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Cuozzo and the Limits of Patent Office Discretion

Thomas B. King and David B. Clark

The U.S. Supreme Court recently granted certiorari in *Cuozzo Speed Technologies v. Lee*, its first foray into patent office *inter partes* review practice. IPRs are a type of agency adjudication that determine whether patents are valid. The decision to grant cert was not surprising, given that *Cuozzo* involves a fundamental question of patent interpretation that deeply divided the Federal Circuit. But the Supreme Court surprised many by granting cert on a second issue: the Federal Circuit's power to review whether the Patent Trial and Appeal Board exceeded its statutory authority when it determines whether or not to institute review.

The Federal Circuit has consistently held that it lacks the jurisdiction to review a PTAB decision to institute review. But the soundness of those holdings is questionable. Under well established precedent, all agency action is presumptively subject to judicial review, absent "clear and convincing evidence" of congressional intent to the contrary.

And here, although Congress likely intended to halt review as to the substantive merits of an institution decision, whether it did so for other questions, such as whether the PTAB's procedures exceeded its authority, appears much less likely. Thus, the blanket rule precluding review of any aspect of a PTAB's decision to institute review appears improper.

Excerpted from Law360. To read the full article, please click here (subscription required).

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The Recent Federal Circuit Decision in *Acorda Therapeutics v. Mylan Pharmaceuticals* May Not be the Last Word on Jurisdiction in ANDA Cases

Paul Dietze and Mini Kapoor

On March 18, 2016, the Federal Circuit held that Mylan Pharmaceuticals, Inc. ("**Mylan**"), a generic drug manufacturer, was subject to specific jurisdiction in Delaware because of Mylan's filing an abbreviated new drug application ("**ANDA**") and "contemplate[d] plans to engage in marketing of the proposed generic drugs" in the state.[1] The ruling affirmed two different decisions by judges in the United

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States District Court for the District of Delaware that Mylan was subject to specific jurisdiction in Delaware.[2]

I. Procedural Posture of the Cases

Mylan filed two separate ANDAs with the U.S. Food & Drug Administration ("**FDA**") seeking permission to market generic versions of two pharmaceutical products marketed by Acorda Therapeutics, Inc. and AstraZeneca AB under the statutory scheme outlined in the Hatch-Waxman Act (the "**Act**"). As permitted under the Act, Mylan certified that the patents of the brand name drug companies listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("**the Orange Book**") were either invalid or would not be infringed by Mylan's marketing of its proposed generic version of the drugs. Each certification is deemed an artificial act of infringement under the Act, permitting brand name drug companies to sue the generic drug company. Acorda and AstraZeneca sued Mylan for patent infringement in two separate lawsuits filed in Delaware. Mylan moved to dismiss in both cases, arguing that they were not subject to either general or specific jurisdiction.[3]

Specifically, Mylan, citing the Supreme Court's decision in *Daimler*,[4] argued that it was not subject to general jurisdiction in Delaware because it did not have contacts with Delaware that were so continuous "as to render it essentially at home in the forum state," and was not subject to specific jurisdiction because it did not satisfy the minimum contacts requirement.[5] Both district court decisions held that Mylan was subject to specific jurisdiction in Delaware.[6] The district court decisions, however, differed as to whether or not Mylan was subject to general jurisdiction in Delaware.

II. The Opinion

On appeal, the majority opinion of the Federal Circuit panel affirmed specific jurisdiction without addressing general jurisdiction.[7] The panel identified Mylan's ANDA filings as "formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs" and held the particular actions that "Mylan has already taken—its ANDA filings—for the purpose of engaging in that injury-causing and allegedly wrongful marketing conduct in Delaware" were sufficient to satisfy the minimum contacts requirement.[8] The court also identified the significant expense a generic drug company incurs in the ANDA application process as evidencing an ANDA filer's plans to market the drug.[9] The court further noted that Mylan's distribution channels in Delaware make clear that these future marketing activities would "unquestionably take place in Delaware (at least)."[10] The court concluded that the planned sales were "close enough" to the subject of the lawsuits to satisfy the minimum contacts requirement and justify specific jurisdiction in Delaware.[11]

Having found the minimum contacts requirement satisfied, the court considered whether Delaware's exercise of jurisdiction would "offend traditional notions of fair play and substantial justice."[12] The court held that other considerations, such as those identified in B*urger King*, would not render jurisdiction unreasonable.[13]

III. The Logical Implications

By establishing specific personal jurisdiction by virtue of filing an ANDA with plans to direct sales of a generic drug into a particular state, a generic drug manufacturer, such as Mylan, will be subject to specific jurisdiction in any state in which they intend to market the generic drug. Almost always, this will be any state in the country.

Prior to the Supreme Court's ruling in *Daimler*, branded-drug companies often asserted jurisdiction in a state based on general jurisdiction, arguing that the generic company was subject to jurisdiction in the state because they intended to sell the generic version of the drug in the state. In *Daimler*, however, the Supreme Court held that general jurisdiction cannot attach unless the defendant's contacts with the forum state are "so continuous and systematic as to render [the non-resident corporate defendant] *essentially* at home in the forum State."[14] A corporation is essentially at home only in its state of incorporation

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and the state where its principal place of business is located.[15] *Daimler* specifically rejected the notion that general jurisdiction will lie "in every State in which a corporation engages in a substantial, continuous, and systematic course of business."[16] This decision in Daimler raised the concern as to whether branded-drug companies could continue to rely on general jurisdiction to file suits in the forum of their choice. The court's ruling in *Acorda*, by establishing specific jurisdiction by filing an ANDA with plans to sell the drug in a state, however, arguably makes the high bar for general jurisdiction established in *Daimler* of little significance in ANDA cases.

Thus, under *Acorda*, branded-drug companies are likely to continue to have wide latitude in selecting the forum in which to sue an ANDA filer. Delaware and New Jersey, where ANDA cases are often brought, are likely to continue to be forums of choice for ANDA cases.

IV. Expected Future Litigation

A letter filed by Mylan on March 25, 2016 in an unrelated case indicates that Mylan plans to seek panel and en banc rehearing in *Acorda*.[17] The letter provides a preview of Mylan's potential arguments for rehearing. Mylan is expected to argue that *Acorda's* holding that Mylan is subject to specific jurisdiction in every state "is contrary to the basic notion of specific jurisdiction and the more basic constitutional guarantees at the heart of the Supreme Court's due process/personal jurisdiction jurisprudence."[18] Mylan is further expected to argue that *Acorda* was wrongly decided because it "simply recreates the pre-*Daimler* status quo by allowing courts throughout the nation to rely on specific jurisdiction where general jurisdiction is no longer applicable."[19] Mylan is also expected to argue that *Acorda's* reliance on Mylan's future contacts in Delaware is contrary to Supreme Court's *Walden* decision.[20] Finally, Mylan is expected to argue that finding jurisdiction based on Mylan's ANDA filing is misplaced in light of *Zeneca*, where the federal circuit "held that submission of an ANDA to the FDA in Maryland did not authorize the exercise of jurisdiction over the ANDA filer by Maryland federal courts."[21] *Acorda*, Mylan argued, makes "*Zeneca* merely academic."[22]

Regardless of the Federal Circuit's final ruling, the losing party may very well file a petition for certiorari with the Supreme Court seeking review of the Federal Circuit's decision. That both sides were represented at the Federal Circuit by former Solicitor Generals (Theodore Olson for Acorda and AstraZeneca and Paul Clement for Mylan) shows that each side considers this case to be important and that they are prepared to ask the Supreme Court to consider the matter.

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[1] *Acorda Therapeutics Inc. et al. v. Mylan Pharm. Inc.*, No. 2015-1456 and *AstraZeneca AB v. Mylan Pharm. Inc.*, No. 2015-1460, 2016 WL 1077048 (Fed. Cir. March 18, 2016).

[2] *Acorda Therapeutics Inc. & Alkermes Pharma Ireland Ltd. v. Mylan Pharm. Inc. & Mylan Inc.*, 78 F. Supp. 3d 572 (D. Del. 2015) (Stark, C.J.); *AstraZeneca AB v. Mylan Pharm. Inc.*, 72 F. Supp. 3d 549 (D. Del. 2014) (Sleet, J.).

[3] *Acorda*, No. 1:14-cv-00935, 2014 WL 8772659 (Defs.' Br. Supp. Mot. Dismiss) (Aug. 27, 2014); *AstraZeneca*, No. 14-696, 2014 WL 4745288 (Defs.' Br. Supp. Mot. Dismiss) (June 26, 2014).

[4] *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014).

[5] *Acorda*, No. 1:14-cv-00935, 2014 WL 8772659 (Defs.' Br. Supp. Mot. Dismiss 3, 6) (Aug. 27, 2014); *AstraZeneca*, No. 1:14-00696, 2014 WL 4745288 (Defs.' Br. Supp. Mot. Dismiss 5, 13) (June 26, 2014).

[6] *Acorda*, 78 F. Supp. 3d at 597; *AstraZeneca*, 72 F. Supp. 3d at 560.

[7] Judge O'Malley opined that by virtue of voluntarily electing to do business in Delaware, and registering and electing an agent for service of process in the state, Mylan was subject to general jurisdiction in Delaware. *Acorda*, Nos. 2015-1456 & 2015-1460, 2016 WL 1077048 at *11 - *12 (Judge O'Malley *concurring*).

[8] *Acorda*, Nos. 2015-1456 & 2015-1460, 2016 WL 1077048 at *8 -*9.

[9] *Id.* at *11 - *12.

[10] *Id.* at *13.

[11] *Id.*

[12] *Id.* at *13 -*14 (quoting *Int'l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945)).

[13] *Burger King Corp. v. Rudzewicz*, 471, U.S. 462, 477 (1985).

[14] *Daimler*, 134 S. Ct at 758 n.11 (emphasis added).

[15] *Id.* at 760.

[16] *Id.* at 760-61 (internal quotations omitted).

[17] *Takeda GmbH, et al., v. Mylan Pharm. Inc.* 1:15-cv-00093 (Defs.' Letter Status Rep.) (Mar. 25, 2016).

[18] *Id.*

[19] *Id.*

[20] *Walden v. Fiore*, 134 S. Ct. 1115 (2014).

[21] *Zeneca Ltd. v. Mylan Pharm., Inc.*, 173 F.3d 829 (Fed. Cir. 1999).

[22] *Takeda GmbH, et al., v. Mylan Pharm. Inc.* 1:15-cv-00093 (Defs.' Letter Status Rep.) (Mar. 25, 2016).

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7 Ways to Survive an Alice Patent Challenge

(John) Russell Emerson

(John) Russell Emerson

While the U.S. Supreme Court's Alice decision has led to a wave of software related patents being invalidated by district courts, there are still opportunities for obtaining protection for such inventions from the patent office and keeping them intact in an infringement fight.

The Supreme Court in June 2014 struck down Alice Corp.'s patents on computerized trading methods, holding that abstract ideas implemented with a computer cannot be patented under Section 101 of the Patent Act. As a result, the courts and U.S. Patent and Trademark Office examiners are taking a tougher stance against these patents.

"The major challenge companies face in light of Alice is the challenge of uncertainty," said John Russell Emerson, a partner at Haynes and Boone, LLP. "As the Alice court itself admitted, almost any invention can be described in abstract terms. Thus, the [test] often collapses into a search for an inventive concept, which is a necessarily subjective test for which we have no meaningful guidance."

But attorneys say that prosecuting and asserting software related patents isn't a lost cause. Rather, the process of securing and litigating these IP rights involves a more calculated approach.

Excerpted from Law360. To read the full article, please click here (subscription required).

Circumstances Mandating a Commercial Marketing Notice by a Biosmilar Applicant Ripe for Guidance from the High Court

Scott Cunning and Mini Kapoor

Scott Cunning

Mini Kapoor, Ph.D.

Several cases are pending around the country, but no consensus exists on the circumstances that would require a biosimilar applicant to provide a commercial marketing notice under the Biologics Price Competition and Innovation Act (BPCIA). In light of the implications on the biosimilar's entry to the market, the courts' interpretation on whether and when notice is required is of considerable significance to the biologics and biosimilar field.

Excerpted from the Houston Law Review. To read the full article, please click here.

EU and U.S. Finally Reach Deal on New Data Transfer Framework

Gavin D. George

Gavin George

Less than two days after an enforcement moratorium expired, U.S. and EU officials in transatlantic data transfer talks have reached a new "Privacy Shield" framework to replace the Safe Harbor regime struck down in the *Schrems* case last year. The new framework, also known as Safe Harbor 2.0, is expected to increase obligations on U.S. companies that handle the personal data of Europeans, while bringing stronger privacy enforcement by the U.S. Federal Trade Commission ("**FTC**"). The new Privacy Shield framework also includes new limitations on data surveillance by U.S. authorities, which had been a major sticking point during the negotiations.

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As background, EU privacy law prohibits the transfer of personal data to U.S. organizations unless those organizations demonstrate an "adequate level of protection." Until last year, the most common method to demonstrate this adequate level of protection was self-certification under the Safe Harbor principles, a standard administered by the U.S. Department of Commerce and enforced by the FTC. However, last October the European Court of Justice decided the *Schrems* case, which ended protected data transfers under the Safe Harbor principles and casted doubt on other data transfer mechanisms to the U.S. (namely, binding corporate rules and standard contractual clauses). Over the past three months, the U.S. Department of Commerce and the European Commission have been urgently trying to negotiate a replacement for the Safe Harbor regime. European regulators had agreed to an enforcement moratorium until the end of January to allow time for negotiations.

Even though Privacy Shield has now been announced as a replacement for Safe Harbor, the details of the new framework are still to be worked out. As such, it is too early to tell when it will be fully operational and how U.S. businesses will certify compliance with it. However, one thing that seems certain is that U.S. companies processing European personal data will have to agree to comply with decisions by European regulators in relation to that data. Already in Europe, some are calling the new Privacy Shield framework too weak, and the opinion of the EU's numerous data protection regulators remains unknown. After the details are hammered out by the U.S. Department of Commerce and the European Commission, aspects of the new framework will doubtless come under scrutiny by EU politicians, regulators, and courts.

Though the Privacy Shield framework is still in its preliminary stages and much ambiguity remains, U.S. business should welcome these steps toward more certainly in a post-*Schrems* world. The sudden state of non-compliance with EU privacy rules that erupted after *Schrems* has been a key concern for global companies that rely on international data transfers. Many data-focused companies with data servers and data storage located in the U.S. relied on and invested heavily into the Safe Harbor regime before *Schrems*. Even global companies that do not deal in the commoditization of personal data relied on the regime to move personal information about employees, contractors, and vendors into and out of the EU.

Once Safe Harbor was gone, many companies decided to adopt the EU standard privacy clauses into their contracts and affiliate agreements as a substitute method of demonstrating an "adequate level of protection" for European personal data. However, this alternative is not guaranteed, as the EU standard privacy clauses are at risk of invalidation via an EU court challenge on the same grounds cited in the *Schrems* decision. Because of this uncertainty, many other companies previously reliant on the Safe Harbor regime have taken a wait-and-see approach over the past three months, and should be encouraged that this new Privacy Shield framework has come into clearer focus.

The European Commission is now expected to consider and prepare a draft adequacy decision regarding Privacy Shield over the next few weeks. Once completed, the final Privacy Shield framework will be voted on by the European Commission. A group of European data protection regulators followed the announcement of the Privacy Shield framework by saying that the group would not give any opinion on the legality of EU standard privacy clauses until spring. The end result of these Privacy Shield negotiations with the U.S. will not be an international treaty, but rather an agreement with the U.S. Department of Commerce, the finalization of which will not require congressional or presidential approval. However, the finalization of the Privacy Shield negotiations with the U.S. will most likely be followed by a court challenge against the new framework in the EU.

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IP QUIZ

Trademark Trivia
Is there a likelihood of confusion?

Attempted registration

Registered mark

According to the U.S. Trademark Trial and Appeal Board, the answer is NO.

The Board reversed the U.S. Trademark Office's initial refusal of an application to register the stylized mark DIGITAL COUPONS covering promotional goods and services, including offering coupons and special offers in exchange for product and/or service reviews, in light of a prior registration for the stylized mark DQ DIGITAL QPONS covering overlapping services. Here, although the Board found that the goods and services covered by each mark were "legally identical" and that they would be offered in the same channels of trade, the Board found that confusion between the marks was not likely because of the "fundamental differences" between the marks.

Of particular importance in the Board's analysis was the highly descriptive nature of the term (or phonetic equivalent) DIGITAL COUPONS with respect to the goods and services at issue. Given that significance, the Board asserted that consumers were more likely to equate that term with the relevant goods and services than with the source of those goods and services. Thus, the decision turned on the "prominent visual distinctions" between the two marks. The Board found that the letters DQ were the dominant portion of the Registered mark and the inclusion of the "mouse" design element in the applied-for mark was dissimilar enough from the registered mark to distinguish the parties as the sources of their respective goods and services.

In re Hy-Vee, Inc., Serial No. 86105555 (March 25, 2015) [not precedential].

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Trademark Practitioner Jennifer Lantz Returns to Haynes and Boone Palo Alto Office

The Palo Alto office of Haynes and Boone proudly welcomes the return of esteemed trademark lawyer **Jennifer Lantz** as a partner, adding her rich experience to an internationally recognized trademark practice that successfully protects and enforces some of the world's most famous marks.

Read more.

Haynes and Boone Associate Jade O. Laye Selected to Join Leadership Council on Legal Diversity

Jade O. Laye, an associate in the Intellectual Property Practice Group at Haynes and Boone has been selected for the 2016 Leadership Council on Legal Diversity (LCLD).

Laye joins an esteemed class of lawyers nationwide who have been selected to participate in the year-long program designed to offer fellows an opportunity to network and learn from top leaders in the legal field.

Read more.

Patent Lawyer Kenyon Jenckes Strengthens the Corporate and Intellectual Property Experience in Haynes and Boone's Orange County Office

Haynes and Boone proudly welcomes seasoned patent lawyer **Kenyon Jenckes**, who adds his 20 years of experience in corporate and law firm environments to the growing capabilities of the firm's Orange County office.

Jenckes was previously with Qualcomm Inc., where he spent more than 10 years as a senior patent counsel supervising as well as preparing and prosecuting patent applications over a wide range of technologies and managing portfolios nationally and internationally. Prior to that, he practiced law for more than eight years in the California law firm environment.

Read more.

If you have any questions, please visit the Haynes and Boone Intellectual Property Law page of our website.

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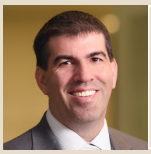

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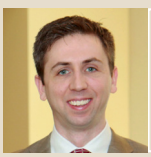

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