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Navigating Venue and Multi-District Litigation in Hatch-Waxman Cases

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Navigating Venue and Multi-District Litigation in Hatch-Waxman Cases

Overview

- Venue in Hatch-Waxman Patent Litigation
  - *TC Heartland* and Patent Venue
  - *Valeant v. Mylan*
  - Impact of *Valeant*
- Use of Multi-District Litigation ("MDL") in Hatch-Waxman Litigation
  - Overview of the MDL Process
  - Considerations for using MDL in Hatch-Waxman

Venue in Hatch-Waxman Patent Litigation

35 U.S.C. § 1400

- "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 *VE Holding Corp. v. Johnson Gas Appliance Co.,* 917 F.2d 1574 (2017), the Federal Circuit held that "resides" was defined by the general venue statute under 28 U.S.C. § 1391(c).
- Under the general venue statute, a corporation "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." 28 U.S.C. § 1391(c).

Venue and Personal Jurisdiction Pre-*TC Heartland*

- Before the 2017 Supreme Court decision in *TC Heartland*, venue for patent litigation was available anywhere the defendant was subject to personal jurisdiction.
- *Acorda Therapeutics Inc. v. Mylan Pharma Inc.*, 817 F.3d 755 (Fed. Cir. 2016).
  - "Minimum contacts is satisfied by ANDA filings because the ANDA filings are closely tied, in purpose and intended effect, to the future sales of the drugs in Delaware."
  - "The other due process factors, such as the burden on the ANDA filer, do not weigh against litigating the cases in Delaware."
- As a practical matter, generic drug companies could usually be sued in Delaware (or other states where generic drugs would be sold).

TC Heartland LLC v. Kraft Foods Grp. Brands LLC, 137 S. Ct. 1514 (2017)

- The law was clarified in *TC Heartland*.
- "As applied to domestic corporations, 'reside[nce]' in § 1400(b) refers only to the State of incorporation."
- Unless the lawsuit is filed in state of incorporation, plaintiff needs to establish that chosen venue is "where the defendant has committed acts of infringement and has a regular and established place of business."
- Supreme Court did not address further the "acts of infringement" or "regular and established place of business" standards.
- Determining "acts of infringement" creates special challenges for Hatch-Waxman litigation because the act of infringement is "artificial" and occurs before the marketing and sale of a generic product.

"Acts of Infringement" in Hatch-Waxman Litigation

- "Any civil action for patent infringement may be brought in the judicial district . . . where the defendant has committed acts of infringement . . . ." 35 U.S.C. § 1400.
- "It shall be an act of infringement to submit an application under section 505(j) . . . or described in section 505(b)(2) . . . ." 35 U.S.C. § 271(e)(2).
  - "Congress' choice of verb tense in the patent venue statute creates an almost impenetrable problem in the particular context of Hatch–Waxman patent litigation." *Bristol-Myers Squibb Co. v. Mylan Pharm. Inc.*, No. CV 17-379-LPS, 2017 WL 3980155, at *6 (D. Del. Sept. 11, 2017)
  - "[T]he temporal focus of the Hatch–Waxman infringement analysis is the future, *not*—as is true in essentially all other patent infringement suits—the past, or even the present." *Id.*

"Acts of Infringement" in Hatch-Waxman Litigation

- Pre-*Valeant*, there was a split among district courts as to whether courts could consider in the venue analysis of Hatch Waxman where the generic product would eventually be sold.
- Delaware and New Jersey: Courts **<u>may</u>** consider where the ANDA filer intends to market its product upon approval
  - "[A]n applicant's submission of an ANDA, in conjunction with other acts the ANDA applicant non-speculatively intends to take if its ANDA receives final FDA approval, plus steps already taken by the applicant indicating its intent to market the ANDA product in this District, must all be considered for venue purposes." *Bristol-Myers,* 2017 WL 3980155, at *13 (D. Del. Sept. 11, 2017)
  - Adopted *BMS* holding that "acts of infringement" include acts "the ANDA applicant non-speculatively intends to take if its ANDA receives final FDA approval, plus steps already taken by the applicant indicating its intent to market the ANDA product in this District." *Celgene Corp. v. Hetero Labs Ltd.,* No. CV-17-3387, 2018 WL 1135334, at *3 (D.N.J. Mar. 2, 2018)

"Acts of Infringement" in Hatch-Waxman Litigation

- Northern District of Texas: Courts may **only** consider where ANDA filer prepared the submission itself.
  - "This Court declines to find that an act of infringement occurs wherever an ANDA filer intends to market the accused product. In determining proper venue in a Hatch-Waxman Act case, it is appropriate to look to the forum where the ANDA submission itself was prepared and submitted." *Galderma L.P. v. Teva Pharm. USA, Inc.*, 290 F. Supp. 3d 599, 608 (N.D. Tex. 2017).
- The forum where the ANDA submission itself was prepared and submitted could be a different location than where the product will eventually be sold.

Valeant Pharm. N. Am. LLC v. Mylan Pharm. Inc., 978 F.3d 1374 (Fed. Cir. 2020)

- Location of Defendants:
  - Defendant Mylan Pharmaceuticals Inc. ("MPI") is a West Virginia corporation with a principal place of business in West Virginia
  - Mylan Inc. is a Pennsylvania corporation with a principal place of business in Pennsylvania
  - Mylan Laboratories Ltd. ("MLL") is an Indian corporation with a principal place of business in Hyderabad, India.
- MPI, a generic drug company, executed an ANDA seeking approval to market a generic version of Julia®. MPI sent the ANDA from its West Virginia corporate office to the FDA, located in White Oak, Maryland.

Valeant Pharm. N. Am. LLC v. Mylan Pharm. Inc., 978 F.3d 1374 (Fed. Cir. 2020)

- "The question we must answer in this appeal, therefore, is whether the act of infringement identified in § 1400(b) occurs only when and where an ANDA-filer submits its ANDA to the FDA or occurs wherever future distribution of the generic is contemplated."
- Judge O'Malley's opinion:
  - "A plain language reading of [§ 271(e)(2)] directs us to the conclusion that it is the submission of the ANDA, and only the submission, that constitutes an act of infringement in this context."
  - "[V]enue is not proper in all judicial districts where a generic product specified in an ANDA is likely to be distributed. It is proper only in those districts that are sufficiently related to the ANDA submission—in those districts where acts occurred that would suffice to categorize those taking them as a 'submitter' under § 271(e)."

Valeant Pharm. N. Am. LLC v. Mylan Pharm. Inc., 978 F.3d 1374 (Fed. Cir. 2020)

- What is "sufficiently related to the ANDA submission"?
  - "[T]he only concrete locations that will ever be touched by a non-hypothetical past act of infringement are those connected to the submission of the ANDA itself."
  - District court suggested that venue may be available in District of Maryland, where FDA received ANDA. "While it may well be that the District of Maryland satisfies the test for venue that we have laid out here, we do not resolve that question."
  - "We also do not define what all relevant acts involved in the preparation and submission of an ANDA might be, leaving those questions for other cases where the precise contours are presented and briefed."
  - "We do agree with the Delaware district court, however, that acts protected by the safe harbor provisions in § 271(e) are non-infringing for all purposes, including venue."
  - Practically, this means venue is not available based solely on where the ANDA filer tested the drug substance or performed bioequivalence studies.

Impact of *Valeant* on Hatch-Waxman Litigation

- Option 1: State where ANDA filer is incorporated
  - Significant number of generic drug companies are incorporated in Delaware or New Jersey (e.g., Apotex, Teva, Dr. Reddy's Laboratories, Cipla, etc.)
  - ANDA filers that are not incorporated in Delaware or New Jersey may nevertheless consent to venue in these jurisdictions
  - Allows their case to be consolidated with those of other ANDA filers.
  - Once consolidated, defendants can pool resources as well as coordinate discovery and other pretrial (and even trial) proceedings.

- Option 2: Where the ANDA filer under took actions connected to the submission of the ANDA itself.
  - Standard unclear, but would likely include corporate office where ANDA was prepared and transmitted.

Impact of *Valeant* on Hatch-Waxman Litigation

- "[W]here issues arise as to jurisdiction or venue, discovery is available to ascertain the facts bearing on such issues." *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 351 n.13 (1978).
- "To show that discovery is warranted, a party must, at a minimum, state a non-frivolous basis for venue and do so with reasonable particularity." Int'l Bus. Machines Corp. v. Expedia, Inc., No. CV 17-1875-LPS-CJB, 2019 WL 3322542, at *3 (D. Del. July 24, 2019).
- Novartis Pharm. Corp. v. Accord Healthcare Inc., No. CV 18-1043-LPS, 2019 WL 2502535, at *4 (D. Del. June 17, 2019)
  - Venue discovery denied based on allegation that Mylan employee lived in Delaware
  - "Novartis does not allege that MPI materials are stored at the Delaware employee's home; that her home is owned, controlled, or otherwise established by MPI; that the employee's employment is conditioned upon residence in Delaware; or that there is anything to stop the employee from moving out of Delaware, at any time she wishes, for any reason (without any threat to her continued employment by MPI)."
- UCB, Inc. v. Mylan Techs., Inc., No. CV 17-322-LPS, 2017 WL 5985559, at *3 (D. Del. Dec. 1, 2017)
  - Allowed venue discovery based on "Plaintiffs' theory—that the 'places' of any Mylan entity, including Mylan affiliates, subsidiaries, parents, or alter egos, may be attributable to the named Mylan Defendants for purposes of venue."

Impact of *Valeant* on Hatch-Waxman Litigation

- Concern that "a generic company may 'game' the system to avoid venue in certain jurisdictions." *Valeant Pharm. N. Am. LLC v. Mylan Pharm. Inc.*, 978 F.3d 1374, 1383 (Fed. Cir. 2020).
- "[B]rand name drug companies may 'be required to file and maintain largely identical suits in multiple districts' causing an increase in time and expense to resolve the cases and 'result[ing] in inconsistent judgments.'" *Id.*
- Risk of increasing the overall duration of litigation, creating inconsistent decisions, or even delaying generic drug entry.
- Consider MDL if it is not possible to obtain venue for all generics in single district.

Use of MDL in Hatch-Waxman Litigation

MDL Overview

28 U.S.C. § 1407(a)

- When civil actions involving one or more common questions of fact are pending in different districts, such actions may be transferred to any district for coordinated or consolidated pretrial proceedings.
- Such transfers shall be made by the judicial panel on multidistrict litigation authorized by this section upon its determination that transfers for such proceedings will be for the convenience of parties and witnesses and will promote the just and efficient conduct of such actions.
- Each action so transferred shall be remanded by the panel at or before the conclusion of such pretrial proceedings to the district from which it was transferred . . .

MDL Overview

Four key aspects of § 1407(a):

- Only available for civil actions involving one or more common questions of fact.
- MDL is only available for cases pending in different districts. The statute does not affect how district courts consolidate cases that are pending in the same district.
- The JPML can transfer the MDL proceedings to *any* district. The statute does not need to be one of the districts where the cases were pending.
- The MDL proceedings are limited to coordinated or consolidated *pretrial* proceedings.

MDL Overview

28 U.S.C. § 1407(d).

- "The judicial panel on multidistrict litigation shall consist of seven circuit and district judges designated from time to time by the Chief Justice of the United States, no two of whom shall be from the same circuit. The concurrence of four members shall be necessary to any action by the panel."
- Current Judges
  - The Hon. Karen K. Caldwell (Chair) (E.D. Ky.)
  - The Hon. Catherine D. Perry (E.D. Mo.)
  - The Hon. Nathaniel M. Gorton (D. Mass)
  - The Hon. Matthew F. Kennelly (N.D. Ill.)
  - The Hon. David C. Norton (D.S.C.)
  - The Hon. Roger Benitez (S.D. Cal.)
  - The Hon. Dale A. Kimball (D. Utah)

MDL Overview

- Panel only makes two decisions: (1) should the cases be transferred, and (2) to which judge/court.
- Panel does not have the power to direct the transferee judge in the exercise of its powers or discretion in pretrial proceedings.
- Panel weighs four factors to determine "convenience of the parties and witnesses and will promote the just and efficient conduct of such actions."
  - Elimination of duplication in discovery
  - Avoidance of conflicting rules and schedules
  - Reduction of litigation costs
  - Conservation of time and effort of the parties, attorneys, witness, and courts

MDL Procedure

28 U.S.C. § 1407(c)

- Proceedings for the transfer of an action under this section may be initiated by--
  - **(i)** the judicial panel on multidistrict litigation upon its own initiative, or
  - **(ii)** motion filed with the panel by a party in any action in which transfer for coordinated or consolidated pretrial proceedings under this section may be appropriate. A copy of such motion shall be filed in the district court in which the moving party's action is pending.

- Hearing on transfer decision shall be held. However, the hearing can be waived by parties *Id.*
- Judge assigned by the JPML. § 1407(b).
- No review of JPML orders, except by extraordinary writ. § 1407(e).

MDL in Hatch-Waxman Litigation

- "Actions involving the validity of complex pharmaceutical patents and the entry of generic versions of the patentholder's drugs are particularly well-suited for transfer under Section 1407." *In re: Alfuzosin Hydrochloride Pat. Litig.*, 560 F. Supp. 2d 1372, 1374 (U.S. Jud. Pan. Mult. Lit. 2008).

- In Hatch Waxman cases, "[c]entralization under Section 1407 will
  - eliminate duplicative discovery,
  - prevent inconsistent pretrial rulings (particularly on claim construction issues), and
  - conserve the resources of the parties, their counsel and the judiciary."

  Id.; see also In re Brimonidine Pat. Litig., 507 F. Supp. 2d 1381, 1381 (J.P.M.L. 2007)

MDL in Hatch-Waxman Litigation

- No minimum number of cases for consolidation
  - Even though only three actions are pending in this litigation, we have long acknowledged that "actions involving the validity of complex pharmaceutical patents and the entry of generic versions of the patent holder's drugs are particularly well-suited for transfer under Section 1407."
  - "Given the complexity of the allegations and regulatory framework governing Hatch-Waxman cases, as well as the need for swift progress in litigation involving the potential entry of generic drugs into the market, placing all actions before a single judge should foster the efficient resolution of all of the actions."

In re Kerydin, 366 F. Supp. 3d at 1371 (2019)

MDL in Hatch-Waxman Litigation

- No minimum number of cases for consolidation:
  - *In re: Armodafinil*, 755 F. Supp. 2d 1360 (J.P.M.L. 2010) (eight actions consolidated)
  - *In re: Alfuzosin Hydrochloride*, 560 F.Supp.2d 1372 (J.P.M.L. 2008) (four actions and one potential tag-along action)
  - *In re Brimonidine*, 507 F. Supp. 2d 1381 (J.P.M.L. 2007) (two actions consolidated)
  - *In re Metoprolol Succinate*, 329 F. Supp. 2d 1368 (J.P.M.L. 2004) (four actions consolidated)

MDL: Location of Transferee Court

- JPML may transfer "to any district."
  - As a practical matter, the JPML will usually transfer proceedings to the district where the majority of underlying cases have been filed, or where the patents have been previously litigated.

Illustrative cases:

- *In re Brimonidine*, 507 F. Supp. 2d 1381 (J.P.M.L. 2007)
  - Two underlying actions pending in the Central District of California and the District of Delaware.
  - MDL transferred to District of Delaware because the court previously managed case involving two of the same five patents.
- *In re Metoprolol Succinate Pat. Litig.,* 329 F. Supp. 2d 1368 (J.P.M.L. 2004)
  - Two Eastern District of Missouri actions and two District of Delaware actions.
  - Transferred to Eastern District of Missouri because the Missouri district is the location of the first-filed action.
- *In re Sitagliptin Phosphate ('708 & '921) Patent Litig.*, 402 F. Supp. 3d 1366 (J.P.M.L. 2019)
  - Fourteen underlying actions in two different districts: Delaware and Northern District of West Virginia.
  - Transferred to Delaware because thirteen cases were pending there.

MDL: Role of Transferee Court

- Manage/control discovery
  - Impose limits on joint depositions, discovery deadlines, etc.
  - Prevent duplicative discovery (e.g. “Defendant Groups collectively may depose each witness offered as an expert by Plaintiff.”)
- Pre-trial rulings (motions for dismissal/summary judgment; *Daubert*; admissibility of evidence, etc.)
- Claim construction
  - Single *Markman* schedule for consolidated cases
  - Transferee court can adopt claim construction for consolidated cases
- Settlement

MDL: Role of Transferee Court

- Absent consent to trial in the transferee court by the generic drug company defendant, the transferee court must remand the case to the original jurisdiction for trial.

- *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 30 (1998)
  - Transferee Court cannot remand case to itself for trial.
  - "§ 1407 not only authorizes the Panel to transfer for coordinated or consolidated pretrial proceedings, but obligates the Panel to remand any pending case to its originating court when, at the latest, those pretrial proceedings have run their course."

Scheduling Considerations

- Earlier judgment can trigger collateral estoppel
- *Biogen Int'l GmbH v. Amneal Pharm. LLC*, 487 F. Supp. 3d 254, 269 (D. Del. 2020)
  - December 2019: Delaware holds bench trial
  - February 2020: Northern District of West Virginia holds bench trial
  - June 18, 2020: Northern District of West Virginia issues opinion invalidating patents *before* Delaware Court
  - Court held that judgment of invalidity rendered in the Northern District of West Virginia applied to Delaware under the principles of collateral estoppel
- Proposed Scheduling Order should consider potential for inconsistent judgments and trial timing.

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Multi-District Litigation ("MDL") Panels Will Play a Larger Role in Hatch-Waxman Litigation After *Valeant*

Stanley E. Fisher & Michael Xun Liu[1]

In *Valeant Pharmaceuticals North America LLC v. Mylan Pharmaceuticals Inc.*, the Federal Circuit clarified venue for Hatch-Waxman cases and addressed a split among district courts on where ANDA filers could be sued after *TC Heartland*.[2] The Supreme Court in *TC Heartland* held that venue in patent infringement is only available where (1) the defendant is incorporated or (2) where it has a regular and established place of business and committed acts of infringement.[3]

In the wake of *TC Heartland*, some district courts held that an ANDA filer commits acts of infringement under 28 U.S.C. § 1400 only where it prepares its ANDA, whereas others reasoned that an ANDA filer commits acts of infringement in any jurisdiction where it intends to distribute the ANDA product.[4] In *Valeant*, the Federal Circuit took the narrower view of "acts of infringement," and held that infringement occurs only where the ANDA filer took actions related to its ANDA submission.[5]

Some commentators have predicted that *Valeant* could further alter the venue landscape of Hatch-Waxman litigation.[6] In particular, there is concern that, because generic companies prepare ANDAs in different locations, branded pharmaceutical companies will now be faced with the future prospect of litigating patents covering the same drug in a greater number of courts across the country, which could in turn increase the overall duration of litigation, risk inconsistent decisions, or even delay generic drug entry.[7]

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[2] *Valeant Pharm. N. Am. LLC v. Mylan Pharm. Inc.*, 978 F.3d 1374, 1384 (Fed. Cir. 2020).

[3] *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514, 1517 (2017).

[4] *See Valeant*, 978 F.3d at 1380–81 (discussing district court opinions).

[5] *Id.* at 1384.

[6] Ryan Davis, *Fed. Circ. Ruling May Reshape Hatch-Waxman Litigation Map*, LAW360 (Nov. 17, 2020, 8:40 PM), https://www.law360.com/ip/articles/1329940/fed-circ-ruling-may-reshape-hatch-waxman-litigation-map?spotlight=1; Zachary Silbersher, *How will the CAFC's Valeant v. Mylan venue case change the landscape of pharmaceutical patent litigation?*, MARKMAN ADVISORS (Nov. 9, 2020), https://www.markmanadvisors.com/blog/2020/11/9/how-will-the-cafcs-valeant-v-mylan-venue-case-change-the-landscape-of-pharmaceutical-patent-litigation; Alex Menchaca, *Federal Circuit Dramatically Narrows Scope of Proper Venue in Paragraph IV Litigation*, ORANGE BOOK BLOG (Nov. 11, 2020), https://www.orangebookblog.com/2020/11/federal-circuit-dramatically-narrows-scope-of-proper-venue-in-paragraph-iv-litigation.html.

[7] *Id.*

While the impact of *Valeant* may take time to realize, this decision need not herald a dramatic change in Hatch-Waxman litigation. A significant portion of Hatch-Waxman cases can remain in Delaware and New Jersey, where many generic pharmaceutical companies are incorporated. And in cases with large numbers of ANDA filers (and some generic filers located outside those venues), pre-trial consolidation through multi-district litigation (MDL) can reduce the risk of inconsistent decisions and streamline litigation across jurisdictions. Before and after *TC Heartland*, the MDL process has been used in numerous proceedings, including by these authors, to streamline pre-trial proceedings.[8] And it will remain a useful tool in the post-*Valeant* world.

Hatch-Waxman Cases will Continue to be Filed in Delaware or New Jersey

After *Valeant*, generic drug companies will continue to be subject to suit in their states of incorporation, regardless of where they prepared the ANDA. For the significant number of generic drug companies incorporated in Delaware or New Jersey, *Valeant* is unlikely to change where they will face ANDA suits.

Likewise, ANDA filers that are not incorporated in Delaware or New Jersey may nevertheless consent to venue in these jurisdictions. This allows their case to be consolidated with those of other ANDA filers. And once consolidated, defendants can pool resources as well as coordinate discovery and other pretrial (and even trial) proceedings. Generic drug companies who are not the first-filer, or in situations with multiple first-filers, may be particularly inclined to consent to a venue where there are other defendants. Without the promise of a 180-day regulatory exclusivity, these ANDA filers often have less incentive to shoulder the entire burden of litigating contested issues of infringement, validity, or enforceability in another jurisdiction, before a different judge, and on a separate schedule.

Risk of Delay and Inconsistent Decisions are Mitigated by MDL Process

In cases where there are multiple ANDA filers, at least one of whom is not subject to venue in Delaware or New Jersey, branded pharmaceutical companies can also rely on MDL to consolidate pre-trial proceedings. As a general matter, the Judicial Patent on Multidistrict Litigation (JPML) will consolidate pretrial proceedings if there are civil actions involving one or more common questions of fact, and doing so would be "for the convenience of parties and witnesses and will promote the just and efficient conduct of such actions."[9]

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[8] *See, e.g.*, *In re Palbociclib Patent Litig.*, 396 F. Supp. 3d 1360 (J.P.M.L. 2019) (mem.); *In re Sitagliptin Phosphate ('708 & '921) Patent Litig.*, 402 F. Supp. 3d 1366 (J.P.M.L. 2019) (mem.); *In re Kerydin (Tavaborole) Topical Sol. 5% Patent Litig.*, 366 F. Supp. 3d 1370 (J.P.M.L. 2019); *In re: Armodafinil Patent Litig.*, 755 F. Supp. 2d 1359 (J.P.M.L. 2010) (mem.); *In re: Alfuzosin Hydrochloride Patent Litig.*, 560 F. Supp. 2d 1372 (J.P.M.L. 2008); *Allergan, Inc. v. Exela Pharmsci, Inc. (In re Brimonidine Patent Litig.)*, 507 F. Supp. 2d 1381 (J.P.M.L. 2007); *AstraZeneca AB v. Andrx Pharms., LLC) In re Metoprolol Succinate Patent Litig.*, 329 F. Supp. 2d 1368 (J.P.M.L. 2004).

[9] 28 U.S.C. § 1407(a).

The JPML has specifically recognized that Hatch-Waxman cases "are particularly well-suited for transfer under Section 1407."[10] As a result, even before *TC Heartland*, Hatch-Waxman litigants relied on MDL to consolidate pre-trial proceedings.[11]

Moreover, although MDL is often associated with class action litigation (mass torts, antitrust, etc.) involving a large number of underlying cases, the process can also be used to consolidate as few as two underlying actions.[12] As the JPML recently explained, even when there are only several underlying actions, "given the complexity of the allegations and regulatory framework governing Hatch-Waxman cases, as well as the need for swift progress in litigation involving the potential entry of generic drugs into the market, placing all actions before a single judge should foster the efficient resolution of all of the actions."[13]

Delaware and New Jersey Courts are Likely to Play Key Role in Hatch-Waxman MDL

After the JPML consolidates the underlying actions, it also selects a transferee court to manage pretrial proceedings. By statute, the JPML can transfer the consolidated case to "any district."[14] As a practical matter, however, the JPML will usually transfer proceedings to the district where the majority of underlying cases have been filed,[15] or where the patents have been previously litigated.[16] In many cases, this will be Delaware or New Jersey, since a majority of generic drug companies are incorporated there.[17] Accordingly, Delaware and New Jersey courts will continue to play a key role in Hatch-Waxman litigation in many cases.

At the end of the MDL process, absent consent to trial in the transferee court by the generic drug company defendant, the transferee court must remand the case to the original jurisdiction for trial. This certainly creates some risk for inconsistent decisions. The risk, however, is mitigated by the fact that the transferee court will have already resolved pretrial proceedings, including potentially case dispositive issues like claim construction.

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[10] *In re Alfuzosin Hydrochloride Patent Litig.*, 560 F. Supp. 2d at 1374.
[11] *In re Armodafinil Patent Litig.*, 755 F. Supp. 2d 1360; *In re Alfuzosin Hydrochloride Patent Litig.*, 560 F. Supp. 2d 1372; *In re Brimonidine Patent Litig.*, 507 F. Supp. 2d 1381; *In re Metoprolol Succinate Patent Litig.*, 329 F. Supp. 2d 1368.
[12] *In re Brimonidine Patent Litig.*, 507 F. Supp. 2d 1381; *In re Metoprolol Succinate Patent Litig.*, 329 F. Supp. 2d 1368.
[13] *In re Kerydin(Tavaborole) Topical Sol. 5% Patent Litig.*, 366 F. Supp. 3d at 1371 (rejecting argument that three underlying actions are too few to justify centralization)
[14] 28 U.S.C. § 1407.
[15] *In re Palbociclib Patent Litig.*, 396 F. Supp. 3d at 1361; *In re Kerydin (Tavaborole) Topical Sol. 5% Patent Litig.*, 366 F. Supp. 3d at 1372; *In re Armodafinil*, 755 F. Supp. 2d at 1360; *In re: Alfuzosin*, 560 F.Supp.2d at 1372.
[16] *In re Brimonidine Patent Litig.*, 507 F. Supp. 2d at 1382.
[17] *In re Palbociclib Patent Litig.*, 396 F. Supp. 3d at 1361; *In re Kerydin (Tavaborole) Topical Sol. 5% Patent Litig.*, 366 F. Supp. 3d at 1372; *In re Armodafinil Patent Litig.*, 755 F. Supp. 2d at 1360; *In re: Alfuzosin Hydrochloride Patent Litig.*, 560 F. Supp. 2d at 1372; *In re Brimonidine Patent Litig.*, 507 F. Supp. 2d at 1382.

The transferee court will also conduct trials over any actions originally filed in its jurisdiction or if the defendant has consented to trial in the transferee court. In MDL with a large number of underlying cases, such as mass tort litigation, the transferee court will often select one or more cases for bellwether trials to resolve common issues or promote settlement.[18] Although Hatch-Waxman litigation typically do not involve selecting a bellwether case for trial, the results of a trial in the transferee court can still narrow the issues for subsequent trials or at least inform other courts and parties about the strengths and weakness of their relative positions and thus promote settlement.

Finally, it has been these authors' experiences that the trial court in the original jurisdiction can sequence trial proceedings such that the trial court may benefit from a prior ruling on common issues in the transferee court.[19] In at least one recent MDL, however, the transferee court in Delaware remanded an underlying action to West Virginia for trial.[20] Although the West Virginia court held trial after the Delaware court did, it nonetheless issued a decision invalidating the patents first.[21] As a result, the Delaware court held the patentee was collaterally estopped from litigating the validity of those patents.[22] The conduct of two validity trials in parallel, with a race to a decision, does not promote judicial efficiency. It is hoped that the parties can work together, with the courts in the various jurisdictions, to sequence validity trials in an efficient manner, in the future.

Valeant resolves an important and unsettled question about venue in Hatch-Waxman cases. At the same time, it also raises questions about what constitutes "actions related to the ANDA submission."[23] But *Valeant* is unlikely to dramatically alter the landscape of Hatch-Waxman litigation..

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[18] *See In re Chevron U.S.A., Inc.*, 109 F.3d 1016, 1019 (5th Cir. 1997) (discussing Bellwether selection process).
[19] *See Merck Sharp & Dohme Corp. v. Mylan Pharm. Inc.*, C.A. No. 1:19-cv-101 (N.D.W.V. Aug. 2, 2019).
[20] *Biogen Int'l GmbH v. Amneal Pharms. LLC*, No. 17-823 (MN), 2020 WL 5549084, at *2 (D. Del. Sept. 16, 2020).
[21] *Id.* at *1–2.
[22] *Id.* at *11.
[23] *Valeant*, 978 F.3d at 1381.