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The authors suggest that whether *TC Heartland* applies to BPCIA actions is an open question given the statutory and policy differences between 28 U.S.C. § 1400(b) and the BCPIA.

Will *TC Heartland* Control Venue in BPCIA Litigation?

BY SASHA S. RAO AND CHARLES L. GHOLZ

In the wake of the U.S. Supreme Court's decision in *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514, 122 U.S.P.Q.2d 1553 (2017), many have taken for granted the decision's applicability to patent infringement actions of all types, including litigation based on the Biologics Price Competition and Innovation Act of 2009 (BPCIA). However, reference product sponsors need not yet resign themselves to a future of litigation in the biosimilar applicants' states of incorporation.

The Supreme Court's analysis is firmly rooted in the legislative history of the patent venue statute, 28 U.S.C. § 1400(b). However, Section 1400(b) is at odds with the legislative history and intent of the BPCIA, its mechanics, and the nature of ''artificial infringement.'' Moreover, the Supreme Court's denial of Mylan's petition for certiorari to reverse the jurisdiction-broadening decision by the U.S. Court of Appeals for the Federal Circuit in a Hatch-Waxman matter just months before suggests that the Supreme Court may not have intended *TC Heartland* to reach ANDA and BPCIA litigation.

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The views expressed herein are those of the authors and are not necessarily shared by their employer or its clients.

Primer on BPCIA Procedure

The BPCIA established an abbreviated regulatory approval pathway at the FDA for a biological product that is biosimilar to or interchangeable with an already-approved biological product, known as a ''reference product.'' 42 U.S.C. § 262(k). The intent was similar to that of the Hatch-Waxman statutory framework—to facilitate the introduction of ''generic'' biosimilars while not unduly diminishing the value of patents that protect the reference products.

To this end, ''[t]he BPCIA facilitates litigation during the period preceding FDA approval so that the parties do not have to wait until commercial marketing to resolve their patent disputes.'' *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1670, 122 U.S.P.Q.2d 1685, 1688 (2017). Thus, BPCIA litigation occurs prior to the traditional acts of infringement defined by 35 U.S.C. § 271(a). Under the BPCIA, it is ''an act of infringement to submit'' an application seeking approval of a biological product ''if the purpose of such submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.'' 35 U.S.C. § 271(e)(2)(C). This type of ''preapproval infringement'' in the absence of actual infringing products in the stream of commerce is known as ''artificial infringement.'' *Sandoz*, 137 S. Ct. at 1670.

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After the FDA accepts a biosimilar application for review and the applicant provides the reference product manufacturer (the ''sponsor'') with a copy of the application and other ''information that describes the process or processes used to manufacture the biological product,'' 42 U.S.C. § 262(l)(2)(A) and (B), the parties exchange lists of patents for which they believe a claim of patent infringement ''could reasonably be asserted'' by the sponsor. *Id.* at § 262(l)(3)(A)(i) and (B)(i). The patents on or that could have been included on these lists are all considered to have been ''artificially infringed'' as a result of the applicant's submission to the FDA. 35 U.S.C. § 271(e)(2)(C)(i) and (ii). In addition, the applicant provides its invalidity, unenforceability, and noninfringement arguments. 42 U.S.C. § 262(l)(3)(B)(ii)(I).

The sponsor then submits, ''with respect to each patent described [by the applicant], on a claim by claim basis, the factual and legal basis of the opinion of the reference product sponsor that such patent will be infringed by the commercial marketing of the biological product that is the subject of the [biosimilar] application and a response to the statement concerning validity and enforceability.'' *Id.* at § 262(l)(3)(C). Thus, in BCPIA litigation, a significant amount of litigation preparation has already occurred prior to the filing of a complaint in district court.

The BPCIA then provides two stages of litigation: one in which certain agreed-upon patents are litigated immediately and the other, triggered by the applicant's notice of commercial marketing, involving any patents that were included on the parties' § 262(l)(3) lists but not litigated in the first phase. *Sandoz*, 137 S. Ct. at 1671. The sponsor must bring an action in court within 30 days of the date of the agreement of which patents to litigate immediately or of the date of the exchange of patent lists. 42 U.S.C. § 262(l)(6)(A). If infringement is found for the patents litigated immediately, remedy is provided by Section 271(e)(4). *Sandoz*, 137 S. Ct. at 1672. For the second stage, either party may seek declaratory relief. 42 U.S.C. § 262(l)(9)(A).

TC Heartland Appears Conclusive on Section 1400(b), But Not End of Story for BCPIA Litigation

For patent infringement actions, Congress established a separate venue statute, 28 U.S.C. § 1400(b), which provides that ''[a]ny civil action for patent infringement may be brought in the judicial district where the defendant resides, or where the defendant has committed acts of infringement and has a regular and established place of business.'' However, until *TC Heartland*, the Federal Circuit and district courts interpreted amendments to the general venue statute, 28 U.S.C. § 1391, to have modified Section 1400(b). This meant that they uniformly ruled that venue for patent infringement was proper wherever personal jurisdiction could be had over the defendant. *VE Holding Corp. v. Johnson Gas Appliance Co.*, 917 F.2d 1574, 1583, 16 U.S.P.Q.2d 1614, 1620 (Fed. Cir. 1990).

Delivered by Justice Clarence Thomas, the *TC Heartland* opinion derives much of its logic from the statutory history of Section 1400(b). Specifically, in 1897, Congress enacted Section 1400(b)'s predecessor to ''plac[e] patent infringement cases in a class by themselves, outside the scope of general venue legislation.'' *Brunette Machine Works, Ltd. v. Kockum Indsutries, Inc.*, 406 U.S. 706, 713, 174 U.S.P.Q. 1, 4 (1972). The patent-specific venue statute took its modern form in 1948, and the Court emphasized in 1957 that Section 1400(b) ''is the sole and exclusive provision controlling venue in patent infringement actions, and . . . is not to be supplemented by . . . § 1391(c).'' *Fourco Glass Co. v. Transmirra Products Corp.*, 353 U.S. 222, 229, 113 U.S.P.Q. 234, 237 (1957). ''The Court observed that Congress enacted § 1400(b) as a standalone venue statute and that nothing in the 1948 recodification evidenced an intent to alter that status.'' *TC Heartland LLC*, 137 S. Ct. at 1519. Throughout its iterations, the venue rule dictated that a domestic corporation resides in its state of incorporation. *Id.* at 1519. Despite amendments to the general venue statute, Section 1391(c), section 1400(b) remained unaltered. The Court narrowed the issue before it to ''whether Congress changed the meaning of § 1400(b) when it amended § 1391(c),'' *Id.*, and it concluded that Congress had not. The Court reached its conclusion that, for purposes of Section 1400(b), a domestic corporation ''resides'' only in its state of incorporation on the basis that ''[t]he current version of § 1391 does not contain any indication that Congress intended to alter the meaning of § 1400(b) as interpreted in *Fourco*.'' *Id.* at 1520.

Section 1400(b) Incompatible With BPCIA-Type Infringement

In *TC Heartland*, the Supreme Court seems to have unshackled venue from personal jurisdiction at least so far as ''where the defendant resides'' is now restricted to a domestic defendant's state of incorporation. In traditional infringement suits, plaintiffs can otherwise rely on the second half of Section 1400(b). That is, they may establish venue according to ''where the defendant has committed acts of infringement and has a regular and established place of business.'' However, that luxury is not so plainly available to Hatch-Waxman and BPCIA plaintiffs. As BPCIA litigation is necessarily preapproval and thus before any infringing products have entered the market, attempting to find the locus of the acts of infringement is nonsensical. Market preparations disclosed in the applicant's notice of commercial marketing, 42 U.S.C. § 262(l)(3)(C) & (I)(8), would also not suffice since Section 1400(b) looks only to past acts of infringements (i.e., ''where the defendant has committed acts of infringement'').

Furthermore, this past-tense statutory language is incongruous with the future threat that makes such controversies actionable. *See Acorda Therapeutics, Inc. v. Mylan Pharm., Inc.*, 817 F.3d 755, 761-62, 118 U.S.P.Q.2d 1304, 1306-08 (Fed. Cir. 2016). Litigation authorized by Sections 271(e)(2) and (5) meets Article III's requirement of a case or controversy because ''the future real-world market acts as sufficiently connected to the [abbreviated regulatory statutory pathway] that triggers the litigation.'' *Id.* at 762. In other words, jurisdictional questions for artificial acts of infringement are forward looking. Thus, Section 1400(b) with its requisite ''committed acts'' of infringement collides with the basis for standing in artificial infringement actions.

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Legislative Intent Limiting Venue for Traditional Patent Infringement Litigation Conflicts With BPCIA Intent and History

''Congress adopted the predecessor to § 1400 (b) as a special venue statute in patent infringement actions to eliminate the 'abuses engendered' by previous venue provisions allowing such suits to be brought in any district in which the defendant could be served.'' *Schnell v. Peter Eckrich & Sons, Inc.*, 365 U.S. 260, 262, 128 U.S.P.Q. 305, 306 (1961). In other words, Section 1400(b) is designed to protect the defendant from the inconveniences it would otherwise suffer if plaintiff were to be given liberal latitude in its selection of venue. *See Dickey-John Corp. v. Richway Sales*, 78 F.R.D. 66, 67, 200 U.S.P.Q. 148 (N.D. Ill. 1977) (Section 1400 ''was enacted to prevent patent venue from lying in just any judicial district in which the defendant could be found. It was intended that the forum of a patent infringement suit should be one reasonably convenient to the defendant.''). As one district court applying *Fourco* explained, ''The patent venue statute reflects a legislative policy recognizing the technical and intricate nature of patent litigation.'' *Bradford Novelty Co. v. Manheim*, 156 F. Supp. 489, 491, 115 U.S.P.Q. 278, 280 (S.D.N.Y. 1957). Furthermore, ''Because of the obvious difficulty involved in a court attempting to ascertain from the mass of technical data presented the pertinent and determinative facts, Congress saw fit to narrowly confine the venue provisions applicable to this type action [sic].'' *Id.*

There are no such surprises and inconveniences for BPCIA applicants. The statutorily choreographed preapproval litigation process gives the applicant significant advantages. The applicant controls the scope of the first phase as ''[t]he number of patents on the sponsor's list is limited to the number contained in the applicant's list . . . .'' *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1671, 122 U.S.P.Q.2d 1685, 1689 (2017). In addition, the applicant controls the timing of the second phase because the applicant ''chooses when to begin commercial marketing and when to give notice.'' *Id.* at 1672. The biosimilars applicant is not a hapless party who unwittingly becomes victim of a marauding patent holder. The Federal Circuit recently observed that, for generic-type applicants, ''A State's exercise of jurisdiction over a defendant planning such conduct can hardly come as a surprise to the defendant and does nothing to offend 'traditional notions of fair play and substantial justice.' '' *Acorda v. Mylan*, 817 F.3d at 762 (*citing Int'l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945)).

Indeed, the forum shopping that is a perennial concern of the courts is more subdued in BPCIA litigation than in traditional patent infringement actions. There is already a strong motivation to file in the proper forum. If the plaintiff-sponsor files in the wrong venue, it risks having its action dismissed and falling outside the 30-day statutory period to file suit. 42 U.S.C. § 262(l)(6). The economic stakes are generally high in most patent cases. However, in biological product matters, the dismissal of the suit can be commercially catastrophic for the sponsor. While certainly some degree of forum shopping is inevitable, there is that much more motivation to ''get it right the first time,'' and the risk of abuse is lower in the BPCIA context.

The patent-specific venue provision of Section 1400(b) was enacted to protect defendants. However, in contrast to traditional patent infringement litigation, the nuances of the BPCIA together with *TC Heartland*'s holding leave sponsor-plaintiffs in a position where the biosimilar applicants hold all the jurisdictional cards—both when to file and where to file would be dictated by defendants if *TC Heartland* applies. This would appear to resurrect the mirror issue Section 1400(b) was meant to correct many years ago.

Legislative History of BPCIA Suggests Congress Intended Section 1391 and Not Section 1400(b) to Apply

Congress considered two competing amendments introduced in March 2009 to the Public Health Service Act, 42 U.S.C. § 262, to establish a pathway for the licensure of biosimilar biological products: ''Promoting Innovation and Access to Life-Saving Medicine Act,'' 111 H.R. 1427, sponsored by Rep. Henry Waxman, and the ''Pathway for Biosimilars Act,'' 111 H.R. 1548, sponsored by Rep. Anna Eshoo. The intent of both was similar, but the specifics of the proposals differed in a key respect that impacts this discussion.

In her remarks introducing her bill, Eshoo announced that her amendments would provide a ''simple, streamlined patent resolution process'' that ''would take place within a short window of time—roughly 6-8 months after the biosimilar application has been filed with the FDA.'' Introduction of the Pathway for Biosimilars Act, 155 Cong. Rec. E 687, 688 (March 17, 2009) (Remarks of A. Eshoo). Additionally, ''It will help ensure that litigation surrounding relevant patents will be resolved expeditiously and prior to the launch of the biosimilar product, providing certainty to the applicant, the reference product manufacturer, and the public at large.'' *Id.*

The Waxman bill similarly refers to ''prompt judicial resolution of patent disputes'' and bringing biosimilars ''to market as expeditiously as possible, consistent with fair and prompt resolution of patent disputes.'' 111 H.R. 1427, § 3(b)(1)(B).

However, the previously referred to ''key'' difference between the two bills was in their treatment of venue.

The Waxman bill proposed amending the venue transfer statute, 28 U.S.C. § 1404, to add, among other provisions, that, ''In any action for patent infringement brought by the holder or owner of the patent pursuant to Section 351(k)(18)(C) of the Public Health Service Act, the defendant may move to transfer the action to any other district in which jurisdiction is proper.'' 111 H.R. 1427, § 3(b)(1). The Waxman bill went further to include its statutory purpose in a venue dispute resolution amendment, requiring courts considering a motion to transfer venues to give greatest weight to ''(A) The interest in identifying a district court in which the case will be adjudicated expeditiously'' and ''(B) The strong public interest in obtaining prompt judicial resolution of patent disputes so that the biological product which is the subject of the patent dispute may be brought to market as expeditiously as possible, consistent with fair and prompt resolution of patent disputes.'' *Id.*

However, the Eshoo bill proposed *no* changes to the venue statute.

At first glance, strictly following *TC Heartland* and adjudicating all BPCIA disputes based on the state of in-

corporation of the domestic applicant seem to be consistent with the intent of the drafters of both bills, particularly that of Waxman. This limitation would tend to minimize venue battles that could cause the delay so anathema to the drafters of these bills. However, Congress did not adopt Waxman's bill. Instead, the Eshoo bill, which proposed no amendments to any venue statutes, prevailed and reflects the BPCIA's current silence on this procedural matter.

This is not a consequence of venue issues simply being overlooked.

Testimony given before the Subcommittee on Courts and Competition Policy called out and argued against these venue amendments. *See* Hearing before the Subcommittee on Courts and Competition Policy, Ser. No. 111-73 (July 14, 2009). Commenting positively on the Eshoo bill, the Biotechnology Industry Organization remarked that the Eshoo bill ''preserves the autonomy of the courts to manage litigation, and does not attempt to change well-established rules governing civil procedure, evidence and venue.'' *Id.* at 25. The American Intellectual Property Law Association also testified in favor of maintaining the ''existing law of venue,'' *Id.* at 196, and argued that the bill should ''not attempt to alter the law of venue.'' *Id.* at 205.

In contrast, Congress heard that amending the venue statute as proposed by the Waxman bill ''would constrain the district court's discretion to consider other traditional factors such as the convenience of the witnesses and parties, and the interests of justice.'' *Id.* at 212.

At the time of these hearings, proper venue in patent cases was defined by the Federal Circuit's decision in *VE Holding*, which held that venue was permissible in any court having personal jurisdiction over the defendant in a patent infringement action. 917 F.2d at 1583. In other words, the general venue statute of Section 1391 rather than Section 1400(b) was being applied. Congress considered an opportunity to restrict venue but declined to do so.

Congress Did Limit Venue in Hatch-Waxman But Not in BPCIA

The BPCIA and Hatch-Waxman Act, known formally as the Drug Price Competition and Patent Term Restoration Act (P. L. 98-417), share similar statutory objectives and means. Both create abbreviated pathways to regulatory approval at the FDA and litigation protocols to protect patents. Both their litigation processes are triggered by statutorily defined acts of artificial infringement. Thus, it is natural to compare the two. Particularly, with over 25 years of Hatch-Waxman experience to draw from, Congress might have drafted the BPCIA with the lessons learned from its elder statutory sibling.

In the Hatch-Waxman Act, Congress limited venue selection when either the applicant or the patent owner brings a declaratory judgment action. If the applicant brings a civil action ''for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval,'' the civil action ''shall be brought in the judicial district where the [patent owner] has its principal place of business or a regular and established place of business.'' 21 U.S.C. § § 355(c)(3)(D)(i)(II) and (j)(5)(C)(i)(II).

In contrast, in BPCIA litigation, either party may sue for declaratory relief. *Sandoz v. Amgen*, 137 S. Ct. at 1672. Notably, these provisions state that the party may ''bring any [declaratory] action under section 2201 of title 28,'' a non-patent-specific provision. 42 U.S.C. § 262(l)(9)(A). Importantly, there are no restrictions placed on venue for either party. *Id.* at § 262(l)(9).

One must be careful not to read too much into legislative silence. However, considering the lack of venue restricting language in light of the Waxman bill and the Hatch-Waxman Act, this silence is deafening.

Congress's Remedy Provisions Suggest it Considered Artificial Infringement a Different Harm

Also emblematic of Congress's intent to treat traditional acts of infringement and the Section 271(e)(2) artificial infringement of the BPCIA differently is the difference in remedies available to the parties. If remedies are a reflection of the harm caused, different remedies suggest different harms.

The injured plaintiff in a traditional infringement action is recompensed pursuant to 35 U.S.C. § 284, which awards ''damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court.'' This can, of course, be amplified greatly in cases of willful infringement. *Halo Electronics, Inc. v. Pulse Electronics, Inc.*, 136 S. Ct. 1923, 1928, 118 U.S.P.Q.2d. 1761, 1763 (2016).

However, for artificial acts of infringement under the BPCIA, ''the *sole and exclusive remedy* that may be granted by a court, upon a finding that the making, using, offering to sell, selling, or importation into the United States of the biological product that is the subject of the action infringed the patent, shall be a reasonable royalty.'' 35 U.S.C. § 271(e)(6)(B) (emphasis added). In fact, ''damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of . . . [a] biological product.'' *Id.* at § 271(e)(4)(C).

Supreme Court May Have Dropped Hint Denying Certiorari in *Acorda v. Mylan*

In *Acorda Therapeutics, Inc. v. Mylan Pharms., Inc.*, the Federal Circuit considered the issue of personal jurisdiction in a case of artificial infringement in the Hatch-Waxman context. 817 F.3d 755, 758-59, 118 U.S.P.Q.2d 1304 (Fed. Cir. 2016), *cert denied*, No. 16-360 (U.S. Jan. 9, 2017). The court held that the district court would have personal jurisdiction over the defendant if that party would be subject to the jurisdiction of a court of general jurisdiction in the state where the district court is located. *Id*. at 759. Furthermore, the court held that the defendant's Abbreviated New Drug Application (ANDA) and its distribution channels established the requisite minimum contacts with the state of jurisdiction. *Id.* at 762. Mylan is incorporated in West Virginia and has its principle place of business there. *Id.* at 758. However, the Federal Circuit affirmed that jurisdic-

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tion was proper in the state of filing, Delaware. *Id.* at 764.

Mylan petitioned for certiorari to reverse this decision which allows nationwide specific personal jurisdiction over Hatch-Waxman defendants. The questions proposed in Mylan's briefs were: (1) ''Whether the Federal Circuit correctly held that Mylan is subject to specific personal jurisdiction in Delaware because Mylan's ANDA filing concretely declared its plan to market its generic version of Ampyra in Delaware,'' and (2) ''Whether Mylan consented to general personal jurisdiction in Delaware when it registered to do business in the State and appointed an agent for service of process.''

The Supreme Court did not grant review of Mylan's proposed questions. Only a few months before the *TC Heartland* decision, the Supreme Court denied certiorari on these issues.

While *Acorda Therapeutics* is not a venue decision, the disposition encourages some pause before blindly applying *TC Heartland* in every patent infringement matter. This denial, at the very least, indicates that the Supreme Court may not be on a mission to restrict jurisdiction in all patent cases.

Conclusion

As a decision rooted in Section 1400(b), it is not clear whether *TC Heartland* is applicable to BPCIA litigation considering the statutory and policy differences between the BPCIA and Section 1400(b). Unlike traditional patent infringement actions, the defendant in BPCIA litigation is never caught unaware and enters litigation deliberately with statutorily created advantages. As such, the safeguard that Section 1400(b) was created to provide are irrelevant and arguably confers an unfair advantage to biosimilar applicants if paired with *TC Heartland*.

For practical purposes, BPCIA practitioners will and should continue to cite *TC Heartland*. However, the application of this decision to BPCIA venue selection is ripe for challenge.