

Establishing Personal and General Jurisdiction in A Paragraph IV Case in the Aftermath of *Daimler and Mylan*

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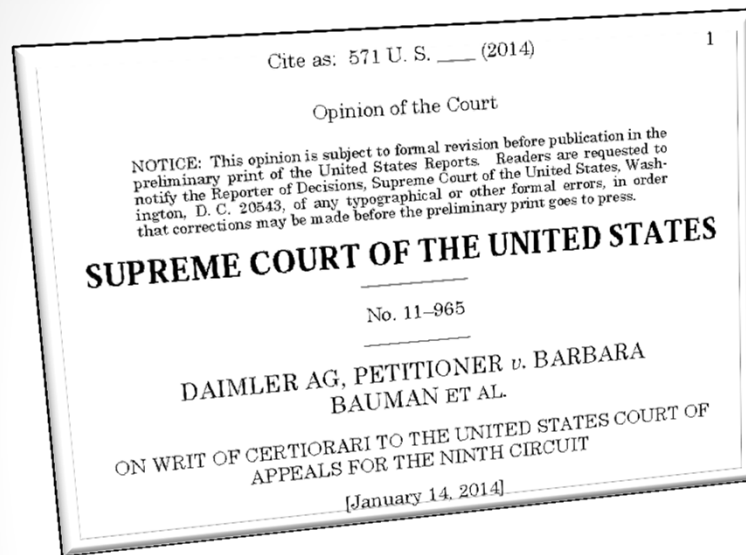
Agenda

- Overview of Personal Jurisdiction
- The Impact of *Daimler AG v. Bauman*
- Overview Of Recent Cases
- Strategic Considerations And Takeaways

Personal Jurisdiction Pre-*Daimler*

- District Courts exercise personal jurisdiction over Hatch-Waxman parties based on “general jurisdiction”
 - **Specific jurisdiction** arises because of defendant’s purposeful direction to the forum, and where the activities in the state give rise to the claim itself
 - **General jurisdiction** does not depend on the nature of the claim in that the contact is “continuous and systematic” (e.g., Technical acts of infringement + substantial revenue from other drug sales)

The Supreme Court Clarifies The Rule



Daimler AG v. Bauman **134 S. Ct. 746 (2014)**

- A case involving Argentinians suing a German company in N.D. Ca. for its subsidiary's overseas actions -- and connected to N.D. Ca. by a different subsidiary (incorporated in DE, PPB in NJ)
- Supreme Court held that the general jurisdiction inquiry is not whether a foreign corporation's contacts with a forum are "in some sense 'continuous and systematic'"
- Rather, the test is whether the contacts "are so 'continuous and systematic' as to render [the foreign corporation] **essentially at home** in the forum."

The Impact On Hatch-Waxman Cases Seemed Grave

- Generics cannot just be subject to jurisdiction wherever they have sales
 - That would result in subjecting generics to jurisdiction everywhere, a concept that the *Daimler* Court found to be “unacceptably grasping”
- Complications for forum selection
 - *Daimler* is broadly written
 - Should Ps sue only in “home districts”? Even if LRs are unfavorable?
 - Risk of dismissal and no stay – at-risk launch, jury trial

District Court Cases

Specific Jurisdiction

- Allergan, Inc. v. Actavis, Inc., No. 2:14-CV-188, 2014 WL 7336692 (E.D. Tex. Dec. 23, 2014)
- AstraZeneca AB v. Mylan Pharm., Inc., 72 F. Supp. 3d 549 (D. Del. 2014)
- Acorda Therapeutics, Inc. v. Mylan Pharm. Inc., No. CV 14-935-LPS, 2015 WL 186833 (D. Del. Jan. 14, 2015)
- Eli Lilly & Co. v. Mylan Pharm., Inc., No. 1:14-CV-00389-SEB-TA, 2015 WL 1125032 (S.D. Ind. Mar. 12, 2015)
- Eli Lilly & Co. v. Nang Kuang Pharm. Co., No. 1:14-cv-1647, 2015 U.S. Dist. LEXIS 111510 (S.D. Ind. Aug. 24, 2015)
- Novartis Pharm. Corp. v. Zydus Noveltch Inc., No. 14-CV-1104-RGA, 2015 WL 4720578 (D. Del. Aug. 7, 2015)

District Court Cases

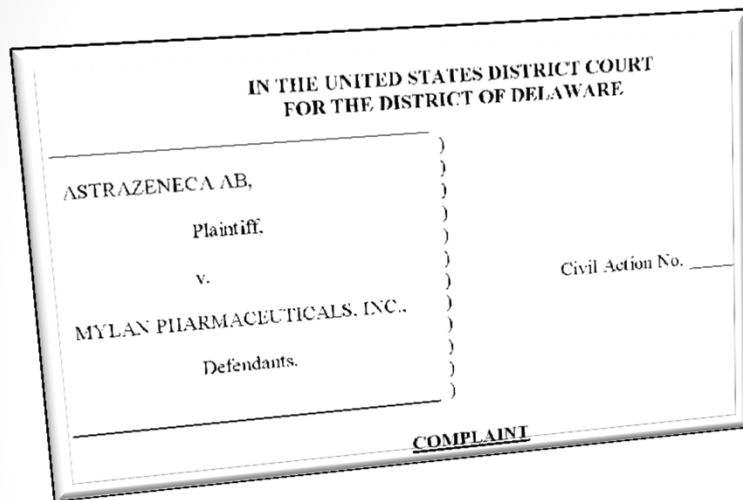
“Consent” General Jurisdiction

- Acorda Therapeutics, Inc. v. Mylan Pharm. Inc., No. CV 14-935-LPS, 2015 WL 186833 (D. Del. Jan. 14, 2015)
- Forest Labs., Inc. v. Amneal Pharm. LLC, No. CV 14-508-LPS, 2015 WL 880599 (D. Del. Feb. 26, 2015)
- Novartis Pharm. Corp. v. Mylan Inc., No. CV 14-777-RGA, 2015 WL 1246285 (D. Del. Mar. 16, 2015)
- Otsuka Pharm. Co. v. Mylan Inc., No. CIV.A. 14-4508 JBS, 2015 WL 1305764 (D.N.J. Mar. 23, 2015)
- Senju Pharm. Co. v. Metrics, Inc., No. CIV.A. 14-3962 JBS, 2015 WL 1472123 (D.N.J. Mar. 31, 2015)

No Personal Jurisdiction

- Purdue Pharma L.P. v. Collegium Pharm., Inc., No. CV 15-260-SLR, 2015 WL 4653164 (D. Del. Aug. 6, 2015)

Mylan Raises The Defense In Delaware – But What Result?



AstraZeneca AB v. Mylan Pharms., Inc.,
No. 1:14-cv-696 (D. Del. Nov. 5, 2014)
(Sleet, J.) (on appeal)

- AstraZeneca made three arguments in support of personal jurisdiction:
 - 1) Mylan is subject to general jurisdiction in Delaware
 - 2) Mylan consented to general jurisdiction in Delaware
 - 3) Mylan is subject to specific jurisdiction in Delaware
- The court addressed each argument in its opinion

Mylan Raises The Defense In Delaware – But What Result?

- ***AstraZeneca AB v. Mylan Pharms., Inc.*, No. 1:14-cv-696 (D. Del. Nov. 5, 2014) (Sleet, J.) (on appeal)**
 - General Jurisdiction:
 - Mylan was not “at home” in Delaware
 - Mylan’s registration to do business in Delaware did not, without more, subject Mylan to general jurisdiction in Delaware
 - “AstraZeneca notes only that Mylan is registered to do business in Delaware and has a broad network of third-party contacts within the state. Such allegations fail to show activity ‘comparable to domestic enterprise in [Delaware]. . . . Upholding jurisdiction on these allegations alone would permit the ‘exercise of general jurisdiction in every [s]tate,’ a result specifically precluded by the Supreme Court.”
 - “[F]amiliarity with the court system in Delaware is insufficient to render a defendant at home here, as envisioned by *Daimler*.”

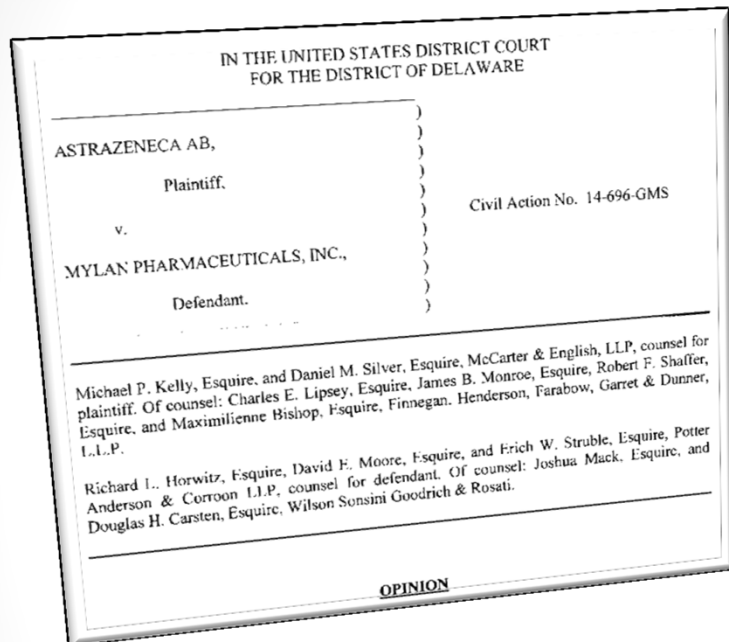
Mylan Raises The Defense In Delaware – But What Result?

- ***AstraZeneca AB v. Mylan Pharms., Inc.*, No. 1:14-cv-696 (D. Del. Nov. 5, 2014) (Sleet, J.) (on appeal)**
 - Consent to General Jurisdiction:
 - “In light of the holding in *Daimler*, the court finds that Mylan’s compliance with Delaware’s registration statutes--mandatory for *doing business* within the state--cannot constitute consent to jurisdiction”
 - Specific Jurisdiction:
 - “[T]he act of filing an ANDA and the paragraph IV notification provide sufficient minimum contacts with the state of Delaware under a specific jurisdiction analysis.”
 - An ANDA filing is a “real act” with consequences that would be “suffered in Delaware”

Mylan Raises The Defense In Delaware – But What Result?

- ***AstraZeneca AB v. Mylan Pharms., Inc.*, No. 1:14-cv-696 (D. Del. Nov. 5, 2014) (Sleet, J.) (on appeal)**
 - Specific Jurisdiction:
 - Mylan argued that “its activities are not purposefully directed at the state of Delaware, where AstraZeneca U.S. is organized”
 - Court rejected Mylan’s argument as “creat[ing] the untenable position that its conduct is not directed to any jurisdiction.”
 - Court noted that “Mylan’s contact with Delaware is not illusory,” in view of the fact that Mylan’s Paragraph IV certification was sent to AstraZeneca U.S. in Delaware.

Mylan Raises The Defense In Delaware – But What Result?



AstraZeneca AB v. Mylan Pharms., Inc.,
No. 1:14-cv-696 (D. Del. Nov. 5, 2014)
(Sleet, J.) (on appeal)

- Specific Jurisdiction:
 - The court noted that the Federal Circuit had “eliminated the possibility that Maryland (the location of the FDA and where ANDAs are filed) could exercise specific jurisdiction over ANDA filers, in order to avoid creating a supercourt with jurisdiction in all cases.”
 - *Zeneca Ltd. v. Mylan Pharm., Inc.*, (Fed. Cir. 1999). 173 F.3d 829
 - As a result, “the only possible alternative forum is the state of residence for the patent holder.”

A Split In Delaware On Jurisdiction

- ***Acorda Therapeutics, Inc. v. Mylan Pharms. Inc., No. 1:14-cv-935 (D. Del. Jan. 14, 2015) (Stark, J.) (on appeal)***
 - Acorda made the same three arguments as AZ
 - Judge Stark found that Mylan had consented to general jurisdiction and was subject to specific jurisdiction:
 - “While...the Court agrees with Mylan that this Court cannot exercise general personal jurisdiction over either of the Mylan Defendants on the basis that they are ‘at home’ in Delaware -- *Daimler* does not change the fact that Mylan Pharma consented to this Court’s exercise of personal jurisdiction when it registered to do business and appointed an agent for service of process in the State of Delaware. In addition, Plaintiffs have met their burden to establish that this Court has personal jurisdiction over Mylan Pharma based on specific jurisdiction”



A Split In Delaware On Jurisdiction

- ***Acorda Therapeutics, Inc. v. Mylan Pharms. Inc., No. 1:14-cv-935 (D. Del. Jan. 14, 2015) (Stark, J.) (on appeal)***
 - Mylan was not “at home” in Delaware. But Mylan was deemed to have consented to general jurisdiction in Delaware because it is registered to do business there
 - A “consent theory” based on having a registered agent
 - “The undersigned Judge is aware, of course, that a fellow member of this Court has reached a contrary conclusion on this point. . . . However, in the view of the undersigned Judge, when courts have clearly held that compliance with a state’s registration statute confers general jurisdiction, corporations have the requisite notice to enable them to structure their conduct so as to be assured where they will, and will not, be subject to suit.”



A Split In Delaware On Jurisdiction

- ***Acorda Therapeutics, Inc. v. Mylan Pharms. Inc.*, No. 1:14-cv-935 (D. Del. Jan. 14, 2015) (Stark, J.) (on appeal)**
 - Judge Stark found specific jurisdiction based on the transmission of a notice letter by Mylan Pharms. Inc. and resulting injury to Acorda
 - Acorda is based in NY, but was incorporated under Delaware law
 - “One factual distinction between *AstraZeneca* and the instant case is that in *AstraZeneca* Mylan Pharma had mailed its paragraph IV certification letter to the plaintiff . . . in Delaware, where *AstraZeneca* is both incorporated and has its principal place of business. . . . 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.”



A Split In Delaware On Jurisdiction

- ***Acorda Therapeutics, Inc. v. Mylan Pharms. Inc.*, No. 1:14-cv-935 (D. Del. Jan. 14, 2015) (Stark, J.) (on appeal)**
 - Judge Stark ordered discovery into the relationship between parent Mylan Inc. and subsidiary Mylan Pharms. to determine whether jurisdiction could be granted based on agency theory
 - Raises concerns for foreign generics filing ANDAs through wholly-owned subsidiaries



A Split In Delaware On Jurisdiction

- ***Forest Labs., Inc. v. Amneal Pharms. LLC*, No. 14-508 (D. Del. Feb. 26, 2015) (Mag. Burke) (D. Del. Mar. 30, 2015) (Stark, J.)**
 - Magistrate Judge Burke issued a report and recommendation recommending that Mylan’s motion to dismiss be denied
 - Mylan consented to personal jurisdiction by complying with Delaware’s registration statute
 - “[T]he Court agrees with the result in *Acorda*, and respectfully declines to follow the holding in *AstraZeneca AB*.”



A Split In Delaware On Jurisdiction

- ***Forest Labs., Inc. v. Amneal Pharms. LLC*, No. 14-508 (D. Del. Feb. 26, 2015) (Mag. Burke) (D. Del. Mar. 30, 2015) (Stark, J.)**
 - Judge Stark adopted the R&R and denied motion to dismiss
 - “Given the detailed reasoning provided in the Report, as well as the lengthy discussion . . . in *Acorda*, and further given that Mylan has . . . raised no arguments that are not adequately addressed in [the R]eport and/or *Acorda*, the Court finds it unnecessary to address Mylan’s Motion to Dismiss or its Objections any further.”



A Split In Delaware On Jurisdiction

- ***Novartis Pharms. Corp. v. Mylan Inc.*, Nos. 14-777, 14-820 (D. Del. Mar. 16, 2015) (Andrews, J.)**
 - Judge Andrews found that defendant Mylan Pharms. had consented to general jurisdiction by complying with the Delaware registration statutes (co-defendant Mylan Inc. had not registered and thus not consented)
 - “I am not sure I have anything to add to what my colleagues have already said. The factual history of the rivastigmine litigation . . . parallels very closely with the litigation history in *Acorda*. On the general jurisdiction question, I am going to follow *Acorda* and *Forest Labs*.”
 - Followed *Acorda* and ordered jurisdictional discovery as to Mylan Inc.



A Split In Delaware On Jurisdiction

- ***Novartis Pharms. Corp. v. Zydus Novel Tech Inc.*, No. 14-cv-1104 (D. Del. Aug. 7, 2015) (Andrews, J.)**
 - Zydus is a NJ corporation based in Vermont
 - Plaintiffs did not dispute the lack of general jurisdiction
 - The Court found no specific jurisdiction and dismissed:
 - “Zydus Noveltech has not registered to do business in Delaware, and does not have an agent to accept process in the state. Zydus Noveltech has not previously litigated in Delaware Defendant probably anticipated being sued in Delaware . . . , but Defendant’s anticipation is not by itself significant for the specific jurisdiction analysis. Defendant has no property, staff or offices in the state and does not conduct any business here. No work related to preparing the ANDA or product was conducted in this District.”



A Split In Delaware On Jurisdiction

- ***Novartis Pharms. Corp. v. Zydus Novel Tech Inc.*, No. 14-cv-1104 (D. Del. Aug. 7, 2015) (Andrews, J.)**
 - Court found no specific jurisdiction
 - “Specific jurisdiction cannot be exercised merely because an ANDA notice letter was sent to a Delaware corporation, in another state”
 - “It does not follow that the injury should be where the Plaintiff is incorporated, Delaware, rather than where the letter was directed, New Jersey.”



Some Consistency In New Jersey?

- ***Otsuka Pharm. Co. v. Mylan Inc.*, No. 14-cv-4508 (D.N.J. Mar. 23, 2015) (Simandle, J.)**
 - Three Mylan subsidiaries -- Mylan Inc., Mylan Pharms. and Mylan Labs (India)
 - Mylan Inc. and Mylan Pharms. deemed to have consented to general jurisdiction in NJ because it is registered to do business there
 - Mylan Labs: no jurisdiction



Some Consistency In New Jersey?

- ***Boehringer Ingelheim Pharma GmbH & Co. KG v. Teva Pharms. USA, Inc.*, No. 14-cv-7811 (D.N.J. July 16, 2015) (Cooper, J.)**
 - Relied on *Otsuka v. Mylan* to deny Mylan's motion to dismiss based on its consent to jurisdiction
- ***Senju Pharm. Co. v. Metrics, Inc.*, No. 14-3962 (D.N.J. Mar. 31, 2015) (Simandle, J.)**
 - Metrics deemed to have consented to general jurisdiction in NJ because it accepted service through a registered agent there
 - Its parent company Mayne was not subject to general jurisdiction in NJ; jurisdictional discovery granted with respect to specific jurisdiction of parent company



Other Districts Weigh In

- ***Allergan Inc. v. Actavis Inc.*, No. 2:14-cv-638 (E.D. Tex. Dec. 23, 2014) (Gilstrap, J.)**
 - DJ suit brought by Allergan against Actavis
 - Court did not decide the issue of general jurisdiction due to the fact it found that it found specific jurisdiction over defendants
 - ANDA would cause harm to Texas where the drug was manufactured and distributed
 - Actavis was licensed to distribute drugs in the state
 - Actavis was targeting generic market in Texas



Other Districts Weigh In

- ***Eli Lilly & Co. v. Mylan Pharms. Inc.*, No. 1:14-cv-389 (S.D. Ind. Mar. 12, 2015) (Barker, J.)**
 - Plaintiffs failed to establish general jurisdiction over Mylan
 - Mylan subject to specific jurisdiction by sending a paragraph IV certification notice letter to Lilly in Indiana
- ***Eli Lilly & Co. v. Nang Kuang Pharm. Co.*, No. 1:14-cv-1647, 2015 U.S. Dist. LEXIS 111510 (S.D. Ind. Aug. 24, 2015) (Pratt, J.)**
 - Jurisdictional discovery denied but similar holding



Resolution at the Federal Circuit

- **Cases:** *AstraZeneca AB v. Mylan Pharms., Inc.*, No. 1:14-cv-696 (Sleet, J.); *Acorda Therapeutics, Inc. v. Mylan Pharms. Inc.*, No. 1:14-cv-935 (Stark, J.)
- **Docketed:** March 17, 2015
- **Questions Presented:**
 1. Does Mylan's compliance with Delaware's registration statutes (8 Del. C. §§ 371 and 376) constitute consent to general jurisdiction?
 2. Does the Constitution permit Delaware to exercise specific personal jurisdiction over Mylan in ANDA suits?
- **Likely Decision:** May/June 2016

Predicting Outcomes - General Jurisdiction

1. Legal – Did *Daimler* change the game on consent?
 - Mylan: Starting with *Int'l. Shoe* and now *Daimler*, key inquiry is relationship to the forum
 - Circuit Split
 - Legal fallacy
 - Astra/Acorda: The US and DE Supreme Courts already decided the issue
 - Early Supreme Court cases
 - No Consent in *Daimler*
2. Practical
 - Mylan: National presence means jurisdiction in 50 states
 - Astra/Acorda:
 - Only 12 states with statute or judicial decision
 - The flip means virtually no general jurisdiction

Predicting Outcomes - Specific Jurisdiction

1. Legal - Does the prospect of future sales support specific jurisdiction?
 - Mylan:
 - Suit-related conduct must create connection (*Walden*)
 - Stream of commerce (*Asahi Metals*)
 - Astra/Acorda:
 - Future activity is just fine (*Calder*)
 - Established network
2. Practical
 - See General Jurisdiction
 - Missing the boat for decades



Looking Ahead

Still no controlling authority from Federal Circuit

↳ *AstraZeneca v. Mylan* and *Acorda v. Mylan* are briefed but not yet calendared

Expect generics to raise the defense, particularly in non-traditional ANDA jurisdictions and where an intra-District split is possible

File safety suits but consider generic “at home” jurisdictions as a first place to file

Be prepared for jurisdictional discovery

Looking Ahead

Motions to transfer and MDL consolidation suits?

Generics setting up “home” jurisdictions to game Local Rules?

Discussion

Predictions for *AZ v. Mylan* and *Acorda v. Mylan*

Generic Strategies

Brand Strategies

Policy Considerations