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New Strategies for Venue in Hatch-Waxman Litigation



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Venue can have a dramatic impact on Hatch-Waxman Act litigation. Brands and generics are constantly looking for new strategies to secure a favorable venue. Until recently, the ability of brands to choose and hold venue has resulted in almost all Hatch-Waxman cases going to federal courts in Delaware or New Jersey. In those districts, it can be very difficult for generics to have a summary judgment motion heard and the time to disposition may take at least a full 30 months during which time a stay of Food and Drug Administration approval remains in effect.

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Recent cases have provided litigants with new tools to try to control venue in Hatch-Waxman cases. The Supreme Court's 2014 decision in *Daimler AG v. Bauman* significantly changed the requirements for establishing general personal jurisdiction.[1] As a result of *Daimler*, Delaware and New Jersey courts may not have general personal jurisdiction over generic filers, and brands therefore may not be able to have their choice of those venues. Disputes over the application of *Daimler* have opened up a new avenue to fight jurisdiction. Interim appeals of jurisdictional challenges in Delaware are already showing that the new venue disputes have the potential to involve the U.S. Court of Appeals for the Federal Circuit in a series of decisions that may resemble recent battles over venue in the Eastern District of Texas.

Brands and generics thus need to be thinking about how seemingly inconsequential corporate acts may have huge consequences for venue. For example, recent decisions in Delaware have been certified for interlocutory appeal to determine whether personal jurisdiction can be founded not only on where a generic filer is incorporated or headquartered, but also where it is registered to do business or where it sends its paragraph IV notice letter. These decisions are so controversial, uncertain, and in conflict with one another, that the district-court judges have taken the unusual step of certifying them for interlocutory appeal to obtain guidance

[1] 134 S. Ct. 746 (2014).

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from the Federal Circuit.[2] Until the Federal Circuit, and perhaps the Supreme Court, provides Hatch-Waxman litigants with some clarity as to what is sufficient to confer personal jurisdiction, these are cases that should be in the forefront of the minds of Hatch-Waxman litigants as they develop their litigation strategies.

I. Venue in Hatch-Waxman cases is potentially outcome determinative.

Battles over venue are frequently fought in patent cases. For years, patent litigants fought about whether venue could or should be lodged in the U.S. District Court for the Eastern District of Texas. Due to its ''trial-friendly'' reputation, plaintiffs frequently filed in the Eastern District of Texas and defendants filed many motions to transfer venue. This is likely because those litigants believed that remaining in Texas could very well be outcome-determinative at the trial level: litigants believed that patent holders had a much better chance of getting to trial and getting to trial relatively quickly than they would in some other venues.

Venue decisions are similarly important in Hatch-Waxman Act cases. Time to disposition varies widely across venues and can be essential for both plaintiffs and defendants in these cases. For example, even when a generic ultimately wins on the merits, if the resolution takes too long, it can effectively be a win for the brand. This is because, during pendency of the case, the brand maintains its market exclusivity.

Certain districts are widely known for being significantly faster than others. For example, between 2008 and 2014, the average time to trial in patent cases in the Eastern District of Virginia was 514 days, while the average in the Northern District of Illinois was almost four times that, at 2,026 days. Certain districts, such as the District of Delaware, are very reluctant to hear summary judgment motions, particularly in Hatch-Waxman cases that end in a bench trial. Moreover, districts differ in their familiarity with the idiosyncrasies of Hatch-Waxman cases. Litigating in venues that are less experienced in handling these cases could cause unpredictability in the timing, procedure, and outcome of the cases. [3].

Similarly, the ability to defeat or obtain summary judgment can be very important in speeding time to resolution.

II. The new issue is personal jurisdiction, but the consequences are the same.

The Supreme Court's decision in *Daimler* significantly limited the reach of general personal jurisdiction.[4] General personal jurisdiction exists wherever a corporation is incorporated or has a ''presence.''[5] Before *Daimler*, it was generally accepted that a corporation had a ''presence'' that satisfied general jurisdiction wherever it did business. In *Daimler,* the Court clarified that its holding in *International Shoe,* wherein it used the often cited words ''continuous and systematic,'' was related to specific jurisdiction, not general jurisdiction.[6] The Court held that to support a finding of general jurisdiction, a corporation's affiliations with the state must be ''so continuous and systematic as to render it essentially at home in the forum state.''[7] Thus, the Court rejected Daimler's argument, that general jurisdiction exists in every state in which a corporation engages in a substantial, continuous, and systematic course of business, holding Daimler's construction to be ''unacceptably grasping.''[8] As such, *Daimler* narrowed the *scope* of ''presence'' to include only a corporation's single principal place of business.[9] Thus, a corporation may no longer be subject to general personal jurisdiction outside of its state of incorporation and the location of its headquarters, except in ''exceptional'' cases.[10] It is not yet certain which fact patterns will be considered to constitute ''exceptional'' cases.

Daimler will particularly affect venue in Hatch-Waxman cases because brand companies often rely on general jurisdiction to bring suit in a specific forum that is perceived as being favorable to brands. Post-*Daimler*, brands may need to rely on specific personal jurisdiction to avoid litigating in a generic's home state.

Specific personal jurisdiction is more difficult to establish in Hatch-Waxman cases because, in most cases, it arises out of conduct related to the suit that the defendant directs into the forum state, such as sales of an accused product within the forum. We expect to see robust litigation over what facts will be sufficient to confer specific personal jurisdiction in Hatch-Waxman cases.

In typical Hatch-Waxman cases, the litigation arises prior to FDA approval and launch of the accused product, so there are no sales on which to base specific personal jurisdiction. Thus, brands that cannot establish specific personal jurisdiction are now limited to filing in venues which are the generic's state of incorporation or the state where the generic's headquarters are located. These states may not be brand favorites such as Delaware, New Jersey, or New York. If a brand files in a venue that does not have personal jurisdiction, the case will necessarily have to be transferred to what may be the generic's preferred venue.

III. The Delaware decisions.

Two recent decisions out of the District of Delaware—one from Judge Gregory M. Sleet and the other from Chief Judge Leonard P. Stark—illustrate tac-

[2] *See* Order Granting Motion for Certification for Interlocutory Appeal, Acorda Therapeutics Inc. v. Mylan Inc., No. 14-935-LPS (D. Del. Jan. 30, 2015); Order Granting Mylan Pharms. Inc.'s Motion for Certification for Interlocutory Appeal, AstraZeneca AB v. Aurobindo Pharma Ltd., No. 14-664-GMS (D. Del. Nov. 11, 2014) (note this is the consolidated case name; the original case name was *AstraZeneca AB v. Mylan Pharms. Inc.,* No. 14-696-GMS, and this article makes references to documents filed in both cases).

[3] *See* Docket Navigator, *2014 Year in Review* 24, *available at* http://home.docketnavigator.com/year-review/.

[4] *Daimler,* 134 S. Ct. 746.

[5] International Shoe Co. v. Washington, 326 U.S. 310, 321 (1945).

[6] *Daimler,* 134 S. Ct. at 761 (quoting *International Shoe,* 326 U.S. at 317).

[7] *Id.* (internal quotation marks and citation omitted).

[8] *Id.*

[9] *Id.* at 760 (citing Goodyear Dunlop Tires Operations, S.A. v. Brown, 131 S. Ct. 2846 (2011)).

[10] *Id.* at 761 n.19.

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tics and disputes that are likely to arise around specific personal jurisdiction in Hatch-Waxman cases. Even though the decisions issued from the same federal district, the decisions are somewhat contradictory. Until the Federal Circuit weighs in, there will be much uncertainty both for brands trying to maintain venue in the District of Delaware and for generics trying to transfer out of that district.

A. Judge Sleet's Decision

Judge Sleet was the first district court judge to apply *Daimler's* limited general jurisdiction standard in a Hatch-Waxman case. He confronted the issue last November in his decision in *AstraZeneca AB v. Mylan Pharms. Inc.*, Judge Sleet first found that the generic company, Mylan, was not subject to general jurisdiction in Delaware, but ultimately concluded that specific jurisdiction existed.[11]

In reaching his decision, Judge Sleet first considered whether general jurisdiction existed, noting that ''[i]n ANDA litigation, general jurisdiction traditionally provided the basis to assert jurisdiction over generic drug company defendants.''[12] Judge Sleet, however, went on to explain that *Daimler* changed the bar for general jurisdiction: the circumstances under which a corporation may be considered ''at home'' in the forum are now considerably narrower.[13] The brand, AstraZeneca, argued that Mylan's contacts were sufficient to confer general jurisdiction because Mylan was registered to do business there. [14] in Delaware and had a ''broad network of third-party contacts within the state.''[15] Judge Sleet disagreed, explaining that if these allegations were sufficient to establish general jurisdiction, it would permit any state to exercise personal jurisdiction over Mylan, a result specifically prohibited by the Supreme Court in *Daimler*.[16] Judge Sleet also found Mylan's litigation history in Delaware insufficient to confer general jurisdiction because it failed to rise to the level of an ''exceptional case'' as delineated in *Daimler*.[17] Because Mylan was not incorporated in Delaware and didn't have its principal place of business in Delaware, Judge Sleet found that general jurisdiction did not exist.[18]

Next, Judge Sleet considered AstraZeneca's argument that Mylan consented to general jurisdiction in Delaware by complying with statutory registration requirements to do business there. Judge Sleet observed there was a circuit split regarding ''statutory consent,'' wherein some circuits have upheld findings of general jurisdiction on registration alone, while others have required a minimum-contacts analysis.[19] Judge Sleet recognized that the U.S. Court of Appeals for the Third Circuit had found general jurisdiction based on registration alone, and also noted that little guidance had been provided regarding *Daimler*'s impact on the split.[20] Judge Sleet found that *Daimler* did affect the issue, holding that compliance with a state's registration statutes could not constitute consent to jurisdiction.[21] He reasoned that because many states have enacted registration statutes, ''[f]inding mere compliance with such statutes sufficient to satisfy jurisdiction would expose companies with a national presence to suit all over the country, a result specifically at odds with *Daimler*.''[22] Thus, Judge Sleet held that Mylan had not consented to general jurisdiction in Delaware by registering to do business there.

Finally, Judge Sleet considered whether Mylan was subject to specific jurisdiction in Delaware. While he noted that ''specific jurisdiction has historically been disfavored by courts as a basis to exercise jurisdiction over generic drug company defendants in ANDA cases,'' he found it necessary to consider specific jurisdiction because ''the standard for general jurisdiction —the typical avenue for bringing ANDA cases — has changed.''[23] Judge Sleet explained that, in the unique context of ANDA cases, where the infringement is a ''highly artificial act,'' there is no apparent situs for injury. But he reasoned that AstraZeneca's cause of action arose from Mylan filing an ANDA and mailing its paragraph IV letter to AstraZeneca, located in Delaware.[24] Judge Sleet therefore concluded that the act of filing an ANDA and mailing a paragraph IV letter to the contested venue was sufficient to establish specific jurisdiction in Delaware.

As practitioners in the Hatch-Waxman area will be aware, a generic filer is required by statute and regulation to mail its notification letter to the NDA holder(s) and to the patent owner(s) at addresses found in the records of the patent office and the FDA. Thus, the seemingly inconsequential act of establishing the correct addresses for mailing a paragraph IV notice may now be determinative of personal jurisdiction and therefore control the court in which venue for the litigation is established.

B. Chief Judge Stark's decision

Recently, Chief Judge Stark considered similar personal jurisdiction issues in *Acorda Therapeutics, Inc. v. Mylan Inc*. That case involved two distinct yet related defendants: the parent company, Mylan Inc., and its subsidiary, Mylan Pharma. In his personal jurisdiction analysis, Chief Judge Stark considered jurisdiction over each of the entities separately, finding that Mylan Inc. was not subject to personal jurisdiction in Delaware, while personal jurisdiction existed as to Mylan Pharma.[25]

In accordance with Judge Sleet's decision, Chief Judge Stark also held that neither entity was subject to general personal jurisdiction in Delaware because, after *Daimler*, neither could be considered ''at home'' in the forum. Neither entity was incorporated in Delaware, nor had a principal place of business there.[26]

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[11] *See* AstraZeneca AB v. Mylan Pharms., Inc., No. 14-696-GMS, 2014 U.S. Dist. LEXIS 156660 (D. Del. Nov. 5, 2014).
[12] *Id.* at *7.
[13] *Id.*
[14] While Mylan was registered to do business in Delaware, it was not incorporated in Delaware. *Id.* at *3.
[15] *Id.* at *8.
[16] *Id.* at *9.
[17] *Id*.
[18] *Id.* at *10.
[19] *Id.* at *11–12.
[20] *Id.* at *12–13.
[21] *Id.* at *13–14.
[22] *Id.* at *15.
[23] *Id.* at *16.
[24] *Id.* at *21–22.
[25] *See* Acorda Therapeutics, Inc. v. Mylan Inc., No. 14-935-LPS, 2015 U.S. Dist. LEXIS 4056 (D. Del. Jan 14, 2015).
[26] *Id.* at *18–20.

However, Chief Judge Stark's decision diverged from Judge Sleet's decision regarding consent to general jurisdiction. While Chief Judge Stark found that Mylan Inc. did not consent to general jurisdiction because it had not registered to do business in Delaware, he found that Mylan Pharma did consent to personal jurisdiction in Delaware by registering pursuant to the statute.[27] Chief Judge Stark recognized that his decision was at odds with Judge Sleet's decision on the same issue.[28] Chief Judge Stark explained the difference in the holdings by stating that in his view, *Daimler* did not eliminate consent by voluntary compliance with a state's registration statute as a basis for general jurisdiction.[29] Chief Judge Stark noted:

> It seems an odd result that while there is not general jurisdiction over a corporation in every state in which the corporation does business, general jurisdiction may exist over a corporation in every state in which that corporation appoints an agent to accept service of process as part of meeting the requirements to register to do business in that state.[30] Nevertheless, he concluded that, although the result was odd, it was entirely permissible.[31]

Chief Judge Stark also found Mylan Pharma subject to specific jurisdiction, finding that Acorda's cause of action arose out of ''Mylan Pharma's activities that are, and will be, directed to Delaware.''[32] He reasoned that Mylan Pharma sent its paragraph IV letter to Acorda, and even though it did not send the letter into Delaware, it directed activity at the forum because Acorda is incorporated in Delaware. Further, Chief Judge Stark explained that the ANDA filing is a prerequisite to FDA approval, which is necessary for Mylan Pharma to sell its generic drug product in the future throughout the U.S., including Delaware.[33] Chief Judge Stark also explained that at the time Mylan Pharma sent its paragraph IV letter, Acorda had already begun litigation involving the same drug in Delaware. Mylan Pharma therefore should have known that Acorda would also bring suit in Delaware against Mylan Pharma.[34] While, in this case, the paragraph IV letter was not sent to Delaware, Chief Judge Stark noted that he agreed with Judge Sleet that mailing a paragraph IV letter into Delaware is a factor to consider:

> The undersigned Judge agrees with Judge Sleet that mailing a paragraph IV certification letter into Delaware is an additional activity directed at Delaware that should be considered in assessing whether this court can exercise specific jurisdiction. It does not follow, however, that the absence of a mailing into Delaware eliminates the possibility of exercise of specific jurisdiction.[35]

It is readily apparent that Chief Judge Stark's logic would permit suit in any forum in which a patent holder or NDA holder is incorporated, thus restoring substantial control over venue to the brand.

C. Certification for interlocutory appeal

The two Delaware judges differed from each other on two main issues: (1) whether registering to do business in Delaware may constitute consent to general jurisdiction, and (2) whether the act of sending a paragraph IV letter into Delaware alone is enough to confer specific jurisdiction. The judges were split on the first issue: Judge Sleet held that registering does not constitute consent to jurisdiction, while Chief Judge Stark held the opposite. On the second issue, Judge Sleet held that sending the letter into Delaware was enough. Chief Judge Stark, on the other hand, noted that sending a letter into Delaware is an ''additional activity'' directed at Delaware that should be considered, but did not say he would consider it sufficient. He also explained that he did not consider sending a letter into Delaware necessary to confer specific jurisdiction there.

After issuing each of these decisions, both judges took the unusual step of certifying them for interlocutory appeal. Judge Sleet certified his entire decision, rather than certifying just the question Mylan raised in its briefing, which was limited to whether sending a paragraph IV letter into Delaware could confer specific jurisdiction. Judge Sleet noted that he did this because he considered Mylan's limited question to be an oversimplification of his holding.[36] Chief Judge Stark certified an appeal on two bases: (1) whether compliance with Delaware's business registration statutes constitutes consent to general jurisdiction, and (2) whether Delaware may exercise specific jurisdiction over Mylan Pharma in this ANDA suit.[37]

1. The generic's argument against personal jurisdiction

In its petition to the Federal Circuit for interlocutory review in the *AstraZeneca* case, Mylan argued that the act of sending a paragraph IV letter to the patent owner and the NDA holder cannot confer personal jurisdiction. Mylan analogized the paragraph IV letter to a letter threatening an infringement suit, something that the Federal Circuit has previously held is insufficient to confer personal jurisdiction.[38] Instead, according to the Federal Circuit, there must be other activities directed at the forum relating to the cause of action besides the letter threatening infringement.[39] Mylan asserted that allowing a paragraph IV letter to confer jurisdiction in the state where it was sent would run counter to the Federal Circuit's decision in *Silent Drive*. ''If sending voluntary letters threatening infringement litigation does not give rise to specific jurisdiction in the address-

[27] *Id.* at *31.
[28] *Id.* at *40.
[29] *Id.* at *42.
[30] *Id.*
[31] *Id.*
[32] *Id.* at *48.
[33] *Id.*
[34] *Id.* at *48–49.
[35] *Id.* at *55–56.

[36] Order Granting Mylan Pharms. Inc.'s Motion for Certification for Interlocutory Appeal, slip op. at 1–2 n.1, AstraZeneca AB v. Aurobindo Pharma Ltd., No. 14-664-GMS (D. Del. Nov. 11, 2014).
[37] Order Granting Motion for Certification for Interlocutory Appeal, Acorda Therapeutics Inc. v. Mylan Inc., No. 14-935-LPS (D. Del. Jan. 30, 2015).
[38] *See* Mylan Pharms. Inc.'s Petition for Permission to Appeal Pursuant to 28 U.S.C. § 1292(b) at 15, AstraZeneca AB v. Mylan Pharms. Inc., No. 15-117 (Fed. Cir. Dec. 29, 2014).
[39] *Id.* (citing Silent Drive, Inc. v. Strong Industries, Inc., 326 F.3d 1194, 1202 (Fed. Cir. 2003)).

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ee's forum, then neither can sending copies of statutorily required Notice Letters.''[40]

Mylan also argued that finding specific jurisdiction in the state where the letter was sent stands in contradiction to the Supreme Court's recent decision in *Walden v. Fiore*.[41] In *Walden*, the Court held that ''for a State to exercise jurisdiction consistent with due process, the defendant's suit-related conduct must create a *substantial connection* with the forum State.''[42] Further, the connection ''must arise out of the contacts that the defendant *himself* creates with the state, for the minimum contacts analysis looks to the defendant's contacts with the forum State itself, not the defendant's contacts with the persons who reside there.''[43]

Mylan argued that sending a paragraph IV letter creates no purposeful or substantial connection with a state. A Hatch-Waxman infringement suit is based on the highly artificial act of filing an ANDA, and the infringing act is complete upon filing it with the FDA in Maryland. The notional act of infringement thus actually could be argued to occur in Maryland, but the Federal Circuit has eliminated this argument for Maryland as an option for specific jurisdiction in ANDA cases.[44] Mylan argued that sending a statutorily required letter is not purposeful, and does not create a substantial, suit-related connection with the state to which the letter is sent.[45] Mylan continued that because the district court was concerned that *Daimler* may leave ANDA plaintiffs with few places to sue infringers, the court impermissibly expanded specific jurisdiction to compensate.[46] But general and specific jurisdiction are separate concepts, and ''[o]ne does not expand as the other contracts.''[47]

2. The brand argument for personal jurisdiction

In its opposition brief, AstraZeneca argued that, in addition to sending its paragraph IV letter into Delaware, Mylan had sufficient other contacts with the state to confer specific jurisdiction.[48] AstraZeneca argued that under Federal Circuit precedent, a single, litigation-related contact may satisfy the minimum contacts requirement for specific jurisdiction.[49] Here, not only did Mylan send a litigation-related letter to Delaware, but also had extensive other contacts with the state, rendering jurisdiction there fair and reasonable.[50] AstraZeneca argued that Mylan affected AstraZeneca's interests in Delaware, had strong commercial ties to Delaware through which it would market its infringing product upon FDA approval, was registered to do business in Delaware, held pharmaceutical licenses in Delaware, and made use of Delaware sales networks.[51] These contacts, AstraZeneca argued, were directly related to AstraZeneca's allegations of threatened infringement.[52]

In addition, AstraZeneca said that the district court's decision to exercise specific jurisdiction over Mylan was ''jurisprudentially wise.''[53] Because Hatch-Waxman cases routinely involve a large number of national companies, the ability to consolidate these cases into one district in front of a single judge, greatly reduces the burden on the parties and the courts. AstraZeneca argued that changing the status quo threatens expensive and duplicative trials in these cases.[54]

IV. Pharmaceutical companies should consider these decisions in their litigation strategies.

If the Federal Circuit upholds Judge Sleet's decision that the act of sending a paragraph IV letter into a state is enough to confer specific jurisdiction there, companies will need to consider how this seemingly insignificant statutory requirement may affect their overall business and litigation strategies. Brands may want to try to force paragraph IV letters to be sent into their favored forum, while generics may want to avoid sending such letters into such a forum.

The rules for exactly who must receive a paragraph IV letter seem clear at first glance, but upon closer examination, they appear to be somewhat ambiguous. For example, 21 U.S.C. § 355(j)(2)(B) requires an applicant to give notice to:

> (i) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and
>
> (ii) the holder of the approved application under this subsection for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

The implementing regulations[55] state: ''The name and address of the patent owner or its representative may be obtained from the United States Patent and Trademark Office.''[56] If the holder of the approved application does not reside or maintain a place of business in the United States, then the generic applicant must notify the application holder's attorney, agent, or other authorized official.[57] ''The name and address of the ap-

[40] *Id.* at 4.
[41] 134 S. Ct. 1115 (2014).
[42] *Id.* at 14 (quoting *Walden,* 134 S. Ct. at 1121)(emphasis in original)).
[43] *Id.* (quoting *Walden*, 134 S. Ct. at 1121–22 (internal quotation marks omitted)(emphasis in original)).
[44] *Id.* at 16 (citing Zeneca Ltd. v. Mylan Pharms., Inc., 173 F.3d 829 (Fed. Cir. 1999)).
[45] *Id.* at 14–15.
[46] *Id.* at 16–17.
[47] *Id.* at 17.
[48] AstraZeneca AB's Opposition to Mylan's Petition for Permission to Appeal Pursuant to 28 U.S.C. § 1292(b) at 7, AstraZeneca AB v. Mylan Pharms. Inc., No. 15-177 (Fed. Cir. Jan.12, 2015).
[49] *Id.* at 6 (citing Red Wing Shoe Co. v. Hockerson-Halberstadt, Inc., 148 F.3d 1355 (Fed. Cir. 1998) (explaining that cease-and-desist letters may satisfy the minimum contacts requirement)).
[50] *Id.* at 7.
[51] *Id.* at 8.
[52] *Id.* at 8.
[53] *Id.* at 13.
[54] *Id.*
[55] Note that the FDA recently proposed updated rules on paragraph IV letters, but did not clarify the particular issue of determining the correct addresses for the letters. *See* Abbreviated New Drug Applications and 505(b)(2) Applications, 80 Fed. Reg. 6801 (proposed Feb. 6, 2015), *available at* http://www.gpo.gov/fdsys/pkg/FR-2015-02-06/html/2015-01666.htm.
[56] 21 C.F.R. § 314.95(a)(1).
[57] § 314.95(a)(2).

plication holder or its attorney, agent, or authorized official may be obtained from the Orange Book Staff.''[58]

These rules may allow some debate over who exactly is the patent owner, who is an agent or representative, and who is ''designated.'' A brand may try to strategically ''designate'' a representative to receive its paragraph IV letters in its favored forum. A generic, on the other hand, may try to ignore such designation and send its paragraph IV letter directly to the NDA application holder and patent owner as provided by the statute. Or, if the representative is located in a more favorable forum, the generic may decide to send its letter to the designated representative rather than to the patent owner and NDA application holder.

Brands may use this uncertainty in personal jurisdiction over generic companies to their benefit by filing in a forum where the paragraph IV letter was sent to intentionally provoke a fight over personal jurisdiction, thereby increasing delay of the ultimate resolution of the case. If this happens, generics may want to think about filing a competing declaratory judgment action in its home forum. This tactic, however, has the potential to run afoul of the statutory requirements for an ''action for certainty'' when a brand does not sue within 45 days of the date of the paragraph IV letter.

To avoid such a consequence, a generic may be able to argue that because the brand filed the lawsuit in a forum without jurisdiction, the lawsuit does not have the effect of satisfying the 45 day requirement. Thus, because without jurisdiction, a lawsuit may be considered in effect not to have been filed, the generic would be allowed to file an action for certainty. So long as the generic is candid with the court about what it is doing, there may be little downside to filing a declaratory judgment action as a precautionary measure.

Even if generics are allowed to file declaratory judgment actions in this manner, it will be important for generics to file motions to dismiss for lack of personal jurisdiction early in the infringement case in the first forum. As with any motion to dismiss, however, there is no certainty as to how quickly a district court judge will issue a decision on such a motion.

Should generics succeed in arguing for more limited jurisdiction and in forcing suits into their home forums, it is foreseeable that multi-district practice will emerge in cases involving multiple filers who are reasonably proximate in time. Brands can be expected to seek MDL consolidation of cases that are venued in disparate forums but which involve common issues of patent validity. Some commentators have predicted that MDL in Hatch-Waxman cases will likely be venued in Delaware, New Jersey, and New York.

[58] *Id.*

V. Potential outcomes of the District of Delaware decisions.

The Federal Circuit has an opportunity to clear up the uncertainty that has arisen in Delaware as it relates to whether being registered to do business in a state is sufficient to confer general jurisdiction and whether sending a paragraph IV letter into a forum is sufficient to confer specific jurisdiction. It is at least possible that the Supreme Court may take an interest in this matter, given its willingness to take up patent cases and personal jurisdiction cases.

The FDA also has the ability to at least clarify the rules for paragraph IV notices and clear up some of the confusion. For example, it could make the rules more precise concerning exactly to whom a paragraph IV letter must be sent, and at what address. Interested parties may want to comment on FDA's proposed rule to ensure that FDA understands the importance of this particular topic on Hatch-Waxman litigation. The comment period is open until May 7. Although a rule clarification is unlikely to affect how courts ultimately decide personal jurisdiction, it may at least avoid satellite litigation around the propriety of the addressees chosen for paragraph IV notice letters that may be generated by personal jurisdiction issues.

While it is currently unclear what the outcome of these cases will be, these issues are ones that Hatch-Waxman litigants should keep in mind, not only while considering venue at the time a paragraph IV notice letter is sent, but long before. Indeed, litigants should keep these issues in mind when considering the choice of designating NDA and patent owners and their agents, and when considering when and where to incorporate, register, and perform other tasks that may have a substantial impact on specific personal jurisdiction.

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