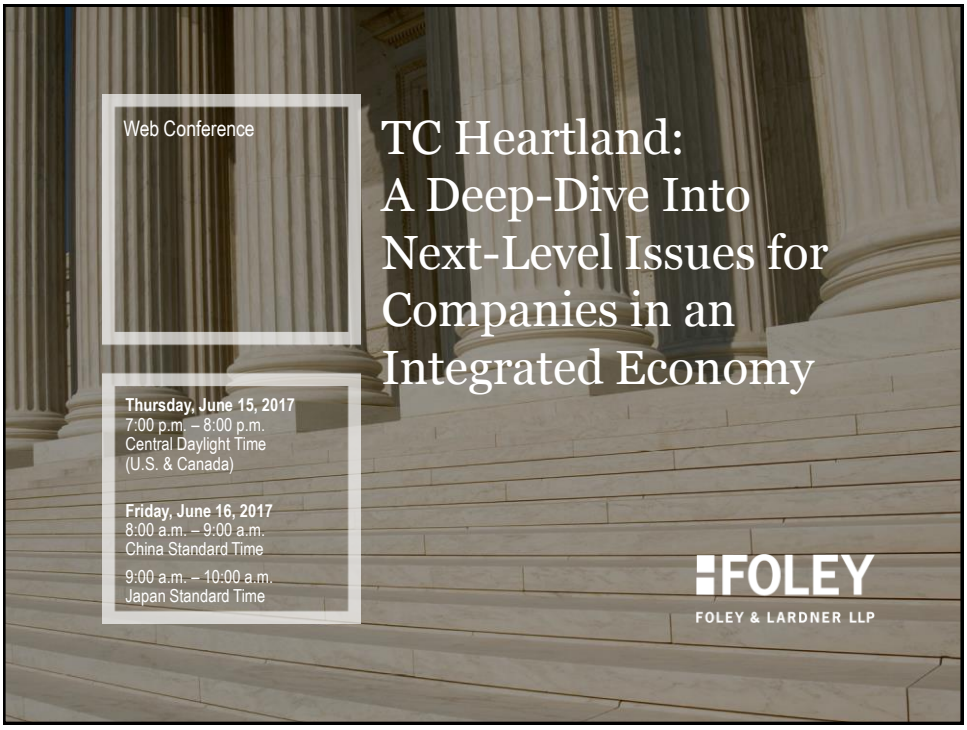

Roadmap of Presentation

- **Venue Background and *TC Heartland***
  - Pre-*TC Heartland* and U.S. Supreme Court's *TC Heartland* opinion
- **Patent Venue Issues Post-*TC Heartland***
  - Retroactivity and Waiver: Venue in currently pending cases
  - New focus on "regular and established place of business" prong
- **Patent Owner Strategies Seeking Favorable Venue and Potential Countermeasures**
  - Targeting Non-U.S. corporations
  - Other strategies involving multi-defendant cases
  - Multidistrict litigation and the ITC
- ***TC Heartland* Impact on Pharma Industry (Hatch-Waxman and Biosimilars)**

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Background on Venue in Patent Cases and the *TC Heartland* Decision

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Venue in Patent Cases – Patent Venue Pre-*TC Heartland*

- In a Federal Court case, personal jurisdiction and venue are two separate legal requirements that must be met in order for that case to proceed
- The venue statute governing patent cases, 28 U.S.C. § 1400, states:

  …

  (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.

- In 1957, the Supreme Court interpreted § 1400 in ***Fourco Glass Co. v. Transmirra Products Corp.***, 353 U.S. 222, and held that "resides" for the purposes of venue means a ***domestic*** corporation "resides" only in its state of incorporation
- After ***Fourco***, venue was proper over a ***domestic*** corporation in patent cases (1) in its state of incorporation; or (2) where it committed acts of infringement and had a "regular and established place of business"

Venue in Patent Cases – Patent Venue Pre-*TC Heartland*

- Subsequent to ***Fourco***, the general venue statute, 28 U.S.C. § 1391 was amended which raised questions as to whether its broader definition of residency applied to the "resides" requirement for patent cases under 28 U.S.C. § 1400
- The current version of the general venue statute, 28 U.S.C. § 1391, states in relevant portion:

  (a) Applicability of section. Except as otherwise provided by law –

  (1) this section shall govern the venue of all civil actions brought in district courts of the United States;

  …

  (c) Residency. For all venue purposes –

  …

  (2) 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

Venue in Patent Cases – Patent Venue Pre-*TC Heartland*

- The Federal Circuit, in ***VE Holding Corp. v. Johnson Gas Appliance Co.***, 917 F.2d 1574 (1990), considered whether the broader residency definition set forth in § 1391(c)(2) applied to patent cases
- Based on the broad incorporation language of "[f]or purposes of venue under this chapter," the Federal Circuit held that the residency test set forth in § 1391 overrode the narrower definition of "resides" set forth by the Supreme Court in ***Fourco***
- Thus, after ***VE Holding***, for the purposes of meeting the venue requirements of § 1400(b), a patent infringement defendant merely had to be "subject to personal jurisdiction [in the pertinent forum] at the time the action is commenced"
- As a result, after ***VE Holding***, district courts conflated the venue inquiry with the personal jurisdiction inquiry and if there were sufficient contacts to yield personal jurisdiction then defendants also "resided" in that forum and venue was proper under the residency definition set forth in § 1391(c)(2)

Venue in Patent Cases – The *TC Heartland* Decision

- In a nutshell, the ***TC Heartland*** decision reversed the Federal Circuit's long-standing ***VE Holding*** decision and reinstated the narrower residency definition set forth in ***Fourco***
- In contrast to the Federal Circuit's ***VE Holding*** opinion, the Court held that the residency amendments to the general venue statute, § 1391, were not meant to affect patent cases as the venue requirements for patent cases were set forth exclusively by Congress in § 1400
- Thus, the Court held that the residency determination based on § 1400 as set forth in ***Fourco*** should control the venue inquiry in patent cases and ***VE Holding*** was overruled

Venue in Patent Cases – The *TC Heartland* Decision

- **After *TC Heartland*, as to *domestic* corporations, venue in a patent case is proper if the venue is:**
  - **(1) in the state where the company is incorporated; or**
  - **(2) acts of infringement occurred in the forum and the company has a "regular and established place of business"**
- **Two immediate questions arise from the change to the venue rules:**
  1. **How does *TC Heartland* affect pending cases?**
  2. **What constitutes a "regular and established place of business" under § 1400(b)?**

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Analyzing the Impact of the *TC Heartland* Decision

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Effect of *TC Heartland* Decision on Pending Cases

- **There are two legal hurdles litigants in pending cases will have to overcome in order to challenge venue in cases where defendants have responded to the Complaint and not challenged venue:**
  1. **Is *TC Heartland* retroactively applicable to pending cases?**
  2. **Have defendants who are past the pleadings stage waived their venue defenses?**

Effect of *TC Heartland* Decision: Retroactivity

- **Is *TC Heartland* retroactively applicable to pending cases? Supreme Court precedent seems to indicate "yes"; the general retroactivity rule is set forth in *Harper v. Virginia Department of Taxation*, 509 U.S. 86 (1993):**

  > **When this Court applies a rule of federal law to the parties before it, that rule is the controlling interpretation of federal law and must be given full retroactive effect in all cases still open on direct review and as to all events, regardless of whether such events predate or postdate the announcement of the rule.**

- **The Federal Circuit has relied on *Harper* in applying holdings from subsequent legal decisions to pending cases:**
  - ***NeuroRepair, Inc. v. The Nath Law Grp.*, 781 F.3d 1340, 1344 (Fed. Cir. 2015) (citing *Harper* and applying Supreme Court change in law to case on appeal)**
  - ***Heartland By-Prod., Inc. v. United States*, 568 F.3d 1360, 1365 (Fed. Cir. 2009) (citing *Harper* for the proposition that "[t]he general rule is that judicial decisions are retroactive")**

Effect of *TC Heartland* Decision: Waiver

- In cases past the pleadings stage where venue is arguably improper after *TC Heartland*, a critical legal question will be whether the Defendant has waived its venue defense
- Under Fed. R. Civ. P. 12(h)(1), certain defenses such as venue are waivable. *See Hoffman v. Blaski*, 363 U.S. 335, 343 (1960) ("[V]enue, like jurisdiction over the person, may be waived. A defendant…waives venue by failing seasonably to assert it.")
- Numerous circuits note that the determination of waiver is within the discretion of the trial court. *See, e.g., United States v. Ziegler Bolt & Parts Co.*, 111 F.3d 878, 882-83 (Fed. Cir. 1997) ("This court places waiver within the discretion of the trial court, consistent with its broad duties in managing the conduct of cases pending before it"))

Effect of *TC Heartland* Decision: Waiver

- Using their discretion, Courts will likely look to the defendants' conduct to determine whether the venue defense was waived:
  - Did Defendant challenge venue in the first responsive pleading (a Rule 12 Motion or in its answer)? Failure to do so waives the defense under the express terms of 12(h)(1)
  - If raised in its answer, did Defendant diligently pursue its venue defense? If not, Defendant's dilatory conduct may waive the defense:
    - *Wordtech Systems Inc. v. Integrated Network Systems, Corp.*, (E.D. Cal. 2004) (holding that Defendants waived venue defense despite initially objecting in their answer because Defendants allowed several years to pass and noting that "[M]erely filing an initial venue objection does not preclude subsequent waiver of the objection")
    - *Peterson v. Highland Music, Inc.*, 140 F.3d 1313, 1318 (9th Cir. 1998) (holding that Rule 12 defenses including venue "may be waived as a result of the course of conduct pursued by a party during litigation")

Effect of *TC Heartland* Decision: Waiver

- **Even if there was a waiver of the venue defense, Defendants may still be able to assert such a defense under an "intervening change in the law" exception to the rule of waiver**
- **Generally speaking, there is an exception to waiver in cases where there is an "intervening change" in the law. *See, e.g.*:**
  - ***Holzsager v. Valley Hospital*, 646 F.2d 792, 796 (2d Cir. 1981) (rejecting a claim of waiver under Rule 12(h)(1) and noting "a party cannot be deemed to have waived objections or defenses which were not known to be available at the time they could first have been made, especially when it does raise the objections as soon as their cognizability is made apparent");**
  - ***Holland v. Big River Minerals Corp.*, 181 F.3d 597, 605-06 (4th Cir. 1999) (noting that there is a general exception to waiver "when there has been an intervening change in the law recognizing an issue that was not previously available");**
  - ***See also Curtis Publishing Co. v. Butts*, 388 U.S. 130, 143 (1967) ("[A]n effective waiver must…be one of a 'known right or privilege.'")**

Effect of *TC Heartland* Decision: Waiver

- **A 1995 case, *Engel v. CBS, Inc.*, 886 F. Supp. 728, from the C.D. Cal. addresses the intervening law exception specifically relating to a change in the venue law:**
  - **Complaint filed in 1985 and venue was proper under existing statute;**
  - **§ 1391(a) amended in 1992 which, if retroactively applied, rendered venue improper;**
  - **Plaintiff argued that Defendant waived right to challenge venue but the Engel Court disagreed and held that "[d]efendants cannot be faulted for not having raised a defense that they did not know was available to them." *Id.* at 730**
- ***Engel* may be distinguishable (and was distinguished by the *Cobalt Boats* Court) because there was an actual change in the venue statute which is factually different than the issue decided by the *TC Heartland* Court**

Effect of *TC Heartland* Decision: Waiver

- **But did *TC Heartland* reflect a change in the law sufficient to trigger the intervening law exception to waiver?**
- **Yes:**
  - **– *VE Holding* interpreted the 1988 changes to § 1391's residency definitions as applicable to patent cases which greatly expanded possible venues**
  - **– As such, *VE Holding* obviated the Supreme Court's *Fourco* decision which established the definition of venue for the purposes of the patent venue statute, § 1391**
  - **– This is a change in the law as it fundamentally changes the venue test to be applied by the district courts and Federal Circuit in patent cases**
  - **– Supportive of this argument are the multiple unsuccessful petitions for writs of certiorari in cases challenging *VE Holding* and fact that *VE Holding* was binding on the district courts in patent cases for twenty-seven years**

Effect of *TC Heartland* Decision: Waiver

- **But did *TC Heartland* reflect a change in the law sufficient to trigger the intervening law exception to waiver?**
- **No:**
  - **– The Supreme Court is the only judicial body that can overturn Supreme Court precedent**
  - **– Therefore, *VE Holding* did not overturn *Fourco* and *Fourco* remained good law after *VE Holding***
  - **– Despite *VE Holding*, the *Fourco* precedent was readily available for defendants to rely on – just as those in *TC Heartland* did – and failure to make such an argument is a waiver of the venue argument**
  - **– Further, there was no change to the venue statutes (*i.e.*, a "change in law") that prompted *TC Heartland* as *TC Heartland* merely interpreted an existing statute**

Waiver of Improper Venue Defense: *Cobalt Boats* Decision

- **On June 7th, Judge Morgan from the Eastern District of Virginia issued the first opinion that addressed the issue of waiver with respect to *TC Heartland* and an improper venue defense**
- **The critical question was whether the Defendants avoided waiver of an improper venue defense because *TC Heartland* was a change in the law that triggered the "intervening law exception" to the doctrine of waiver**
- **Judge Morgan held that the *TC Heartland* opinion did not trigger the intervening law exception to the doctrine of waiver because *Fourco* was good law available to Defendants at outset of case and *TC Heartland* did not affect that**

Waiver of Improper Venue Defense: *Cobalt Boats* Decision

- **Additional notes on the *Cobalt Boats* decision:**
  - **The case was on the eve of trial which may have influenced the Court's decision**
  - **Defendant Brunswick unquestionably waived its improper venue defense as it did not challenge it in its answer. Thus, its only hope was the intervening law exception to waiver**
  - **In contrast, Defendant Sea Ray did challenge venue in its answer. The Court still found that Sea Ray waived its venue defense because it did not raise venue in the two years of litigation since the answer and the Defendants were clear that they wanted to remain together**
  - **Since it did not need to reach them, the *Cobalt Boats* Court made no determination regarding other aspects of the Motion including "regular and established place of business" under § 1400(b)**

Waiver of Improper Venue Defense: *Cobalt Boats* Decision

- In response to Judge Morgan's decision, the Defendants filed a motion to stay and a petition for mandamus to the Federal Circuit
- A split panel of the Federal Circuit denied the petition
- Judge Newman, in dissent, remarked that there was "little doubt" that *TC Heartland* was a change in the law of venue and that the Federal Circuit should have granted the petition to ensure that *TC Heartland* was being applied consistently by the district courts
- Judge Newman also noted in response to the eve-of-trial arguments by Plaintiff that "it is at trial that the purposes and policy of proper venue become dominant."
- This suggests that there is at least one judge of the Federal Circuit that would decide differently than the *Cobalt Boats* Court on the change in law exception to waiver vis-à-vis *TC Heartland*

§ 1400(b) – "Regular and Established Place of Business"

- Venue under § 1400(b) is proper if there were acts of infringement committed in the venue and the Defendant has a "regular and established place of business" in the venue
- This was a venue requirement prior to *VE Holding* – but since *VE Holding* expanded venue such that a plaintiff only had to show acts of infringement and personal jurisdiction in the venue, the contours of "regular and established place of business" has not been litigated in some time
- A sampling of the pre-*VE Holding* case law gives some hints as to how this will be interpreted but much has changed regarding how companies make, sell, offer to sell, etc. in the intervening 27 years since *VE Holding*
- Also, given its fact–intensive nature, different outcomes will likely be reached by different courts on very similar facts. Nevertheless it is instructive to consider some examples for guidance

§ 1400(b) – "Regular and Established Place of Business"

- **The Federal Circuit's *In re Cordis* decision as to this aspect of §1400 is also notable. *In re Cordis Corp.*, 769 F.2d 733 (Fed. Cir. 1985). *In re Cordis* encourages a flexible approach that goes beyond merely whether there is a physical presence in the forum:**

  [I]n determining whether a corporate defendant has a regular and established place of business in a district, the appropriate inquiry is whether the corporate defendant does its business in that district through a permanent and continuous presence there and not…whether it has a fixed physical presence in the sense of a formal office or store.

- **On its facts, the panel held that venue was proper based on the presence of two full-time sales representatives with supplies and support such as company-owned cars and secretaries even though the defendant corporation did not own or lease an office in the district. *Id.* at 735.**

§ 1400(b) – "Regular and Established Place of Business"

- **Although a district court case, the *Hemstreet v. Caere* case from 1990 is particularly notable as it considers *Cordis* and other previous cases and collects fourteen factors that are relevant to the "regular and established place of business" determination. *See Hemstreet v. Caere Corp.*, No. 90 C 0377, 1990 U.S. Dist. LEXIS 6782, *5-7 (N.D. Ill. 1990)**
- **Out of these fourteen factors, the *Hemstreet* Court noted that the decisions generally focus on two factors:**
  1. **Whether the defendant corporation maintains, controls, and pays for a physical location in the venue from which the corporation conducts business; and**
  2. **Whether the defendant corporation's representatives work exclusively for the corporation and to what extent the corporation has authorized the representatives to do more than merely solicit and forward orders**

§ 1400(b) – "Regular and Established Place of Business"

- **On its facts, the *Hemstreet* Court found that the defendant corporation did meet the "regular and established place of business" requirement of § 1400(b) on the following facts:**
  - **Defendant was incorporated in Delaware and its principal place of business was in the Northern District of California**
  - **Defendant had a single employee in the target venue, the N.D. Ill., and that employee was a district manager who maintained an office in the N.D. Ill. at Defendant's expense**
  - **That employee was responsible for sales across 9 states and Canada from his office in the N.D. Ill. though he spent less than 50% of his time in his office**
  - **All of the order processing, price approval, order satisfaction/billing, etc., was handled by the home office in the N.D. Cal. and the district manager did not have authority to set pricing, approve orders, or bill customers**
  - **Defendant participated in one trade show a year in Illinois**
  - **Sales of over $440,000 worth of products in Illinois between 1987 and 1990**

§ 1400(b) – "Regular and Established Place of Business"

- **As E.D. Texas will likely be a primary focus for many companies, here are some further case law examples from Fifth Circuit courts where venue was proper under § 1400(b):**
  - **A corporate defendant is managed and owned by a resident of the district, and the defendant and parent share many officers and directors. *Sterling Drug Inc. v. Intermedics, Inc.*, No. A-82-CA-578, 1986 WL 15561, at *2 (W.D. Tex. Aug. 6, 1986)**
  - **A division of a corporate defendant that is not accused of infringement is located in the district. The division in the district only had two employees and an office bearing the name of the corporate defendant. *Gaddis v. Calgon Corp.*, 449 F.2d 1318, 1320 (5th Cir. 1971) (holding a district court erred by "requiring a showing that the particular *division* charged with the infringements had a regular and established place of business")**

§ 1400(b) – "Regular and Established Place of Business"

- **As E.D. Texas will likely be a primary focus for many companies, here are some further case law examples from Fifth Circuit courts where venue was <u>not</u> proper under § 1400(b):**
  - **A corporate defendant that used a showroom twice a year to sell its merchandise was not a permanent presence, even if the amount of business conducted at the showroom constituted a substantial portion of the defendant's revenue. *Samsonite Corp. v. Texas Imperial American, Inc.*, No. 3:81-cv-1038-H, 1982 WL 52203, at *2 (N.D. Tex. April 15, 1982)**
  - **No "regular and established place of business" resulted from an independent sales representative in the venue that had no authority to bind the corporate defendant, did not fulfill the orders, had no inventory, and accepted orders that were fulfilled in a different state. *Kay v. J.F.D. Mfg. Co.*, 261 F.2d 95 (5th Cir. 1958)**

Venue Strategies for Plaintiffs After *TC Heartland*

Patent Owner Strategies Seeking Favorable Venue and Potential Countermeasures

(1) Targeting non-U.S. corporations

(2) Other strategies involving multi-defendant cases

(3) Multidistrict litigation and the ITC

Venue Post-*TC Heartland*: Non-U.S. Corporations

28 U.S.C. § 1391(c)(3)

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.

Venue Post-*TC Heartland*: Non-U.S. Corporations

"Section 1391(d) is not derived from the general venue statutes that 1400(b) was intended to replace. Section 1391(d) reflects, rather, the longstanding rule that suits against alien defendants are outside those statutes. Since the general venue statutes did not reach suits against alien defendants, there is no reason to suppose the new substitute in patent cases was intended to do so."

***Brunette Machine Works, Ltd.* v. *Kockum Industries, Inc.*, 406 U.S. 706 (1972)**

Venue Post-*TC Heartland*: Non-U.S. Corporations

- **Where does *TC Heartland* leave patent suits involving foreign corporations?**
  - **The *TC Heartland* opinion expressly says that the Court is not addressing venue for foreign corporations as set forth in *Brunette***
- ***Brunette* is presumably still good law and venue as to foreign corporations is unchanged by *TC Heartland***
  - **But may be subject to further challenges along the lines of arguments raised in *TC Heartland* briefing – namely that *TC Heartland's* affirmation of the primacy of 1400 obviates 1391(c)(3)'s venue rules as to foreign corporations**

Will Plaintiffs Target Non-U.S. Corporation in Venue A?

- Plaintiffs may just sue the non-U.S. corporation
  - For example, such non-U.S. parent corporation instead of U.S. subsidiary
- Beyond arguing against *Brunette*, what strategies can the non-U.S. corporation employ?

Limitations on Suing Non-U.S. Corporation to Obtain Favorable Venue

Issue #1: Still need infringing acts by corporate parent covered by U.S. Patent Law

- **35 U.S.C. § 271**: Requires activities in the U.S., e.g., making, using, selling, offering to sell, or importation
- **35 U.S.C. § 271(b):** Requires active inducement of infringement
- **35 U.S.C. § 271(c)**: Requires offer to sell or sale within the U.S., or importation into the U.S., of a component of a patented invention

Limitations on Suing Non-U.S. Corporation to Obtain Favorable Venue

Issue #2: Need personal jurisdiction

- U.S. company defendants: Show accused infringing sales or other commercial activities in the state
- **Non-U.S. company defendants: Most acts may occur outside the U.S.**

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Non-U.S. Corporations and Personal Jurisdiction

- **U.S. courts may exercise personal jurisdiction over non-U.S. corporations proper when:**
  - **(1) "Minimum contacts" exist between the non-U.S. corporation and the forum state; and**
  - **(2) Exercising personal jurisdiction will not offend "traditional [notions] of fair play and substantial justice"**
    - ***Burger King v. Rudzewicz*, 471 U.S. 462, 476 (1985)**
- **The question of whether there are "minimum contacts" with the forum state turns on which theory of jurisdiction is asserted**
  - **General jurisdiction or specific jurisdiction**

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Non-U.S. Corporations and Personal Jurisdiction

- **General Jurisdiction**
  - Defendants' contacts with the forum state must be continuous and systematic (e.g., state of incorporation and principal place of business)
    - Rarely applied to non-U.S. corporations
      - E.g., where non-U.S. corporation temporarily moves operations and runs the business out of the U.S. *Perkins v. Benguet Consol. Mining Co.*, 342 U.S. 437 (1952)
- **Specific Jurisdiction**
  - Defendant has "'purposefully directed' his activities at residents of the forum" and "the litigation results from alleged injuries that 'arise out of or relate to' those activities."
    - *Burger King v. Rudzewicz*, 471 U.S. 462, 472 (1985)

Non-U.S. Corporations and Personal Jurisdiction (General Jurisdiction)

- ***Goodyear Dunlop Tires Operations v. Brown*, 564 U.S. 915 (2011)**
  - Lawsuit filed in N.C. over bus accident in Paris involving N.C. residents, where accident allegedly caused by a defective Goodyear tire manufactured by subsidiaries located in France, Luxembourg and Turkey
  - Lower court found general jurisdiction based on Goodyear's substantial sales and commercial activities in N.C.
  - Supreme Court reversed: no general jurisdiction
    - Even substantial sales and commercial activity in a state does not render a foreign corporation "at home" in that state
    - Would render any large corporation subject to lawsuit in any state where its products are sold for any claim

Non-U.S. Corporations and Personal Jurisdiction (Specific Jurisdiction)

- ***J. McIntyre Mach., Ltd. v. Nicastro*, 564 U.S. 873 (2011)**
  - Lawsuit filed in N.J. by a resident who was injured using a metal-shearing machine manufactured by McIntyre (English corporation)
    - McIntyre had no contact with N.J. except that the machine was used in N.J.
  - Addressed the "stream of commerce" theory of specific jurisdiction
    - Prior split based on *Asahi Metal Industry. v. Cal.*, 480 U.S. 102 (1987)
    - Is placing a product into stream of commerce enough to create jurisdiction (i.e., is it foreseeable the product could enter the forum)
    - Or, must Defendant take additional steps purposefully directed at the forum?
  - Supreme Court (6-3) reversed lower court exercise of specific jurisdiction
    - But questions still remain based on concurring and dissenting opinions
      - What other steps are sufficient?
      - Several judges unwilling to create general rule in view of current business practices

Non-U.S. Corporations and Personal Jurisdiction

- **Strategies for non-U.S. corporation to challenge personal jurisdiction**
  - Stream of commerce theory based on foreseeability alone is no longer sufficient, there must be some further act directed at the forum state
    - Did the product end up in forum by chance?
      - Or was there a deliberate decision to sell the product in that forum?
    - Does the Defendant directly sell the product to consumers in the forum state, or indirectly through distributors?
      - What level of control does the Defendant have over the distribution?
    - Does the Defendant market to consumers in the forum state?
    - Was the product specifically designed to address certain needs of customers in the forum state?
    - Are there regular and established channels for addressing service/repair or technical support for consumers in the forum state?

Limitations on Suing Non-U.S. Corporation to Obtain Favorable Venue

Issue #3: Service via mail through Hague Convention

- *Water Splash v. Menon*, __ U.S. __, 2017 U.S. LEXIS 3212 (May 22, 2017): Service by mail permissible under Hague Convention where receiving state has not objected to service by mail and where authorized by otherwise-applicable law of receiving state
- **For example, Japan did not formally object to Article 10(a), but there may be separate considerations for service under Japanese law?**

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Will Plaintiffs Target Non-U.S. Corporate Parent in Venue A and U.S. Subsidiary in Venue B?

- Defendants can move to consolidate in Venue B
- If Plaintiff moves for Multidistrict Litigation in Venue A, Defendants can press for Venue B
  - MDL Panel will consider common facts, convenience of parties and witnesses, and whether consolidation promotes just and efficient conduct
  - Defendants can focus on relevant witnesses, documents, U.S. acts focused on U.S. subsidiary in Venue B

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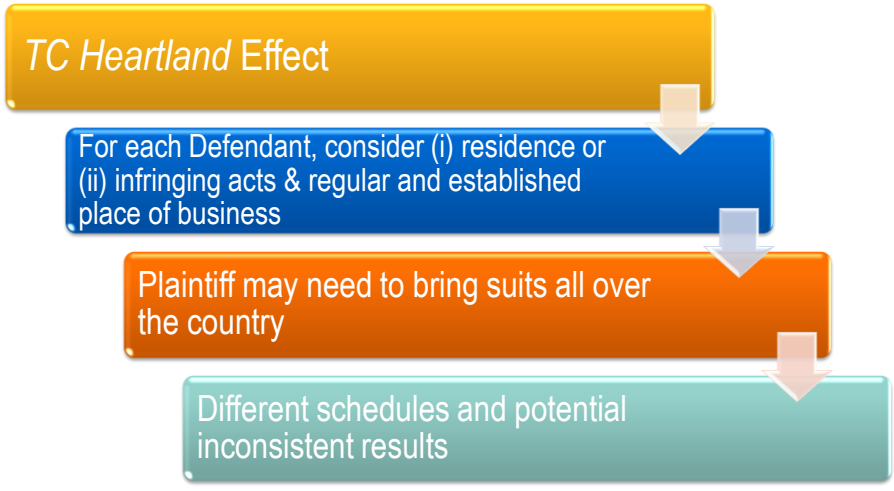
Will Plaintiffs Add Other Retailers or Distributors to Support Venue A?

- Plaintiff may argue that greater concentration of parties in Venue A
- Defendants likely to still press for Venue B
  - Key technology for patent infringement is with manufacturer and U.S. subsidiary
  - Customers may seek to stay their claims pending manufacturer claims

Reinventing Structure of Traditional Multi-Defendant Suits



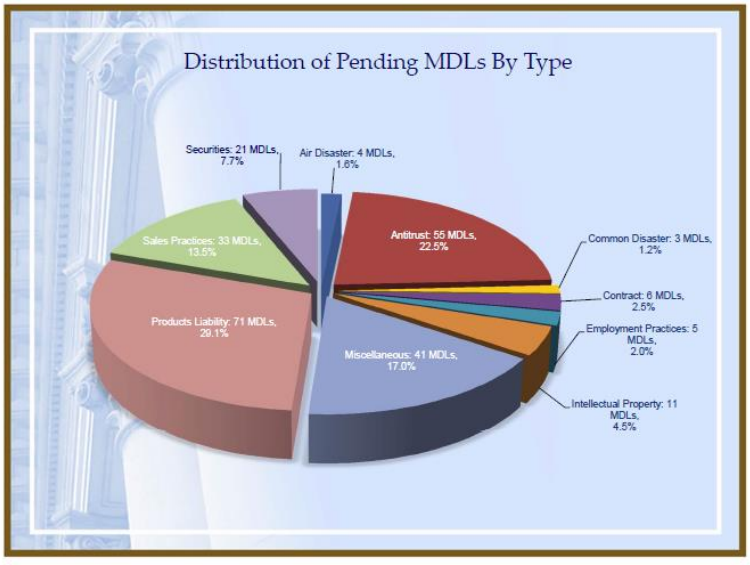
Plaintiffs May File Multiple Suits Including in Desired Venue A, and Use MDL to Bring Other Actions Into Venue A

- With target Defendant(s) properly sued in Venue A, Plaintiff then seeks consolidation through MDL in Venue A under 28 U.S.C. § 1407
  - As a further twist, plaintiff might stagger suits to allow suit in favorable venue to proceed further
- In the past two years, approximately 50% of motions for centralization have been granted. *U.S. Judicial Panel on Multidistrict Litigation 2016 Statistics*

Some Arguments by Target Defendant(s) Opposing an MDL Motion

- Individualized facts among respective defendants
  - Different products, different infringement issues
- Inconvenience of many parties and witnesses
- Various proceedings are at different stages

Expect Increase in MDLs in Patent Litigation Cases



U.S. Judicial Panel on Multidistrict Litigation 2016 Statistics

Expect Increase in International Trade Commission Cases

- Complainant (Plaintiff) must show importation
- Complainant has additional showings for complaint and in the ITC case, such as:
  - Detailed claim charts
  - Compiling evidence of importation
  - Establishing a domestic industry

TC Heartland Impact on Pharma Industry (Hatch-Waxman and Biosimilars)

Venue in Patent Cases – Hatch-Waxman and Biosimilar Litigation

- **Hatch-Waxman and Biosimilar lawsuits present additional unique questions going forward after *TC Heartland***
  - **Where do the infringing acts take place?**
    - **Hatch-Waxman and biosimilar cases present unique scenario as the allegedly infringing product has not yet been commercially manufactured or sold**
    - **How the Courts have viewed personal jurisdiction over ANDA/aBLA applicants may be instructive as to venue as well**
  - **Multiple defendant lawsuits**
  - **How likely are venue challenges?**

Venue in Patent Cases – Hatch-Waxman and Biosimilar Litigation

- Disputes will likely focus on whether venue analysis should be prospective (where products will likely be sold) vs. focused solely on past activities
  - *Acorda Therapeutics v. Mylan*, 817 F.3d 755 (Fed. Cir. 2016) – finding personal jurisdiction based on prospective analysis
- Contacts with forum state that establish personal jurisdiction may support venue as well
  - Registration to conduct business in the state
  - Development and testing of the ANDA/aBLA product
  - Preparation of the ANDA/aBLA
  - Mailing of the PIV notice letter or confidential materials under the biosimilar "patent dance"
- However, one must consider whether the activities are an "act of infringement" or exempted from infringement under the safe harbor of 35 U.S.C. § 271(e)(2)

Venue in Patent Cases – Hatch-Waxman and Biosimilar Litigation

- Many Hatch-Waxman cases involve multiple generic filers
  - Cases are typically filed in New Jersey and Delaware
    - Many generic defendants are subject to personal jurisdiction in New Jersey and Delaware after *Acorda*
    - Efficiencies for both sides in consolidating multiple cases, including for trial
    - Familiarity of New Jersey and Delaware judges with the nuances of Hatch-Waxman specific issues
  - May see a rise in Multidistrict Litigation
    - But, the MDL process only consolidates cases for pretrial proceedings
  - Expect to see "protective suits" filed going forward until more clarity
    - Plaintiff may file in both state of incorporation and preferred forum for consolidating related cases to ensure application of 30-month stay

Venue in Patent Cases – Hatch-Waxman and Biosimilar Litigation

- **Will generic defendants challenge venue going forward?**
  - **Venue after *TC Heartland* is likely to be more limited**
    - **Wider range of states of incorporation + limited "acts of infringement"**
  - **Some generic defendants will certainly prefer litigating in their home state**
    - **Or may perceive advantage of getting a quicker non-infringement ruling before other filers in other forums**
  - **Other generic defendants may forego venue challenges**
    - **Venue challenges will delay resolution, possibly beyond 30-month stay**
    - **Other defendants may prefer New Jersey or Delaware over other options, or may prefer option to be consolidated with other generic filers**

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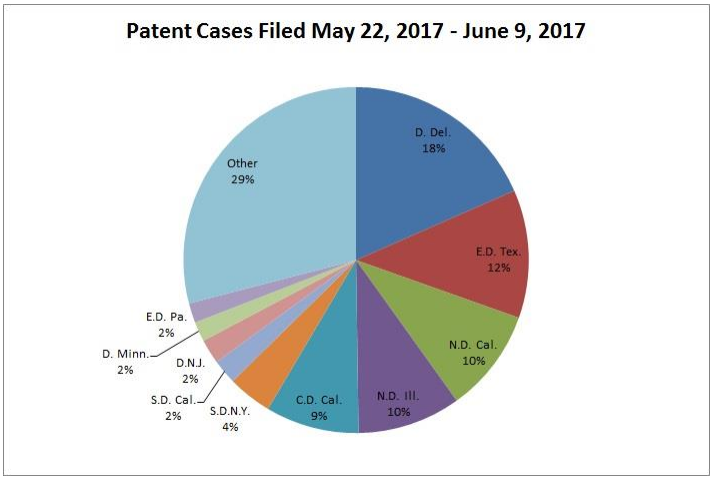
Popular Patent Venues Post-*TC Heartland*



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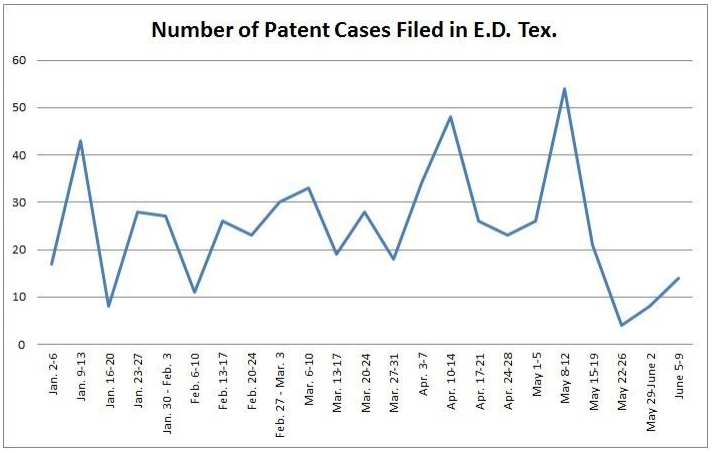
Popular Patent Venues Post-*TC Heartland* – E.D. Texas



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Appendix

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Venue in Patent Cases – Venue <> Jurisdiction

- In a Federal Court case, personal jurisdiction and venue are two separate legal requirements that must be met in order for that case to proceed
- Personal Jurisdiction
  - The personal jurisdiction inquiry asks whether the Court in question has jurisdiction over the parties before it given the parties' connection to the district and actions therein
  - Personal jurisdiction is governed by Supreme Court precedent regarding the bounds of due process under the Constitution and the forum state's long-arm statute
  - Personal jurisdiction will be discussed in more detail later with respect to venue defenses for foreign corporations
- Venue
  - The venue inquiry asks whether the case has been filed in a proper venue according to the statutes governing venue in Federal Court cases
  - Venue in patent cases is governed by statute, specifically 28 U.S.C. §1400.

Venue in Patent Cases – Venue <> Jurisdiction

- Both personal jurisdiction and venue must be challenged by a party at the outset of the case at the pleadings stage
  - Per Fed. R. Civ. P. 12(b)(2) and 12(h), personal jurisdiction over a party can be challenged by a motion or by raising it in a responsive pleading
  - Similarly, per Fed. R. Civ. P. 12(b)(3) and 12(h), venue in a case can be challenged by a motion or by raising it in a responsive pleading
- Failure to challenge personal jurisdiction or venue at the pleadings stage results in waiver of these defenses pursuant to Fed. R. Civ. P. 12(h)(1)
  - However, defendants in currently pending cases that are past the pleadings stage have substantial arguments based on Supreme Court precedent that they could not have waived venue arguments premised on *TC Heartland* because those defenses were not available to them until after *TC Heartland* changed the interpretation of the patent venue statute

Venue in Patent Cases – Patent Venue Pre-*TC Heartland*

- Regarding ***foreign*** corporations, the longstanding venue rule pre-*TC Heartland* was that a foreign corporation could be sued in any district as it was not subject to the residency requirements set forth in § 1400
- This rule was expressly challenged and decided in a Supreme Court case from 1972, *Brunette Machine Works, Ltd. v. Kockum Industries, Inc.*, 406 U.S. 706
- The *Brunette* Court analyzed the longstanding statutes and cases that generally exempted cases involving foreign defendants from the general venue requirements and held that patent cases against foreign defendants fared no different despite the presence of the specific venue statute § 1400:

  "For § 1391(d) is properly regarded, not as a venue restriction at all, but rather as a declaration of the long-established rule that suits against aliens are wholly outside the operation of all the federal venue laws, general and special."

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Non-U.S. Corporations and Personal Jurisdiction (Specific Jurisdiction)

- *J. McIntyre Mach., Ltd. v. Nicastro*, 564 U.S. 873 (2011)
  - Supreme Court (6-3) reversed lower court exercise of specific jurisdiction
  - However, questions still remain
    - Concurring opinion by Breyer and Alito
      - Agreed the lower court judgment should be reversed
      - But, did not believe that the case presented "relevant contemporary commercial circumstances" justifying a new rule of broad application
    - Dissenting opinion by Ginsburg, Sotomayor and Kagan
      - Sufficient minimum contacts existed

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Non-U.S. Corporations and Personal Jurisdiction

- **"Fair play and substantial justice"**
  - **Even if there are minimum contacts with the forum state, the exercise of personal jurisdiction must also not offend "traditional [notions] of fair play and substantial justice"**
  - **Courts will consider other factors as to whether it is reasonable to exercise jurisdiction and non-U.S. corporations can consider whether any of these factors may weigh against the exercise of jurisdiction**
    - **Burden on the Defendant**
    - **Interests of the forum state**
    - **Plaintiff's interest in obtaining relief**
    - **Judicial system's interest in obtaining efficient resolution**

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Thank You

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