

TC Heartland's Impact on Hatch-Waxman and Biosimilars Litigation

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Agenda

- Overview of *TC Heartland*
- Where do defendants “reside”?
- Where have defendants “committed acts of infringement”?
- What is a “regular and established place of business”?
- Multi-defendant cases
- Effect on Hatch-Waxman strategy
- Biosimilars wrinkles

Overview of *TC Heartland*

- Venue in patent-infringement cases is governed by 28 U.S.C. §1400(b):
 - “Any civil action for patent infringement may be brought in the judicial district where the defendant resides, or where the defendant has committed acts of infringement and has a regular and established place of business.”
- The Supreme Court held in 1957, in *Fourco*, that a corporation “resides” only in its state of incorporation
- Section 1400(b) has not changed since *Fourco*, but Congress amended the definitions of “residence” in the general venue statute (1391(c)).

Overview of *TC Heartland*

- A definition in the general venue statute provides:
 - “[A business entity] shall be deemed to reside, if a defendant, in any judicial district in which such defendant is **subject to the court’s personal jurisdiction** with respect to the civil action in question”
- That definition applies “For all venue purposes”
 - In 1988, Congress made the definition applicable “For purposes of venue under this chapter”
 - In 2011, Congress adopted the current version
- After the 1988 amendment, the Federal Circuit held (in *VE Holding Corp.*) that the definition of “residence” governed patent venue
 - Section 1400 is in the same “chapter”

Overview of *TC Heartland*

- TC Heartland challenged the Federal Circuit's precedent
 - Indiana LLC
 - Sued in Delaware for patent infringement, where it was subject to personal jurisdiction **but** had no regular and established place of business. Moved to dismiss or transfer.
- Federal Circuit adhered to its precedent
- Supreme Court granted certiorari
 - LLC issue not addressed in the Federal Circuit or at the certiorari stage

Overview of *TC Heartland*

- Holding: The meaning of the patent venue statute has not changed since *Fourco*.
 - “Resides,” for a corporation, still means the place of incorporation, and nowhere else.
 - Congress did not clearly intend to overturn the holding of *Fourco* by amending a statute other than the patent venue statute (section 1391(c), with general definitions for venue).
- Court declined to address certain issues
 - Residence of LLCs – remanded to Federal Circuit
 - Residence of foreign corporations

Where do defendants “reside”?

- The easy case: a Delaware corporation.
 - Delaware has only one district.
- Slightly harder case: a corporation incorporated and headquartered in New York.
 - Pre-*Fourco* precedent said that in deciding where a corporation resides in a multi-district state, look to the principal place of business
 - Principal place of business, for diversity purposes, now means the “nerve center” (*Hertz Corp. v. Friend*)
- Unresolved case: a corporation incorporated in California but headquartered elsewhere
 - 4 districts to choose from, or 1?
 - Statute says “the” district where the defendant resides

Where do defendants “reside”?

- Where do LLCs and other unincorporated entities reside?
 - LLCs were unknown when the relevant statute was written
 - No clear background rule for unincorporated associations (*Denver & Rio Grande*, S. Ct. 1967)
 - One leading court of appeals case (from 1942) said principal place of business
 - Partnerships deemed to “reside” where their partners live
 - But that’s non-transparent
 - Could the business-entity statute apply to LLCs, even though not corporations? Or might *Denver & Rio Grande*’s “doing business” rule apply?
 - “For all venue purposes . . . **an entity with the capacity to sue and be sued in its common name under applicable law, whether or not incorporated**, shall be deemed to reside, if a defendant, in any judicial district in which such defendant is **subject to the court’s personal jurisdiction** with respect to the civil action in question”

Where do defendants “reside”?

- Where does a foreign corporation reside?
 - Old venue statute: “An alien may be sued in any district.”
 - Supreme Court, in *Brunette Machine Works* (1972), says that “principle of broad and overriding application” applies to patent-infringement cases, too
 - Today, venue statute says “For all venue purposes ... a defendant not resident in the United States may be sued in any judicial district, and the joinder of such a defendant shall be disregarded in determining where the action may be brought with respect to other defendants.”
 - But what does “not resident in the United States” mean today?
 - What about a company with substantial U.S. operations, but incorporated/headquartered overseas?
- Options seem to be “Nowhere” and “Everywhere”

Where have Δs “committed acts of infringement”?

- Indirect infringement
 - Federal Circuit case law: acts of inducement or contributory infringement qualify
- Process patents
- What about acts that would be infringement, but are within a safe harbor, are licensed, or infringe an invalid patent?
- Artificial acts of infringement (submitting an ANDA or an aBLA)
 - Where are they “committed”?
 - “To submit ... an application ... if the purpose of such submission is to obtain approval”
 - Maryland? Research facility? Headquarters? Mailbox?
 - *Acorda* may be instructive, but isn’t controlling. Based PJ on plans to infringe in a district, not where the D “has committed” acts of infringement

“Regular and established place of business”?

- Extensively analyzed in lower courts (engaging in a highly fact-intensive inquiry) before the Federal Circuit’s 1990 decision rendered it largely irrelevant
- May not require bricks and mortar, but more than just “doing business.” Mere presence of some sales representatives probably not enough
- Courts held that locations of corporate affiliates don’t count (assuming corporate formalities are observed)
- Many courts also discounted locations of independent contractors

Multi-defendant cases

- “The defendant” = all defendants
- Venue may become a subject of negotiation
 - Seek transfer under 28 U.S.C. § 1404
 - Transfer can be to any district, even one where the action couldn’t originally be brought, if all parties consent
 - 1404 transfer is for all purposes, including trial
- Alternative may be multidistrict litigation (28 U.S.C. § 1407)
 - Time-consuming (eats away at the 30-month stay)
 - Transfer is for pretrial proceedings only, not trial
 - Preclusion gamesmanship
- What if actions are filed in different venues at different times?

Effect on Hatch-Waxman strategy

- Availability of districts familiar with, capable of acting within 30-month stay
- MDLs and effect on joint defense
- A dismissal for improper venue is a dismissal and may result in a judgment
 - Need to file protective actions
 - After a dismissal “without prejudice,” ANDA filer can bring a declaratory-judgment action
 - ANDA filer can choose among many venues, because DJ actions are not governed by *TC Heartland*
 - General venue: transactional venue or defendants’ residence, broadly defined (28 U.S.C. §1391(b))
- Potential forfeiture of 180-day exclusivity
 - “a final decision ... that the patent is ... not infringed”

Biosimilars wrinkles

- Under the BPCIA and *Sandoz v. Amgen*, the exclusive remedy for failure to turn over an aBLA is a declaratory-judgment action
 - Broader choice of venues
- *Sandoz v. Amgen* leaves open (remands) the question whether state law can provide an injunctive remedy that federal law does not
 - But which state law?
 - Forum state choice of law rule, not necessarily forum state law

Questions?

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