No. 19-2402

United States Court of Appeals for the Federal Circuit

VALEANT PHARMACEUTICALS NORTH AMERICA LLC, VALEANT PHARMACEUTICALS IRELAND LTD., DOW PHARMACEUTICAL SCIENCES, INC., and KAKEN PHARMACEUTICAL CO., LTD.,

Plaintiffs – Appellants,

v.

MYLAN PHARMACEUTICALS, INC., MYLAN LABORATORIES LTD., and MYLAN INC.,

Defendants – Appellees.

Appeal from the United States District Court for the District of New Jersey
Case No. 3:18-cv-14305, Judge Peter G. Sheridan

PLAINTIFFS-APPELLANTS' PETITION FOR REHEARING EN BANC

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AMENDED CERTIFICATES OF INTEREST

Counsel for plaintiffs-appellants Valeant Pharmaceuticals North America LLC, Valeant Pharmaceuticals Ireland, Ltd., Dow Pharmaceutical Sciences, Inc., certifies the following:

1. The full name of every party or amicus represented by me is:

Valeant Pharmaceuticals North America LLC, Valeant Pharmaceuticals Ireland, Ltd., Dow Pharmaceutical Sciences, Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

Bausch Health US, LLC, Bausch Health Ireland Ltd., Bausch Health Americas, Inc.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

Bausch Health Companies, Inc.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by the undersigned counsel in the trial court or agency or are expected to appear in this court (and who have not or will not enter an appearance in this case) are:

McDermott Will & Emery LLP: Thomas P. Steindler, Nicole M. Jantzi, Paul M. Schoenhard, Ian B. Brooks, Christopher M. Bruno

Gibbons P.C.: William P. Deni, Jr., Charles H. Chevalier, J. Brugh Lower

5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. *See* Fed. Cir. R. 47.4(a)(5) and 47.5(b):

Valeant Pharmaceuticals North America LLC, et al. v. Zydus Pharmaceuticals (USA) Inc., et al., ("In re Jublia"), Civil Action No. 18-cv-13635 (BRM)(LHG)(D.N.J.)

Bausch Health US, LLC et al. v. Mylan Pharmaceuticals Inc., et al., Civil Action No. 20-cv-02749 (D.N.J.)

Valeant Pharmaceuticals North America LLC, et al. v. Mylan Pharmaceuticals, Inc., et al., Civil Action Nos. 18-cv-184, 19-cv-37 (N.D.W.V.)

Bausch Health US, LLC et al. v. Mylan Pharmaceuticals Inc., Civil Action No. 20-cv-46 (N.D.W.V.)

Dated: December 7, 2020

/s/ Thomas P. Steindler
Thomas P. Steindler

Counsel for plaintiff-appellant Kaken Pharmaceutical Co. Ltd. certifies the following:

1. The full name of every party or amicus represented by me is:

Kaken Pharmaceutical Co., Ltd.

2. The name of the real party in interest (other than those identified in Question 3) represented by me is:

None.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

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4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court (and who have not or will not enter an appearance in this case) are:

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5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal.

Valeant Pharmaceuticals North America LLC, et al. v. Zydus Pharmaceuticals (USA) Inc., et al., ("In re Jublia"), Civil Action No. 18-cv-13635 (BRM)(LHG)(D.N.J.)

Bausch Health US, LLC et al. v. Mylan Pharmaceuticals Inc., et al., Civil Action No. 20-cv-02749 (D.N.J.)

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Bausch Health US, LLC et al. v. Mylan Pharmaceuticals Inc., Civil Action No. 20-cv-46 (N.D.W.V.)

Dated: December 7, 2020

/s/ John D. Livingstone
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STATEMENT OF COUNSEL PURSUANT TO FED. CIR. R. 35(B)(2)

Based on my professional judgment, I believe the panel decision is contrary to the following decisions of this Court: *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997); *Bayer AG v. Elan Pharmaceutical Research Corp.*, 212 F.3d 1241 (Fed. Cir. 2000); *Warner Lambert Co. v. Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003). It is also inconsistent with the Court's rulings in *North American Philips Corp. v. American Vending Sales, Inc.*, 35 F.3d 1576 (Fed. Cir. 1994); *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Contractors USA, Inc*., 617 F.3d 1296 (Fed. Cir. 2010).

Further, based on my professional judgment, I believe this appeal presents the following precedent-setting question of exceptional importance:

Whether a generic drug manufacturer "has committed acts of infringement" under 28 U.S.C. § 1400(b) in a judicial district by submitting an Abbreviated New Drug Application ("ANDA") seeking approval to market an infringing generic drug throughout the United States, including in that judicial district.

/s/ Thomas P. Steindler
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Attorney of Record for
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INTRODUCTION

This case involves a question of first impression—where acts of infringement occur under 35 U.S.C. § 271(e)(2) for purposes of venue.

For decades, federal courts have recognized that the act of infringement defined in § 271(e)(2) includes the intended acts of making, using, and selling the infringing generic product described in an ANDA. Thus, the act of infringement actually adjudicated in Hatch-Waxman cases is whether the intended acts of marketing the generic product would infringe a valid patent. Those acts, of course, will occur nationwide.

The panel opinion here departs from this long-settled proposition and the clear statutory language which supports this construction, to ascribe a separate, limited meaning to the § 271(e)(2) act of infringement for purposes of venue that narrowly includes only submission of the ANDA. The panel concludes that "infringement occurs for venue purposes only in districts where actions related to the submission of an Abbreviated New Drug Application ('ANDA') occur, not in all locations where future distribution of the generic products specified in the ANDA is contemplated." Panel Op. at 3. The panel's ruling is legal error that departs from this Court's long-standing precedents regarding both what is included in the § 271(e)(2) act of infringement and where acts of infringement occur.

The panel's opinion, if left untouched, would effect a detrimental and seismic shift in Hatch-Waxman pharmaceutical patent litigation that will increase uncertainty, delay,

and costs, all at the expense of judicial economy. Since the inception of the Hatch-Waxman Act, branded manufacturers facing multiple generic challenges related to the same drug have normally sued all the generics in a single forum, where such cases are consolidated for pretrial and trial. This produces substantial efficiencies, especially in a case like this one, where nineteen companies sought generic marketing approval. Brand manufacturers receive the benefit of efficiencies gained in litigating the validity of their patents in one case, rather than nineteen. Generic manufacturers typically pool resources and share strategy in joint defense groups, decreasing the costs of litigation (and thus entry when the group is successful) for any individual company. And rather than burden numerous courts around the country, typically just one court's resources are used to resolve what is effectively a single dispute.

Not so anymore. Under the panel's opinion, whether a generic's submission of its marketing application constitutes an act of infringement for venue purposes turns on where a regulatory employee or a consultant hits "Submit" (or perhaps, prepares an ANDA submission, *see* panel Op. at 19 n.8)—a fact that a brand manufacturer will typically have no pre-suit knowledge of. At best, this wastes time with venue-based discovery, transfers, mandamus petitions, and collateral litigation—all of which cuts into the 30-month stay on generic application approval. At worst, it requires both brands and generics to devote resources needlessly to lawsuits around the country where one would suffice.

This all makes no sense. The panel recognized as much when it concluded that "a generic company may 'game' the system to avoid venue in certain jurisdictions" and that "brand 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." Panel Op. at 17 (citations and internal quotation marks omitted). This cannot be what Congress intended when it created the Hatch-Waxman scheme with a goal of expediting resolution of drug patent infringement lawsuits. Nor is this what the plain statutory language requires. Before throwing an entire segment of cases into disarray, the full Court should consider whether such a drastic sea change is truly warranted. It isn't.

For the past 36 years, the act of infringement federal courts have adjudicated under § 271(e)(2) is not whether an ANDA has been filed, but rather whether the intended acts of making, using and selling the generic product for which the ANDA was submitted would infringe a valid patent. If the intended acts are found to infringe a valid patent, 35 U.S.C. § 271(e)(4)(A) provides that the ANDA cannot be approved until the expiration of the patent "which *has been infringed*." Further emphasizing that the act of infringement has already occurred, 35 U.S.C. §§ 271(e)(4)(B) and (C) provide injunctive relief and damages "against an infringer," not a "prospective infringer" or "future infringer."

Congress's use of the past tense to describe the infringement makes clear that the intended acts of making, using and selling the generic product—which *are* the acts of infringement adjudicated in ANDA cases—are deemed part of the § 271(e)(2) act of infringement. They are treated as having occurred *nunc pro tunc* with the submission of the ANDA, even though they have not yet actually occurred. That is precisely why the Supreme Court described § 271(e)(2) as a "highly artificial act of infringement" in *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 676, 678 (1990).

Nonetheless, the panel opinion in this case has now defined the § 271(e)(2) act of infringement differently for venue purposes, divorcing the ministerial act of submitting the ANDA from the purpose of such submission—the intended acts of marketing the generic product on a nationwide basis.

By so limiting the § 271(e)(2) act of infringement, the panel created a special, narrow meaning for venue purposes, contrary to both the language of the statute and three decades of this Court's jurisprudence holding that the act of infringement adjudicated in ANDA cases is *not* limited to the submission of the ANDA. *E.g., Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1570 (Fed. Cir. 1997) ("the patentee's burden of proving ultimate infringement is not met by the filing of the ANDA"). It is also inconsistent with this Court's prior rulings as to *where* acts of infringement occur.

The panel's failure to account for the statute's use of the past tense in § 271(e)(4) to describe the infringement and even to mention *Glaxo* reflects a lack of recognition both

of the mistake the panel made and the resulting conflicts it created. Those conflicts must be resolved. The full Court should hear this case to correct the panel's error.

ARGUMENT

I. The Panel Decision Conflicts With Precedent Regarding *What* the Act of Infringement is Under Section 271(e)(2)

The panel decision holds "that it is the submission of the ANDA, and only the submission, that constitutes an act of infringement in this context." Panel Op. at 14; *see also id.* ("submission of the ANDA *is* the infringing act" (emphasis in original)). This narrow reading of the § 271(e)(2) act of infringement disregards the "purpose" language of § 271(e)(2), the text of § 271(e)(4), and this Court's precedents regarding *what* the act of infringement is under § 271(e)(2)—all of which treat infringement of a patent by the future acts of making, using and selling the generic product as having happened in the past with the submission of the ANDA.

On its face, § 271(e)(2)(A) makes it "an act of infringement to submit . . . [an ANDA or 505(b)(2) application] . . . for a drug claimed in a patent or the use of which is claimed in a patent . . . ***if the purpose of such submission*** *is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent*." The "purpose" language identifies the acts that actually form the basis for the infringement analysis in Hatch-Waxman cases—"whether, if a particular drug were put

on the market, it would infringe the relevant patent." *Bristol-Myers Squibb Co. v. Royce Labs, Inc.*, 69 F.3d 1130, 1135 (Fed. Cir. 1995).

As this Court explained in *Glaxo, Inc. v. Novopharm, Ltd.*, "[t]he statute refers to the question whether *the purpose of the ANDA* is to engage in the commercial manufacture, use, or sale of the patented drug. We conclude that . . . the statute requires an infringement inquiry focused on what is likely to be sold following FDA approval." 110 F.3d at 1568 (emphasis added). And as the Court wrote in *Warner-Lambert Co. v. Apotex Corp.*, "it is abundantly clear that the statute does not make the filing of an ANDA prior to patent expiration an act of infringement unless the ANDA seeks approval to manufacture, use, or sell the drug prior to expiration of a patent that would otherwise be infringed by such manufacture, use, or sale, apart from the provisions of § 271(e)(2)." 316 F.3d 1348, 1355–56 (Fed. Cir. 2003).

Thus, this Court has consistently recognized that the "purpose" language of § 271(e)(2) is an integral part of the defined act of infringement and requires the infringement inquiry in Hatch-Waxman cases to include—indeed, to focus on—the future acts for which approval is sought.

These decisions are consistent with the Supreme Court's explanation of the act of infringement defined in § 271(e)(2) in *Eli Lilly and Co. v. Medtronic, Inc.:*

> This scheme will not work, of course, if the holder of the patent pertaining to the pioneer drug is disabled from establishing in court that there has been an act of infringement. And that was precisely the disability that the new 35

> U.S.C. § 271(e)(1) imposed with regard to use of his patented invention only for the purpose of obtaining premarketing approval. Thus, an act of infringement had to be created for these ANDA and paper NDA proceedings. That is what is achieved by § 271(e)(2)—the creation of a highly artificial act of infringement that consists of submitting an ANDA or a paper NDA containing the fourth type of certification that is in error as to whether commercial manufacture, use, or sale of the new drug (none of which, of course, has actually occurred) violates the relevant patent. Not only is the defined act of infringement artificial, so are the specified consequences, as set forth in subsection (e)(4). Monetary damages are permitted only if there has been "commercial manufacture, use, or sale." § 271(e)(4)(C). Quite obviously, the purpose of subsections (e)(2) and (e)(4) is to enable the judicial adjudication upon which the ANDA and paper NDA schemes depend.

496 U.S. at 678. As the Court explained, it was necessary to create this "highly artificial act of infringement" to establish that "there has been an act of infringement." The Supreme Court clearly recognized Congress's intent that this "highly artificial act" function as a proxy for the intended acts of making, using, and selling the generic product. This function is not performed if, as the panel decision suggests, the intended traditionally infringing acts that are adjudicated in Hatch-Waxman litigation are treated solely as future acts.

Both in theory and in practice, courts have universally treated the future acts for which approval is sought in an ANDA as being part of the completed act of infringement defined under § 271(e)(2).

As confirmed in *Eli Lilly* (quoted above), this reading is supported by the text of § 271(e)(4), which prescribes remedies available upon a finding of infringement under

§ 271(e)(2) in Hatch-Waxman cases. Section 271(e)(4) provides, in pertinent part, as follows:

> (4) For an act of infringement described in paragraph (2)—
>
> (A) the court shall order the effective date of any approval of the drug . . . involved in the infringement to be a date which is not earlier than the date of the expiration of the patent ***which has been infringed***.
>
> (B) injunctive relief may be granted ***against an infringer*** to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug . . .
>
> (C) 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 an approved drug . . .

35 U.S.C. § 271(e)(4).

The bolded text of § 271(e)(4) makes clear that Congress intended to treat the proposed acts of making, using, and selling the generic product as having been committed *in the past* with the submission of the ANDA. Under §§ 271(e)(4)(B) and (C), a generic company found liable for infringement in a Hatch-Waxman case based on such proposed future acts is described as "an infringer," not a "prospective infringer" or "future infringer." In addition, the delay in approval prescribed by § 271(e)(4)(A) is tied to the expiration date of "the patent ***which has been infringed***."

The panel ignores the text of § 271(e)(4) entirely in its opinion, only summarily stating that "[t]he content of the litigation does not, however, turn potential future acts

into past infringement." *Id*. at 15. But the "content of the litigation" *does* turn acts into past infringement, as confirmed by § 271(e)(4). In fact, the statute's use of the past tense eliminates any doubt that Congress intended to treat the intended acts of making, using and selling the drug—which form the basis for a finding of infringement—as having already been committed with the submission of the ANDA, even though they have not yet actually occurred. Indeed, as the panel decision recognizes, in most Hatch-Waxman cases there will *never* be a conventional act of infringement. Panel Op. at 15 ("The result of virtually all Hatch-Waxman litigation is, moreover, that no post-submission infringement happens.").

The act of infringement defined in § 271(e)(2) is properly construed—and has consistently been so construed—as a completed act as of the time of submission of an ANDA, with such act including *nunc pro tunc* the intended future acts of making, using, and selling the drug for the purpose of which the ANDA was submitted.

Until the panel decision, this Court has consistently rejected efforts to limit the act of infringement under § 271(e)(2) solely to "the submission of the ANDA," as the panel decision now does. In *Glaxo, Inc.*, the Court stated simply: "*[T]he patentee's burden of proving ultimate infringement is not met by the filing of the ANDA.*" 110 F.3d at 1570 (emphasis added). And the Court explained in *Warner-Lambert Co.*: "[I]t is abundantly clear that *the statute does not make the filing of an ANDA prior to patent expiration an act of infringement* ***unless*** the ANDA seeks approval to manufacture, use, or sell the drug

prior to expiration of a patent that would otherwise be infringed by such manufacture, use, or sale, apart from the provisions of § 271(e)(2)." 316 F.3d at 1355–56 (Fed. Cir. 2003) (emphasis added); *see also Zeneca Ltd. v. Mylan Pharms., Inc.*, 173 F.3d 829, 832 (Fed. Cir. 1999) (Gajarsa, J.) ("The purpose of the Hatch-Waxman Act was not to transform FDA filings into torts . . .").

The submission of an ANDA cannot be separated from its purpose. The act of infringement defined in § 271(e)(2) is *not* only the submission of an ANDA, as the panel decision wrongly held, but rather is the submission of an ANDA "if the purpose of such submission" is to engage in certain future acts that Congress clearly intended the courts to treat as if they have already occurred. *E.g.*, *Glaxo*, 110 F.3d at 1569 (referring to "[t]his future aspect of the potential infringement").

There is no reason the Court should diverge from that well-settled approach here, simply because, once properly construed, the "act of infringement" defined in § 271(e)(2) is to be applied for purposes of the venue statute. The panel decision is wrong.

II. The Panel Decision Conflicts With This Court's Precedents Regarding *Where* the Act of Infringement Occurs Under Section 271(e)(2)

Relying on its narrow view of *what* the act of infringement is under § 271(e)(2), the panel decision "conclude[s] that, in cases brought under 35 U.S.C. § 271(e)(2)(A), infringement occurs for venue purposes only in districts where actions related to the submission of an Abbreviated New Drug Application ('ANDA') occur." Panel Op. at 3.

The panel's conclusion is inconsistent with this Court's precedents regarding *where* acts of infringement occur.

As the panel noted, this Court has held that traditional acts of infringement ("sale" and "offer for sale") that have both a physical and a conceptual dimension occur in locations where they are purposefully directed. Panel Op. 11 n.7.

In *North American Philips Corp. v. American Vending Sales, Inc.*, 35 F.3d 1576, 1579 (Fed. Cir. 1994), the court held that an infringing "sale" may occur at the location of the buyer. *See also Litecubes, LLC v. N. Light Prods., Inc*. 523 F.3d 1353, 1369–70 (Fed. Cir. 2008) (same). In *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Contractors USA, Inc*., 617 F.3d 1296, 1310 (Fed. Cir. 2010), the Court held that a contract for sale constitutes a "sale" under § 271(a) and that such "sale" occurs at the location of the anticipated performance. The Court also held that an "offer for sale" occurs at "the location of the future sale that would occur pursuant to the offer." *Id*. at 1309.

Here, the § 271(e)(2) act of infringement also has both a physical dimension (the submission of an ANDA) and a conceptual dimension (the intended nationwide marketing and sale of a generic drug). As this Court held in *Acorda Therapeutics Inc. v. Mylan Pharms., Inc*., an ANDA is purposefully directed nationwide. 817 F.3d 755, 759-60 (Fed. Cir. 2016) (emphasizing the "purpose" language of § 271(e)(2)).

Thus, consistent with this Court's decisions related to *where* traditional acts of infringement occur, the § 271(e)(2) act of infringement is properly understood to occur in the locations to which the ANDA is purposefully directed, *viz*. nationwide.

The panel opinion seeks to distinguish these cases involving traditional acts of infringement on grounds that "the conceptual elements in those cases were connected to common law understandings of 'sales' and 'offers for sale'" and that "[t]here is no analogous common law here that would compel a conclusion that submitting an ANDA has a purely conceptual effect of causing infringement *everywhere* in the United States. To reach such a broad interpretation of the infringing act, ***without any textual hook in the statute***, would be a bridge too far." Panel Op. at 17 (bold emphasis added).

Of course there is no "analogous common law here," because § 271(e)(2) is defined by statute without common law underpinnings. But contrary to the panel's assertion, there is a specific "textual hook in the statute," namely § 271(e)(2)'s prescription that the submission of the ANDA is an act of infringement only "if the purpose of such submission is to obtain approval" to market an infringing product. By ignoring the "purpose" language of § 271(e)(2), the panel improperly disregarded the "conceptual dimension" of the act of infringement. Properly considered, that "conceptual dimension" is consistent with traditional act of infringement cases and requires that where the ANDA filer seeks approval to sell its generic drugs throughout the United States, the act of infringement occurs nationwide.

Finally, although the panel decision expressly leaves open the question "what all relevant acts involved in the preparation and submission of an ANDA might be," Panel Op. at 19 n.8, the ambiguities and logical consequences of the panel decision are far-reaching and fraught with uncertainty. For example, the panel does not address how the location of "submission" is to be determined. Is it where the computer used to submit the ANDA is located? Does it include the locations of employees or consultants who assisted in the preparation of the ANDA? Does the process start further upstream, where executive approval is given? Such purely ministerial (and readily manipulated) acts are certainly not the relevant acts of infringement defined by § 271(e)(2), which is concerned not with where acts related to the submission of the ANDA occur but where generic drugs will be marketed and sold.

Ultimately, Judge O'Malley provided the clearest articulation of the (correct) conclusion to the question of where the act of infringement under § 271(e)(2) occurs in concurrence in *Acorda*: "The act of infringement, which the Supreme Court has called 'highly artificial,' is nevertheless a defined and very real act of infringement that takes place wherever the ANDA filer seeks to market its product." 817 F.3d at 772 n.2 (O'Malley, J., concurring) (citation omitted, emphasis added). The panel's contrary decision here is wrong.

CONCLUSION

The petition for rehearing *en banc* should be granted.

DATE: December 7, 2020

Respectfully submitted,

/s/ Thomas P. Steindler

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Addendum

United States Court of Appeals for the Federal Circuit

VALEANT PHARMACEUTICALS NORTH AMERICA LLC, VALEANT PHARMACEUTICALS IRELAND LTD., DOW PHARMACEUTICAL SCIENCES, INC., KAKEN PHARMACEUTICAL CO., LTD.,
Plaintiffs-Appellants

v.

MYLAN PHARMACEUTICALS INC., MYLAN LABORATORIES LTD., MYLAN INC.,
Defendants-Appellees

2019-2402

Appeal from the United States District Court for the District of New Jersey in No. 3:18-cv-14305-PGS-LHG, Senior Judge Peter G. Sheridan.

Decided: November 5, 2020

THOMAS P. STEINDLER, McDermott, Will & Emery LLP, Washington, DC, argued for all plaintiffs-appellants. Plaintiffs-appellants Valeant Pharmaceuticals North America LLC, Valeant Pharmaceuticals Ireland Ltd., Dow Pharmaceutical Sciences, Inc. also represented by IAN BARNETT BROOKS, CHRISTOPHER MICHAEL BRUNO, PAUL MICHAEL SCHOENHARD; CHARLES H. CHEVALIER, Gibbons P.C., Newark, NJ.

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STEFFEN NATHANAEL JOHNSON, Wilson Sonsini Goodrich & Rosati, Washington, DC, argued for defendants-appellees. Also represented by ADAM WILLIAM BURROWBRIDGE; WENDY L. DEVINE, KRISTINA M. HANSON, TUNG ON KONG, San Francisco, CA.

Before NEWMAN, O'MALLEY, and TARANTO, *Circuit Judges*.

O'MALLEY, *Circuit Judge*.

In 2017, the Supreme Court dramatically changed the venue landscape in patent cases. *See TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514 (2017). It held that the general venue provision in 28 U.S.C. § 1391—which provides that a corporation is deemed to "reside" in any judicial district in which it is subject to personal jurisdiction—does not modify the term "resides" in 28 U.S.C. § 1400, the more specific venue statute applicable to patent cases. Specifically, it held that "resides" in § 1400(b) refers only to a corporation's state of incorporation. That means that a corporation may be sued for patent infringement in only two categories of judicial districts: those in the state in which it is incorporated and those in which it has a regular and established place of business and an act of infringement has occurred. *TC Heartland* raised more questions than it answered; we and district courts around the country have been working through those questions since 2017. Today we tackle one more.

Today we answer the question of where "acts of infringement" under § 1400(b) occur with respect to

infringement claims brought pursuant to the Hatch-Waxman Act.[1] We conclude that, in cases brought under 35 U.S.C. § 271(e)(2)(A), infringement occurs for venue purposes only in districts where actions related to the submission of an Abbreviated New Drug Application ("ANDA") occur, not in all locations where future distribution of the generic products specified in the ANDA is contemplated.

Given this conclusion, we affirm the district court's order dismissing the claims against the two U.S.-based defendants pursuant to Rule 12(b)(3) of the Federal Rules of Civil Procedure for improper venue. *See Valeant Pharms. N. Am. LLC v. Zydus Pharms. (USA) Inc.*, No. 18-cv-13635-PGS-LHG, 2019 WL 4179832 (D.N.J. Aug. 14, 2019). For the reasons explained below, however, we vacate and remand the portion of the court's order dismissing the action against the foreign defendant—as to which venue was unquestionably proper—pursuant to Rule 12(b)(6), because the court failed to address the substance of that motion.

I. BACKGROUND

Because this appeal is primarily a venue dispute, the locations of the parties' places of incorporation are important. Less significantly, Valeant Pharmaceuticals North America LLC, Valeant Pharmaceuticals Ireland Ltd., Dow Pharmaceutical Sciences, Inc. ("Dow"), and Kaken Pharmaceuticals Co., Ltd. (collectively "Valeant" or "plaintiffs") reside in a range of locations, including Japan, Ireland, and Delaware. On the defendants' side, Mylan Pharmaceuticals Inc. ("MPI") is a West Virginia corporation with a principal place of business in Morgantown, West Virginia; Mylan Inc. is a Pennsylvania corporation with a principal place of business in Canonsburg,

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[1] The Hatch-Waxman Act is the common name for the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98–417, 98 Stat. 1585.

Pennsylvania; and Mylan Laboratories Ltd. ("MLL") is an Indian corporation with a principal place of business in Hyderabad, India.

The parties are all players in the pharmaceutical industry. Dow holds New Drug Application No. 203567 for the brand name drug Jublia®, approved by the United States Food and Drug Administration ("FDA") on June 6, 2014. Jublia® is a medication used to treat fungal infections (onychomycosis) of toenails. The active ingredient in Jublia® is efinaconazole. There are nine patents listed in the Orange Book for Jublia®.

In June 2018, MPI, a generic drug company, executed an ANDA seeking approval to market a generic version of Jublia®. MPI sent the ANDA from its West Virginia corporate office to the FDA, located in White Oak, Maryland. The ANDA included a Paragraph IV certification that the Orange-Book-listed patents for Jublia® are invalid, unenforceable, or would not be infringed by the ANDA product. MPI notified Valeant of the ANDA submission in August 2018.

On September 26, 2018, Valeant filed suit against Mylan[2] in the District of New Jersey, alleging infringement of Dow's Orange Book patents pursuant to the Hatch-Waxman Act and requesting declaratory judgment of validity of the Orange Book patents.[3] The complaint contained several allegations about Mylan's connection to New Jersey:

- Each Mylan defendant "directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this

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[2] We refer to appellees collectively as "Mylan."

[3] Valeant also filed complaints in the District of New Jersey against eighteen other ANDA filers. None of those filers challenged venue and the cases have been consolidated with trial scheduled for June 2, 2021.

judicial district, and this judicial district is a likely destination for Mylan's generic efinaconazole topical solution." J.A. 147, ¶ 10 (MPI), 148, ¶ 12 (MLL), 149, ¶ 13 (Mylan Inc.).

- Each Mylan defendant does business in New Jersey and is registered to do so. J.A. 147, ¶ 10 (MPI), 148 ¶ 12 (MLL), 149, ¶ 13 (Mylan Inc.).
- Each defendant has previously submitted to the jurisdiction of the court and has a place of business in New Jersey. J.A. 147–48, ¶ 10 (MPI), 148–49 ¶ 12 (MLL), 149, ¶ 13 (Mylan Inc.).
- MPI applied for FDA approval of its generic drug, which will be "purposefully directed at, upon information and belief, New Jersey and elsewhere. [MPI's] ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs." And MPI plans to market and sell its generic drug into New Jersey upon FDA approval. J.A. 148 ¶ 11.

The next day, Valeant filed an essentially identical protective suit against Mylan in the Northern District of West Virginia. *See* Complaint, *Valeant Pharms. N. Am. LLC v. Mylan Pharms. Inc.*, No. 18-cv-00184-IMK, D.I. 1 (N.D. W. Va. Sept. 27, 2018). That suit is ongoing.

In January 2019, Mylan moved to dismiss Valeant's New Jersey District Court complaint against MPI and Mylan Inc. for improper venue pursuant to Federal Rule of Civil Procedure 12(b)(3). Mylan further moved to dismiss MLL and Mylan Inc. for failure to state a claim pursuant to Rule 12(b)(6). As to venue, Mylan did not deny the majority of the venue allegations in Valeant's complaint. Instead, it argued that venue was improper under § 1400(b) because no Mylan defendant resides in New Jersey, the only alleged act of infringement—submission of the ANDA—did not occur in New Jersey, and the Mylan

defendants do not have regular and established places of business in New Jersey.

In response, Valeant argued that it is unduly narrow to limit "an act of infringement" under § 1400(b) to the act of submitting the ANDA. Valeant contended that "the Court must consider Mylan's planned, future acts." J.A. 760. It maintained that, in the Hatch-Waxman context, the language of § 1400(b) must be deemed to contemplate such planned future conduct. In making this argument, Mylan relied heavily on *Bristol-Myers Squibb Co. v. Mylan Pharmaceuticals Inc.*, No. 17-cv-379-LPS, 2017 WL 3980155 (D. Del. Sept. 11, 2017) (holding that venue was appropriate in ANDA cases, even after *TC Heartland*, wherever planned future acts likely would occur).

As to the Rule 12(b)(6) motion, Mylan argued that the complaint alleged that MPI alone submitted the ANDA and MPI was thus the only entity against which a case could be brought under the Hatch-Waxman Act. Valeant answered that liability for submitting an ANDA is not limited to the entity that sends the final ANDA to the FDA. J.A. 404 (citing *In re Rosuvastatin Calcium Patent Litig.*, 703 F.3d 511, 527–28 (Fed. Cir. 2012) (holding that a "submitter" can include those who participate in the preparation of the ANDA and intend to directly benefit from marketing of the product identified in it)).

In August 2019, the district court granted Mylan's motion to dismiss the complaint against all defendants based on improper venue. The court found that the ANDA was submitted from West Virginia, rendering venue proper there. The court then discussed the parties' arguments about the relevance of planned future acts to the venue analysis under § 1400(b). Citing *In re Cray Inc.*, 871 F.3d 1355, 1361 (Fed. Cir. 2017), and *In re ZTE (USA) Inc.*, 890 F.3d 1008, 1014 (Fed. Cir. 2018), for the proposition that the requirements of the venue statute are specific, unambiguous, and not amenable to liberal construction based on

policy concerns, the court concluded that the discussion of venue in *Bristol-Myers Squibb* "does not follow from a plain reading of the statute, which is clear: only where a defendant has committed an act of infringement may a party bring a patent suit." *Valeant Pharms.*, 2019 WL 4179832, at *3. Accordingly, the court concluded that the two places where an act of infringement might have occurred before the filing of the action were West Virginia and Maryland, not New Jersey. The court therefore dismissed the infringement claims.

The district court did not separately address Mylan's Rule 12(b)(6) motion to dismiss as to MLL and Mylan Inc. or explain its rationale for dismissing MLL. It did, however, insert a footnote acknowledging the argument that MLL, a foreign entity, was properly subject to venue in every judicial district. The court stated it would not consider MLL in the venue analysis, but noted that venue would be proper for MLL in West Virginia. *Id.* at *3 n.2.[4]

Valeant timely filed a notice of appeal on September 10, 2019. We have jurisdiction to review the final decision of the district court pursuant to 28 U.S.C. § 1295(a)(1).

II. ANALYSIS

This appeal presents two issues. First, as noted, we have been asked to answer a question of first impression relating to proper venue in Hatch-Waxman cases after *TC Heartland*. Second, we apply well-established law to the question of proper venue for patent cases brought against foreign entities. We affirm the district court's determination that venue was not proper in New Jersey as to the

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[4] The court also dismissed Valeant's declaratory judgment actions. *Valeant Pharms.*, 2019 WL 4179832, at *4. That decision is not contested on appeal.

domestic defendants. We reverse and remand, however, as to foreign defendant MLL.

A. Venue in Hatch-Waxman Cases

For purposes of determining whether venue is proper in a district other than one in a state in which a defendant is incorporated, a court must determine, among other things, "where the defendant has committed acts of infringement." 28 U.S.C. § 1400(b).[5] Under the Hatch-Waxman Act, it is "an act of infringement to submit [an ANDA] for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a drug . . . 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). Once the act of infringement occurs, the patent holder may then commence an action under 35 U.S.C. § 271 for infringement.[6] The litigation then proceeds to address the question of whether any future distribution of the identified generic would infringe a valid patent claim. If so, the court shall enter an order barring the FDA from approving that distribution

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[5] To find that venue is proper, a court must also determine that a defendant "has a regular and established place of business" in the district. 28 U.S.C. § 1400(b). The district court did not reach the question of whether Mylan has a regular and established place of business in New Jersey. As such, we do not address that issue on appeal.

[6] If the patent holder files its action within forty-five days of the ANDA submission the FDA's authority to approve manufacture and distribution of the generic identified in the ANDA is stayed for thirty months so that the litigation may proceed before such activities occur. 21 U.S.C. § 355(j)(5)(B)(iii).

prior to expiration of the infringed patent. 35 U.S.C. § 271(e)(4)(A).

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. We address this question in two parts. We first recount some of our pre-*TC Heartland* case law discussing infringement actions under the Hatch-Waxman Act. We then address the specific arguments made by Valeant and Mylan as to the propriety of venue in New Jersey for this case, and how those arguments fare in light of the two statutory schemes at issue.

1. Statutory and Legal Backdrop

Prior to 2017, defendants hoping to transfer Hatch-Waxman cases to a different district generally objected to a plaintiff's chosen venue on personal jurisdiction grounds. We definitively resolved those arguments in *Acorda Therapeutics Inc. v. Mylan Pharmaceuticals Inc.*, 817 F.3d 755 (Fed. Cir. 2016), where we held that planned future acts were sufficient to justify the exercise of specific personal jurisdiction over a defendant in ANDA cases. In *Acorda*, we held that planned future interactions with the state in the form of marketing activities met the constitutional minimum requirements for personal jurisdiction. *Id.* at 760. While we did not address any statutory venue questions and specifically disclaimed having done so, this holding was important to the then-extant venue analysis because, at that point in time, our case law effectively had equated personal jurisdiction with venue by incorporating the definition of "reside" in the general venue statute, 28 U.S.C. § 1391(c)(2), into § 1400(b). *See VE Holding Corp. v. Johnson Gas Appliance Co.*, 917 F.2d 1574, 1584 (Fed. Cir. 1990) (holding that changes to the general venue statute meant that, in patent cases, corporations reside in every venue where personal jurisdiction is proper). Thus,

if personal jurisdiction over an ANDA filer could be obtained in any district where that filer intended to market the generic product described in the ANDA, then venue under § 1400(b) would be proper in the same district because the ANDA filer would be deemed to "reside" there for venue purposes as well.

The practical significance of *Acorda* was markedly contracted when the Supreme Court changed the venue landscape for patent cases in *TC Heartland*. That decision not only overturned *VE Holding* and its progeny, it reopened the effectively resolved question of where Hatch-Waxman cases could be venued.

When faced with other questions growing out of *TC Heartland*, we have narrowly construed the requirements of venue in patent cases. In *Cray*, for example, we narrowly construed § 1400(b)'s requirement of a "regular and established place of business." 871 F.3d at 1361 ("[T]he requirement of venue is specific and unambiguous; it is not one of those vague principles which, in the interests of some overriding policy, is to be given a liberal construction." (quoting *Schnell v. Peter Eckrich & Sons, Inc.*, 365 U.S. 260, 264 (1961))). We held that (1) there must be "a physical, geographical location in the district from which the business of the defendant is carried out"; (2) the defendant's presence "must for a meaningful time period be stable, established"; and (3) "it must be a place *of the defendant*." *Id.* at 1362–63 (emphasis in original). In *In re Google LLC*, we further reinforced the narrowness of the venue inquiry by clarifying that the venue statute excludes "agents' activities, such as maintenance, that are merely connected to, but do not themselves constitute, the defendant's conduct of business . . . ." 949 F.3d 1338, 1347 (Fed. Cir. 2020); *see also id.* at 1346 ("[T]he Supreme Court has cautioned against a broad reading of the venue statute."). Consistently, we have warned that "[c]ourts should be mindful of [the specific and unambiguous nature of venue] in applying the statute and be careful not to conflate showings that

may be sufficient for other purposes, *e.g.*, personal jurisdiction or the general venue statute, with the necessary showing to establish proper venue in patent cases." *Cray*, 871 F.3d at 1361.

We have had no chance since *TC Heartland* to address the question of where infringement occurs in an ANDA case, however.[7] District courts have struggled with the question and two competing views have emerged. The first significant case to address the question was *Bristol-Myers Squibb*, 2017 WL 3980155. There, the district court identified what it called "an almost impenetrable problem" of reconciling the venue statute's use of the present perfect tense ("where the defendant *has* committed acts of

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[7] The question of where infringement occurs in the Hatch-Waxman context is unique in its lack of pre-*TC Heartland* guidance. We answered the "where" question with respect to traditional acts of infringement years ago in extraterritorial infringement cases. *See, e.g.*, *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Contractors USA, Inc.*, 617 F.3d 1296, 1309 (Fed. Cir. 2010) (stating that the analysis for determining the location of an offer for sale should focus on "the location of the future sale that would occur pursuant to the offer"); *Litecubes, LLC v. N. Light Prods., Inc.*, 523 F.3d 1353, 1369–70 (Fed. Cir. 2008) (holding that an infringing sale may occur in more than one location as a sale has both a physical and a conceptual dimension to it); *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1317 (Fed. Cir. 2005) ("The use of a claimed system under section 271(a) is the place at which the system as a whole is put into service, *i.e.*, the place where control of the system is exercised and beneficial use of the system obtained."); *id.* at 1318 ("[A] process cannot be used 'within' the United States as required by section 271(a) unless each of the steps is performed within this country.").

infringement" (emphasis added)) with the Hatch-Waxman scheme, which focuses on potential future acts. *Id.* at *6–7. Ultimately, the court reasoned that, because the actual substance of ANDA litigation is not about the documents filed with the FDA but about whether potential future conduct would infringe a valid patent, it must be those future acts that are relevant to the venue analysis. *Id.* at *8. The court concluded that "[t]he submission of an ANDA is a stand-in that serves to move forward in time the infringement and invalidity challenges that otherwise would come later in time, such as after approval or marketing of the ANDA drug." *Id.* And, though acknowledging that it was not controlling of the issue presented, the court noted that our *Acorda* decision supported the result reached. *Id.* at *8–10.

When faced with the same question a few months later, one district court in the District of New Jersey adopted the reasoning in *Bristol-Myers Squibb*. *See Celgene Corp. v. Hetero Labs Ltd.*, No. 17-cv-3387-ES-MAH, 2018 WL 1135334, at *3 (D.N.J. Mar. 2, 2018). On that basis, it denied a motion to dismiss for improper venue filed by some of the generic defendants in that case.

A district court in the Northern District of Texas respectfully disagreed with the Delaware court's reasoning. *Galderma Labs., L.P. v. Teva Pharms. USA, Inc.*, 290 F. Supp. 3d 599, 606–09 (N.D. Tex. 2017). The court concluded both that § 1400(b) requires a *past* infringement and that the plain language of the Hatch-Waxman Act does not identify any act of infringement other than the ANDA submission. *Id.* at 607–08. The court reasoned that, because the potential future acts that the Hatch-Waxman act anticipates are speculative—many actions never happen precisely because of the litigation—they cannot control the venue of the action. *Id.* at 608. Noting that *Cray* warned away from conflating the personal jurisdiction and venue analyses, the court held that only the locations where the

ANDA materials were prepared and from which it was submitted are relevant to the venue analysis. *Id.* at 608–09.

The district court's opinion in this case took a position akin to that taken by the district court in the Northern District of Texas. We agree with the district court that venue is improper in New Jersey as to MPI and Mylan Inc. For the reasons discussed below, we hold that venue in Hatch-Waxman cases must be predicated on past acts of infringement—*i.e.*, acts that occurred before the action alleging infringement was filed. And we hold those acts occur only in districts where actions related to the ANDA submission occur.

2. Venue Was Not Available in New Jersey for MPI and Mylan Inc.

We review whether venue is proper under § 1400(b) de novo. *Westech Aerosol Corp. v. 3M Co.*, 927 F.3d 1378, 1381 (Fed. Cir. 2019). This is an issue unique to patent law and is therefore governed by Federal Circuit precedent. *ZTE*, 890 F.3d at 1012.

We begin our analysis with the plain language of the statutes. At least by the time briefing was complete in this appeal, both parties agreed that § 1400(b) requires a past act of infringement. *See* Appellees' Br. 14–21; Appellants' Reply Br. 5. Specifically, "has committed acts of infringement," a present perfect phrase, counsels that the acts accused of infringement must have already occurred. This understanding is supported by Congress's choice of words for the rest of the provision. Congress included two phrases that are plainly in the present tense ("where the defendant resides" and "where the defendant . . . has a regular and established place of business"), indicating that its choice to place the infringement in the past was intentional. The heart of the dispute, therefore, is the nature and scope of the act of infringement defined by 35 U.S.C. § 271(e)(2).

As noted, the Hatch-Waxman Act makes it "an act of infringement to submit [an ANDA] for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . 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). A plain language reading of this provision 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. Valeant makes several arguments as to why we should understand § 271(e)(2) as encompassing more. None persuade us to reach a different conclusion.

Valeant first argues that the Hatch-Waxman act of infringement is "artificial" and, therefore, requires us to look to planned future conduct to define what is really infringing. Appellants' Br. 21–25. The Supreme Court, our court, and district courts have referred to the ANDA submission as an "artificial act of infringement." *See, e.g.*, *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990); *Acorda*, 817 F.3d at 760; *Belcher Pharms., LLC v. Int'l Medication Sys., Ltd.*, 379 F. Supp. 3d 326, 330 (D. Del. 2019). The Hatch-Waxman Act itself never says the act that constitutes infringement is artificial, however. It speaks in real terms—submission of the ANDA *is* the infringing act. It does so, moreover, after declaring other acts, which otherwise may have been infringing, to be non-infringing when undertaken solely for purposes of requesting regulatory approval to market a drug—*i.e.*, solely for purposes of submitting the ANDA. 35 U.S.C. § 271(e)(1). Thus, the statute "artificially" declares certain very real acts of infringement to be non-infringing acts and other acts that would not otherwise constitute infringement to be acts of infringement. But, in both instances the result is real; the statute delineates which acts may or may not give rise to a cause of action under the Hatch-Waxman Act. The language used by

courts to characterize Hatch-Waxman cases does not change that an ANDA submission is a real, albeit statutorily created, act of infringement. *See Eli Lilly*, 496 U.S. at 678 (The Hatch-Waxman Act creates "a highly artificial act of infringement that *consists of submitting an ANDA*." (emphasis added)).

Valeant next focuses on the nature and substance of Hatch-Waxman litigation and argues that the act of infringement must encompass more than just submission of the ANDA. Appellants' Br. 24–25. As noted, it is true that the judicial inquiry on the merits once an action has been commenced considers the ANDA defendant's potential future conduct—*i.e.*, whether the conduct in which that defendant would like to engage would infringe a valid patent. The content of the litigation does not, however, turn potential future acts into past infringement. Under the plain language of the statute, the only past infringing act is the ANDA submission, which creates the right to bring suit in the first instance. The result of virtually all Hatch-Waxman litigation is, moreover, that no post-submission infringement happens. Sales and offers for sale of the ANDA product are either non-infringing as determined through the litigation, or such acts typically never occur. In that ordinary circumstance (where there is no at-risk market entry of the generic), the 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.

Valeant also argues that congressional intent supports its interpretation. Appellants' Br. 34–39. Valeant argues that Congress *must* have meant to allow venue in all the places that might have been available had a generic entered the market at-risk. The statute does not say that, however. Importantly, the Supreme Court told us several things in *TC Heartland*. First, that its own decision in *Fourco Glass Co. v. Transmirra Products Corp.*, 353 U.S. 222 (1957), made clear that Congress enacted § 1400(b) in

1948 to be a standalone venue statute for patent cases. *TC Heartland*, 137 S. Ct. at 1519. Second, that the term "resides" in the first clause of § 1400(b) was meant to have the same meaning in 1948 as the term "inhabits" had in the earlier version of that statute—*i.e.*, that corporations were only subject to suit in patent cases under the first clause of § 1400(b) in their state of incorporation. *Id.* Third, that Congress expressed no intention to alter either clause of § 1400 in 1988 when it enacted amendments to the general venue statute and made that intention even clearer when it enacted the current version of the general venue statute in 2011. *Id.* at 1521. Given this guidance, we similarly must assume that, when Congress enacted the Hatch-Waxman Act in 1984, it did so with a clear understanding of where § 1400(b) allowed patent actions to be commenced at that time. And, we must assume that, when it excepted Hatch-Waxman cases from the new joinder provisions for patent cases enacted in 2011, Congress understood that it was not *sub silentio* also excepting Hatch-Waxman cases from 1400(b). As the Court noted in *TC Heartland*, when Congress intends to effect a change as sweeping as a revision to § 1400(b), "it ordinarily provides a relatively clear indication of its intent in the text" of the statute. *Id.* at 1520 (citing *United States v. Madigan*, 300 U.S. 500, 506 (1937)). We can glean no such clear guidance from the text of the Hatch-Waxman Act.

Valeant further contends that the second clause of the patent venue statute, allowing venue where an act of infringement occurs if the accused infringer has a regular and established place of business, is rendered superfluous by a plain-language reading of the statute. Appellants' Br. 25–26. Surely, a statute should be interpreted to give all of its provisions meaning. *Corley v. United States*, 556 U.S. 303, 314 (2009). But Valeant's argument fails to recognize that the second clause retains meaning in every other type of patent infringement case and will be operative in every

Hatch-Waxman case where the ANDA is submitted from a venue different than the submitter's place of incorporation.

Next, Valeant argues that we should hold that an ANDA submission is a nationwide act of infringement based on a "conceptual" aspect beyond the literal act defined in the statute. Appellants' Br. 28; Appellants' Reply Br. 16–21. It cites *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Contractors USA, Inc.*, 617 F.3d 1296, 1309–11 (Fed. Cir. 2010), where we considered which locations can logically be said to be the locations of sales and offers for sale in patent cases. We held that those acts can occur in more than one location. The analysis looks to both the location of the parties at the time of contracting and to the location of anticipated performance. Valeant argues for a similar, but markedly more expansive, analysis in this case. Valeant would have us hold that the literal act of infringement—submission of the ANDA—encompasses a vast "conceptual" element of nationwide infringement in every judicial district. While we have held that sales and offers for sale have both physical and conceptual elements, *see Litecubes, LLC v. N. Light Prods., Inc.*, 523 F.3d 1353, 1369–70 (Fed. Cir. 2008), the conceptual elements in those cases were connected to common law understandings of "sales" and "offers for sale." There is no analogous common law here that would compel a conclusion that submitting an ANDA has a purely conceptual effect of causing infringement *everywhere* in the United States. To reach such a broad interpretation of the infringing act, without any textual hook in the statute, would be a bridge too far.

Valeant does have strong policy reasons for adopting its reading of the statutes. For example, a generic company may "game" the system to avoid venue in certain jurisdictions. Appellants' Reply Br. 20. And brand 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." *Bristol-Myers Squibb*, 2017 WL

3980155, at *12 n.17. While intuitively persuasive, these policy arguments cannot trump the plain language of § 271(e)(2) and the requirements of § 1400(b). We are, as we must be, guided in our analysis by controlling precedent stating that venue is not amenable to such policy concerns. *See Cray*, 871 F.3d at 1361 (quoting *Schnell*, 365 U.S. at 264). Congress can revise the two statutes to the extent it finds these, or other, policy concerns compelling; all we can do is give the statutes their current plain meaning.

Finally, Valeant looks to *Acorda*. Appellants' Br. 29–33. *Acorda* did not, however, address proper venue—a question of statutory interpretation. It was focused on the narrow constitutional question of whether minimum contacts were present for purposes of personal jurisdiction based on the ANDA submission. We held that submission with an intent to distribute the generic product in a given state was sufficient for personal jurisdiction purposes. *Acorda*, 817 F.3d at 762. *Acorda* said nothing about whether an act of infringement had already occurred in any such state or venue. While our then-current venue law meant *Acorda* had a big impact on the venue analysis in Hatch-Waxman cases, we did not address venue in the case. And, though our venue law has changed, we cannot stretch *Acorda* to reach that issue now. As we indicated then, we would be remiss to treat venue and personal jurisdiction as the same inquiry. *See id.* at 763.

Accordingly, we hold that, in Hatch-Waxman cases, venue 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). We find ourselves bound by the plain language of the statutes and a directive from the Supreme Court that venue "is not one of those vague principles which, in the interest of some overriding policy,

is to be given a liberal construction." *Schnell*, 365 U.S. at 264 (internal quotation marks omitted).

The district court found that no act involved in the submitting of the ANDA occurred in New Jersey. Valeant does not challenge that finding on appeal. We therefore affirm the district court's dismissal of MPI and Mylan Inc. for improper venue.[8]

B. Venue Is Proper for MLL in New Jersey

The district court decision clearly articulates, and it is undisputed, that MLL is properly subject to venue in any judicial district, including the District of New Jersey. *See Valeant Pharms.*, 2019 WL 4179832, at *3 n.2; *see also In re HTC Corp.*, 889 F.3d 1349, 1358 (Fed. Cir. 2018). The court's conclusion dismissing the complaint as to all defendants after only evaluating Mylan's venue argument is, therefore, incongruous. Mylan invites us to affirm on an alternative basis by holding, in the first instance, that Valeant failed to state a claim against MLL and that the district court likely understood that fact. Appellees' Br. 44–46. Whether MLL can be held answerable to claims of

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[8] The district court's suggestion that an act of infringement for purposes of this case may have occurred in the District of Maryland where the FDA received the ANDA is not challenged in this appeal. 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. *See Bristol-Myers Squibb*, 2017 WL 3980155, at *7, 11.

infringement in this case turns on whether MLL's involvement in the submission of the ANDA is sufficient for it to be considered a "submitter," and thus, amenable to suit. *See Rosuvastatin*, 703 F.3d at 527–29. For purposes of a Rule 12(b)(6) motion, the court must decide whether Valeant plausibly alleged sufficient involvement on the part of MLL. *See*, *e.g.*, *Galderma*, 290 F. Supp. 3d at 615–18; *Cephalon, Inc. v. Watson Pharms., Inc.*, 629 F. Supp. 2d 338, 349 (D. Del. 2009). Mylan points to paragraph 29 of the complaint and says Valeant unambiguously asserted that only MPI was involved in submitting the ANDA. Appellees' Br. 44 (citing J.A. 153, ¶ 29). But, as Valeant notes, there are eight other paragraphs in the complaint asserting that "Mylan"—defined to encompass all three entities—"submitted" the ANDA and materials related to it. J.A. 154–64, ¶¶ 35, 46, 57, 68, 79, 90, 101, 112. The district court may well find that these paragraphs are sufficient to state a claim against MLL, despite the phrasing in paragraph 29, or that leave to amend to clarify any apparent confusion would be appropriate. We thus reverse the district court's venue-based dismissal of MLL and remand for further consideration.[9]

III. CONCLUSION

While, as noted, we are sympathetic to the policy concerns associated with limited venue for Hatch-Waxman cases, especially those relating to lost judicial efficiencies in the handling of these mostly multi-defendant cases, we are compelled to our conclusion by the plain language of

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[9] The district court also did not answer whether a claim under § 271(e) has been stated against Mylan Inc. Because we affirm the dismissal of Mylan Inc. under Rule 12(b)(3), we do not address the district court's failure to consider the motion as to that entity under Rule 12(b)(6).

the two statutes at issue.[10] We therefore affirm the district court's dismissal of Valeant's complaint as to MPI and Mylan Inc. for improper venue. As to MLL, because venue is proper in New Jersey for any foreign defendant, we reverse the district court's dismissal and remand.

AFFIRMED-IN-PART, REVERSED-IN-PART, AND REMANDED

COSTS

No costs.

[10] While cumbersome for these types of cases, 28 U.S.C. § 1407 is at least a viable path for consolidation of these cases for pretrial purposes.

United States Court of Appeals for the Federal Circuit

November 6, 2020

ERRATA

Appeal No. 2019-2402

VALEANT PHARMACEUTICALS NORTH AMERICA LLC, VALEANT PHARMACEUTICALS IRELAND LTD., DOW PHARMACEUTICAL SCIENCES, INC., KAKEN PHARMACEUTICAL CO., LTD.,
Plaintiffs-Appellants

v.

MYLAN PHARMACEUTICALS INC., MYLAN LABORATORIES LTD., MYLAN INC.,
Defendants-Appellees

Decided: November 5, 2020
Precedential Opinion

Please make the following change:

On page 6, line 10, change "Mylan" to —Valeant—.

CERTIFICATE OF COMPLIANCE

1. This petition complies with the type-volume limitation of Fed. R. App. P. 35(b)(2) because it contains 3384 words, as determined by the word-count function of Microsoft Word, excluding the parts of the petition exempted by Federal Rule of Appellate Procedure 32(f); and

2. This petition complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this petition has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman 14 point font.

Dated: December 7, 2020

/s/ Thomas P. Steindler
Thomas P. Steindler