuits, venue must be established according to the patent venue statute, 28 U.S.C. § 1400(b), rather than the general venue statute, 28 U.S.C. § 1391. The patent venue statute provides that venue is appropriate “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.” Until recently, a domestic corporation was considered, for purposes of § 1400(b), to “reside[]” anywhere it was subject to personal jurisdiction. In 2017, however, the Supreme Court of the United States held that for purposes of § 1400(b), a corporation “resides” only in the State where it is incorporated: TC Heartland, 137 S.Ct. at 1520.

The Supreme Court first interpreted the meaning of corporate residence for purposes of § 1400(b) in Fourco Glass Company v. Transmirra Products Corporation, 353 U.S. 222 (1957), holding that a corporation resides only in its State of incorporation. In reaching this conclusion, the Court rejected an argument that corporate residence in § 1400(b) should be interpreted in light of the definition of corporate residence set forth in § 1391(c) of the general venue statute. Congress has not amended § 1400(b) since this decision, but has twice amended the general venue statute. Congress passed the first amendment in 1988, when it revised § 1391 to state that the section applied “[f]or purposes of venue under this chapter.” In 1990, the Court of Appeals for the Federal Circuit interpreted that amendment to mean that definitions set forth under § 1391 applied to terms used in § 1400(b). VE Holding Corporation v. Johnson Gas Appliance Company, 917 F.2d 1574 (Fed. Cir. 1990). In 2011, Congress amended § 1391 to its current text to provide definitions “[f]or all venue purposes.” Subsequently, the Federal Circuit affirmed that its interpretation from VE Holding applied to the 2011 amendment.

The amendments to § 1391, as interpreted by the Federal Circuit, greatly expanded the number of states where a domestic corporation was considered to reside. Under the general venue statute, a corporation resides “in any judicial district in which such defendant is subject to the court’s personal jurisdiction with respect to the civil action in question.” 28 U.S.C. § 1391(c) is much broader than the Supreme Court’s interpretation in Fourco that a corporation resides only in its State of incorporation. By vacating the Federal Circuit’s interpretation of corporate residence under § 1400(b) and reinstating the narrower Fourco rule, the Supreme Court in TC Heartland significantly contracted the available venues for patent infringement lawsuits.

III. Impact of the TC Heartland Decision

By holding that a corporation “resides” only in the State in which it is incorporated, TC Heartland placed added emphasis on the remaining portion of § 1400(b), which sets
venue in any jurisdiction “where the defendant has committed acts of infringement and has a regular and established place of business.” Because most defendants will not waive their objections to venue, patent litigation plaintiffs must carefully consider where they will file suit in order to satisfy the statute’s requirements. If a brand drug manufacturer is uncertain about whether venue will be satisfied in a given district after the court applies *TC Heartland*, the manufacturer might opt to file suit in several districts at once in order to ensure that venue is satisfied in at least one of those districts to secure the 30-month stay of FDA approval for a generic competitor. E.g., Matthew Bultman, *Hatch-Waxman Post-TC Heartland: What You Need To Know*, Law360, https://www.law360.com/articles/1045335/hatch-waxman-post-tc-heartland-what-you-need-to-know (May 24, 2018).

Moreover, it is not uncommon for more than one generic drug manufacturer to submit an ANDA for the same product. In such instances, a brand drug manufacturer may seek to sue all of the generic drug manufacturers in a single infringement suit. Before *TC Heartland*, a brand drug manufacturer could bring a single suit in nearly any district in the United States, because venue was coterminous with personal jurisdiction. Now, however, the opportunities to do so will be fewer. The regular course of practice may become, instead, to file infringement suits in several different districts and then seek consolidation into multidistrict litigation. This could increase the burden and case load on the courts.

Soon after the Supreme Court’s decision in *TC Heartland*, the Federal Circuit interpreted the term “regular and established place of business” in § 1400(b). *In re Cray, Inc.*, 871 F.3d 1355 (Fed. Cir. 2017). The Federal Circuit read the text of “regular and established place of business” to mean that “(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.” Id. at 1360. By inserting these relatively vague standards into the test for venue, the Federal Circuit further increased uncertainty regarding the availability of venue in any chosen jurisdiction. This could further motivate litigants to file in more than one jurisdiction, increasing the burden on parties and the courts themselves.

IV. Split in Federal Courts and Proposed Resolution

Section 1400(b) provides that venue is appropriate “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.” The first alternative (“residence”) is

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2 Unlike subject matter jurisdiction, venue objections can be waived.

3 Section 1400(b) is not relevant to venue for declaratory judgment actions. "Venue in a declaratory judgment action for patent noninfringement and invalidity is governed by the general venue statute, 28 U.S.C. § 1391(b) and (c), and not the special patent infringement venue statute, 28 U.S.C. § 1400(b)." *U.S. Aluminum Corp. v. Kawneer Co.*, 694 F.2d 193, 195 (9th Cir. 1982); *Horne v. Adolph Coors Co.*, 684 F.2d 255, 260 (3d Cir. 1982); *Emerson Elec. Co. v. Black & Decker Mfg. Co.*, 606 F.2d 234, 238 (8th Cir. 1979); *Gen. Tire & Rubber Co. v. Watkins*, 326 F.2d 926, 929 (4th Cir. 1964); *Barber-Greene Co. v. Blaw-Knox Co.*, 239 F.2d 774, 776 (6th Cir. 1957). Venue in a declaratory judgment action in the ANDA context is governed by 21 U.S.C. § 355(j)(5)(C)(i)(II) ("A civil action referred to in this subclause shall be brought in
read much more narrowly following TC Heartland, placing more importance on the interpretation of the second alternative (“infringement”). And, as discussed above, the Federal Circuit has recently established a three-element test for the term “regular and established place of business” but courts have still applied that test inconsistently.

The meaning of the phrase “where the defendant has committed acts of infringement” takes on important meaning in the context of ANDA litigation. The issue arises from the disparity between the requirement for a defendant to have “committed acts of infringement” under Section 1400(b) and the artificial act of infringement during ANDA litigation. The cause of action in ANDA litigation, 35 U.S.C. § 271(e)(2), makes it an “act of infringement to submit” certain drug applications for approval. Following TC Heartland, federal courts are divided regarding the meaning of “committed acts of infringement” in the context of an ANDA submission. Some have held that venue is appropriate in districts where future acts of infringement by the ANDA filer are anticipated to occur. Others have read the statute more narrowly and held that venue is satisfied only where the ANDA was prepared and submitted.

An exemplary analysis of the broader, future-looking test came in one of the first cases to address the issue, Bristol-Myers Squibb Co. v. Mylan Pharmaceuticals Inc., No. 17-379-LPS, 2017 WL 3980155 (D. Del. Sept. 11, 2017) (hereinafter “BMS”). There, the District of Delaware held that “acts of infringement” an ANDA filer ‘has committed' include[] all of the acts that would constitute ordinary patent infringement” after FDA approval, including any intended sales of the regulated product in any domestic venue. The court justified this forward-looking conclusion by noting that the “submission of an ANDA is a stand-in that serves to move forward in time the infringement and invalidity challenges that otherwise would come later in time.” Id. at *8-9, citing Acorda Therapeutics Inc. v. Mylan Pharmaceuticals Inc., 817 F.3d 755 (Fed. Cir. 2016) (in Hatch-Waxman cases, personal jurisdiction is evaluated on the basis of anticipated acts of actual infringement). The BMS court reasoned that the same principle should apply to venue. Id. Moreover, the court found that reading the statute literally would result in it never being satisfied—because an ANDA always precedes acts of actual infringement by the generic drug manufacturer—and rules of statutory construction counseled against such a reading. Id. at *10. Other courts in the Third Circuit have subsequently followed the reasoning in BMS. See Javelin Pharmas, Inc. v. Mylan Labs Ltd., 16-224-LPS, 2017 WL 5953296 (D. Del. Dec. 1, 2017); UCB, Inc. v. Mylan Techs, Inc., 17-322-LPS, 2017 WL 5985559 (D. Del. Dec. 1, 2017); Mallinckrodt IP v. B. Braun Medical, Inc., 17-365-LPS, 2017 WL 6383610 (D. Del. Dec. 14, 2017); Celgene Corp. v. Hereto Labs. Ltd., 17-3387 (ES) (MAH), 2018 WL 1135334 (D. N.J. Mar. 2, 2018). In each of those cases, the chosen jurisdiction satisfied the requirements of § 1400(b).
The more restrictive approach has only been adopted once, by the Northern District of Texas in *Galderma Laboratories v. Teva Pharmaceuticals USA, Inc.*, No. 3:17-cv-01076-M, 290 F.Supp.3d 599 (N.D. Tex. 2017). There, the court began by considering 35 U.S.C. § 271(e)(2), which makes submission of an ANDA an act of infringement. 290 F.Supp.3d at 606-7 (citing 35 U.S.C. § 271(e)(2)). Next, the court considered whether the anticipated acts of actual infringement also qualified as “committed” acts of infringement under 28 U.S.C. § 1400(b), answering that question in the negative. *Id.* at 607. The court considered the reasoning in *BMS* but found it unpersuasive based on the plain language of the venue statute. *Id.* at 607-08. The court also distinguished the Federal Circuit’s *Acosta* decision by limiting that case to issues of personal jurisdiction. *Id.* The Northern District of Texas thus interpreted “acts of infringement” as limited to the venues in which an ANDA was prepared and submitted. *Id.* at 608.

Federal courts should adopt the broader, forward-looking definition of “acts of infringement.” This approach is consistent with definition of “acts of infringement” set forth in the general patent infringement statute, 35 U.S.C. § 271(a): “makes, uses, offers to sell, or sells” and “imports.” This definition is also the common-sense definition, which is the meaning of “infringement” widely understood by attorneys, patent holders, and the public. Interpreting “infringement” in § 1400(b) consistently with the term’s well-accepted and common-sense definition will allow the federal courts to act in a predictable, understandable manner. Furthermore, this definition of “acts of infringement” will allow prospective defendants to organize their conduct so as to consistently predict where they can be hauled into federal court for ANDA infringement actions. Finally, this definition has the added benefit (compared to the restrictive, backward-looking definition) of allowing prospective ANDA plaintiffs the most flexibility among venues in which to assert their lawsuits, because the generic drug can be made, used, offered for sale or sold in multiple districts; but, the ANDA application can only be submitted from a single district. Based on these benefits, the broader, forward-looking definition of “where the defendant has committed acts of infringement” is the better of the two definitions and should be adopted.

V. Consistency with Past ABA Actions

Because of the temporal mismatch between the patent venue statute and the Hatch-Waxman Act, this Resolution is consistent with ABA policy defining venue in a patent infringement cases as being proper “only in a judicial district (1) located in the state under whose laws the business entity was formed or (2) where the business entity has committed acts of infringement and has a regular and established place of business.” See 16A108C. For instance, the court in *BMS* notes the “temporal mismatch between § 1400(b) and the Hatch-Waxman Act.” *BMS* at *12. The court further notes that the entire purpose of the ANDA litigation scheme is to resolve patent disputes before a generic drug is launching. See, *BMS* at 13, citing *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). The ANDA-related litigation is not about whether the ANDA submission is unlawful, but rather about “whether a valid patent ‘[will or] will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted,’ which is effectively the same type of analysis involved in a typical patent infringement inquiry.
21 U.S.C. § 355(j)(2)(A)(vii)(IV) (emphasis added).” *BMS* at *14. The infringement analysis, for example, considers whether the future ANDA product will or will not infringe the asserted patent. The *BMS* court thus concluded:

[I]n the context of Hatch-Waxman litigation, the "acts of infringement" an ANDA filer "has committed" includes all of the acts that would constitute ordinary patent infringement if, upon FDA approval, the generic drug product is launched into the market. The submission of an ANDA is a stand-in that serves to move forward in time the infringement and invalidity challenges that otherwise would come later in time, such as after approval or marketing of the ANDA drug. See Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1569 (Fed. Cir. 1997) ("The only difference in actions brought under § 271(e)(2) is that the allegedly infringing drug has not yet been marketed and therefore the question of infringement must focus on what the ANDA applicant will likely market if its application is approved, an act that has not yet occurred."). Despite the fact that allegedly-infringing products have yet to be approved and marketed, the patent infringement inquiry concerns the real-world impact and consequences that would flow from the approval of an ANDA, the submission of which is the triggering act that allows for the infringement suit in the first instance. See Acorda, 817 F.3d at 760. Thus, an applicant submits an ANDA with full knowledge of the effect of its application and with the objective of marketing its drug product in the event that the application is approved. All of this, in the Court's view, must be taken into account in the venue analysis.

*BMS* at *14-15.

Similar to the court's view in *BMS*, this Resolution is based upon the rationale that an ANDA filer's anticipated acts must be included as part of the "acts of infringement" analysis for purposes of determining if venue is proper under the patent venue statute, just as those anticipated acts are included for personal jurisdiction and infringement determinations. The court's lens of analysis is fast-forwarded to the time when the ANDA product is on the market because of the artificial acceleration of the litigation under the Hatch-Waxman Act as part of the carefully constructed compromise to expedite generic entry to the market. In the context of Hatch-Waxman, anticipated acts are properly considered part of the ‘acts of infringement’ that ‘the defendant has committed’ within the meaning of § 1400(b).” *Id.* at 18. It is, therefore, submitted that this Resolution is consistent with the above-referenced ABA policy.

VI. Conclusion

Because of the Supreme Court's narrow interpretation of "residence" under the first prong of the patent venue statute, 28 U.S.C. § 1400(b), in *TC Heartland v. Kraft Food Groups Brands*, and the artificial act of infringement that gives rise to ANDA litigation, district courts are divided and parties face uncertainty as to the meaning of “committed acts of infringement” under the second prong of the patent venue statute. The phrase "where the defendant has committed acts of infringement" under 28 U.S.C. §1400(b) should be
interpreted to mean a district in which the defendant who filed the ANDA submission is anticipated to commit acts of infringement. This broader approach provides venue predictability for parties, promotes conservation of judicial resources, and aligns with the common and statutory meaning of infringement.

Respectfully submitted,

Mark K. Dickson
Chair, Intellectual Property Law Section
August 2019
GENERAL INFORMATION FORM

Submitting Entity: Section of Intellectual Property Law

Submitted by: Mark K. Dickson, Section Chair

1. Summary of Resolution

The Resolution calls for the Association to adopt policy urging federal courts to interpret the clause “where the defendant has committed acts of infringement and has a regular and established place of business,” in the patent venue statute, 28 U.S.C. § 1400(b) when applied to Abbreviated New Drug Application (ANDA) litigation under 35 U.S.C. § 271(e)(2) to mean a district in which the defendant who filed an ANDA application is anticipated to commit acts of infringement.

2. Approval by Submitting Entity

The Section of Intellectual Property Law Council approved the Resolution on October 3, 2018.

3. Has this or a similar resolution been submitted to the House of Delegates or Board of Governors previously?

Yes, 16A108C, which concerns a general statement of venue in a patent infringement case.

4. What existing association policies are relevant to this Resolution and how would they be affected by its adoption?

None.

5. If this is a late report, what urgency exists which requires action at this meeting of the House?

N/A

6. Status of Legislation

None.

7. Plans for implementation of the policy if adopted by the House of Delegates

The policy will provide Association support for legislation or a potential future amicus case addressing the issue.
8. **Cost to the Association (both direct and indirect costs).**

Adoption of the recommendations will not result in additional direct or indirect costs to the Association.

9. **Disclosure of Interest**

There are no known conflicts of interest regarding this recommendation.

10. **Referrals**

The Resolution and Report have been distributed to each of the other Sections, Divisions, Forums, and Standing Committees of the Association in the version accepted and numbered for the agenda by the Rules and Calendar Committee.

11. **Contact Person (prior to meeting)**

Mark K. Dickson  
Section Chair, Section of Intellectual Property Law  
Phase M  
205 De Anza Blvd., Suite 212  
San Mateo, CA 94402-3989  
Ph: 650-346-6675  
mdickson@phasem.com

and

Scott F. Partridge  
Immediate Past Chair, Section of Intellectual Property Law  
Baker Botts LLP  
Houston, TX  
Ph: 713 229-1569  
Scott.Partridge@BakerBotts.com

12. **Contact Persons (who will present the report to the House)**

Scott F. Partridge  
Immediate Past Chair, Section of Intellectual Property Law  
Baker Botts LLP  
Houston, TX  
Ph: 713 229-1569  
Scott.Partridge@BakerBotts.com
EXECUTIVE SUMMARY

1. Summary of the Resolution

The Resolution calls for the Association to adopt policy urging federal courts to interpret the clause “where the defendant has committed acts of infringement and has a regular and established place of business,” in the special venue statute, 28 U.S.C. § 1400(b) when applied to Abbreviated New Drug Application (ANDA) litigation under 35 U.S.C. § 271(e)(2) to mean a district in which the defendant who filed an ANDA application is anticipated to commit acts of infringement.

2. Summary of the Issue that the Resolution Addresses

This report addresses the question of venue for Abbreviated New Drug Application (“ANDA”) litigation purposes in light of the narrowed interpretation of patent venue under 28 U.S.C. § 1400(b) in *TC Heartland, LLC v. Kraft Food Group Brands, LLC*, 137 S.Ct. 1514 (2017). The Supreme Court held in that case that the state where a corporation “resides” is only the state where it is incorporated. *Id.* at 1520. This narrow interpretation of corporate residence has placed added emphasis on the remaining portion of § 1400(b), which permits venue to be laid in any jurisdiction “where the defendant has committed acts of infringement and has a regular and established place of business.” The ANDA context presents a unique uncertainty about the meaning of this clause because ANDA infringement suits often begin before the generic drug has been produced. The ANDA cause of action, 35 U.S.C. § 271(e)(2), makes it an “act of infringement to submit” certain drug applications for approval. Following *TC Heartland*, courts are divided regarding the meaning of “committed acts of infringement” in the context of an ANDA submission. Some courts have held that venue is appropriate in districts where future acts of infringement are anticipated to occur. Other courts have read the statute more restrictively, holding that venue is satisfied only where the ANDA submission was prepared and submitted, which would only be known to the ANDA filer.

3. Please Explain How the Proposed Policy Position Will Address the Issue

The Resolution addresses this uncertainty by urging federal courts to interpret the clause “where the defendant has committed acts of infringement and has a regular and established place of business,” in the patent special venue statute, 28 U.S.C. § 1400(b), when applied to Abbreviated New Drug Application (ANDA) litigation under 35 U.S.C. § 271(e)(2) to mean a district in which the defendant who filed an ANDA application is anticipated to commit acts of infringement.” The Resolution urges courts to adopt this interpretation of the venue statute to provide venue predictability for parties, promote conservation of judicial resources, and align with the common and statutory meaning of infringement.
4. **Summary of Minority Views or Opposition Internal and/or External to the ABA Which Have Been Identified**

We are aware of no ABA minority view or opposition.