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Judge Jackson's Patent, FDA Rulings Show She Is 'Super Smart' And Would Be Beneficial For Pharma

by Brenda Sandburg

Supreme Court nominee issued three decisions on Hatch-Waxman regime as district court judge, including case in which she ruled against the FDA's denial of orphan drug designation and another in which she deferred to the agency's view on exclusivity. Her analysis of facts may play a role if the court takes up a case on administrative agency deference.

While pharmaceutical-related cases that go before the US Supreme Court do not fall along the ideological divide, there is one issue on which Ketanji Brown Jackson's appointment to the court may be a factor: whether administrative agencies should be given deference when laws are ambiguous.

As US District Judge on the US District Court for the District of Columbia, Jackson issued two decisions in cases that challenged the US Food and Drug Administration's interpretation of the statute governing eligibility for market exclusivity. In one case she ruled against the agency while suggesting a work-around, and in the other she ruled for it.

When Justice Neil Gorsuch and Justice Brett Kavanaugh were nominated to the Supreme Court, their views on the "Chevron deference" doctrine garnered attention. Under this doctrine, courts first determine if a statute is ambiguous and if they find that it is, defer to an agency's interpretation of it. The doctrine is named for the Supreme Court's 1984 decision in Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc. Judicial deference to the FDA is at issue whenever someone challenges an agency decision.

Gorsuch had questioned Chevron deference in an opinion prior to joining the high court, saying the time may have come "to face the behemoth." (Also see "*Judge Gorsuch Could Be Pharma Ally In FDA Disputes*" - Pink Sheet, 20 Feb, 2017.) Some felt Kavanaugh would also be interested in

revisiting or limiting the doctrine. (Also see "*Judge Kavanaugh May Be Good US Supreme Court Pick For Pharma*" - Pink Sheet, 10 Jul, 2018.)

While the issue has not yet come before the court, Nicholas Groombridge, a partner at Paul, Weiss, Rifkind, Wharton & Garrison, said his sense is that the conservative majority has been looking for an appropriate case and eventually one will come along. As for what impact this might have on the pharma industry, he said it is unclear as a decision could be beneficial on some things and not others. (Also see "*What Justice Ginsburg's Death Means For Pharma*" - Pink Sheet, 20 Sep, 2020.)

From the small sample size of Judge Jackson's opinions, Groombridge said it seems like she is generally favorable to Chevron deference.

In one case, Depomed, Inc. filed suit against the FDA when the agency withheld orphan exclusivity for Gralise (gabapentin) for management of post-herpetic neuralgia because Depomed did not show it was clinically superior to *Pfizer Inc.*'s gabapentin drug Neurontin for the same indication.

Jackson found that Depomed was entitled to a period of seven-year orphan marketing exclusivity because it had met the two statutory requirements of the Orphan Drug Act: it was designated an orphan drug by FDA and it was approved for marketing. She indicated that FDA could prevent a drug from obtaining orphan exclusivity simply by not designating it an orphan drug. (Also see "*FDA's Orphan Drug Exclusivity Policy May Face Second Court Challenge*" - Pink Sheet, 28 Mar, 2016.)

In a 2017 opinion, Jackson deferred to the FDA's view that a drug's market exclusivity applies against another product only when the two drugs share the same active moiety. In that case, *Otsuka Pharmaceutical Co. Ltd.* claimed its atypical antipsychotic Abilify Maintena (long-acting injectable aripiprazole) was legally equivalent to *Alkermes plc*'s Aristada (aripiprazole).

Otsuka had asked the court to vacate the FDA's approval of Aristada, arguing it was due three years of exclusivity for conducting a clinical trial in support of a supplemental new drug application. The US Court of Appeals for the District of Columbia Circuit affirmed her decision. (Also see "*FDA Wins Abilify Exclusivity Battle; Court Rejects Otsuka's 'Legal Equivalence'*" - Pink Sheet, 5 Sep, 2017.)

William Jay, head of Goodwin Procter's Supreme Court and appellate litigation practice, who argued the case for Alkermes before the DC Circuit, said Jackson wrote a thoughtful decision about the intersection of the two statutes and ended up giving the FDA deference in its interpretation of the statutes and its regulations.

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He noted that in one of the two decisions she has written as a circuit judge, Jackson looked with skepticism on an agency's decision to change its opinion. In that case, American Federation of Government Employees, AFL-CIO v. Federal Labor Relations Authority, Jackson found that the FLRA's decision to adopt a new threshold for when collective bargaining is required was not sufficiently explained, and thus arbitrary and capricious. Jay said these are very small data points to make a conclusion but noted that Jackson has been grounded by precedent.

'Sophisticated And Nuanced Understanding' Of Hatch-Waxman Regime

On 25 February, President Biden nominated Jackson, 51, to become associate justice of the Supreme Court. If confirmed, she would fill the vacancy left by Justice Stephen Breyer who is retiring at the end of the term, and would be be the first Black woman to serve on the court. The Senate Judiciary Committee is scheduled to begin hearings on her confirmation on 21 March.

Jackson was confirmed to the US Court of Appeals for the District of Columbia Circuit by a vote of 53-44 last year. Prior to that she had been a DC district court judge since 2013. Jackson graduated *magna cum laude* from Harvard University in 1992 and *cum laude* from Harvard Law School in 1996. She was a law clerk for Justice Breyer, and for US District Judge Patti Saris of the US District Court for the District of Massachusetts, and Judge Bruce Selya of the US Court of Appeals for the First Circuit.

Jackson has a broad range of experience. She had a two-year stint in the Office of the Federal Public Defender, served on the US Sentencing Commission and was confirmed as vice chair of the commission in 2010. She worked at several law firms, including Goodwin Procter and Morrison & Foerster. As an appellate litigator at MoFo, she drafted and filed briefs and petitions in the US Supreme Court. She also spent a year as a staff reporter and researcher at *Time* magazine between college and law school.

In her responses to the Senate Judiciary Committee's *questionnaire*, Jackson noted that during her tenure on the district court she wrote 578 opinions. Three of these decisions involved pharmaceutical patent disputes.

In addition to the Depomed and Otsuka cases, Jackson issued a ruling on the process for patent certification. *Takeda Pharmaceuticals USA Inc.* sued the FDA alleging the agency improperly approved *Hikma Pharmaceuticals plc*'s gout medication Mitigare (colchicine) because it did not reference Takeda's colchicine drug Colcrys or certify to Colcrys patents.

Jackson found that the FDA's approval of Mitigare was consistent with the Food, Drug, and Cosmetic Act, the agency's regulations, its citizen petition responses, and the policies and practices under which it operates. (Also see "*Takeda's Take On Patent Certification Rules In Colchicine Dispute Rejected*" - Pink Sheet, 21 Jan, 2015.)

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Groombridge said these decisions show she is very comfortable with the byzantine complexity of the Hatch-Waxman statute and understands the tensions at play in keeping a balance between maintaining incentives for pharmaceutical innovation and making generic drugs available.

"She has a sophisticated and nuanced understanding of the regime. Why would that not be an excellent thing for pharma?" Groombridge said. "She is super smart, keenly interested and unafraid of complicated subject matter."

Groombridge said he was also impressed with her mastery of facts in a product liability case involving a Medtronic insulin pump. "Her opinion was written in a very nuanced way and was sympathetic to the plaintiff," he noted.

In that case, Kubicki v. Medtronic, Inc., Caroline Kubicki, a 19 year-old type 1 diabetic who was a sophomore at George Washington University, experienced severe hypoglycemia and suffered a traumatic brain injury as a result of low blood sugar levels. Her parents sued Medtronic alleging negligence and failure to provide adequate warnings about its insulin pump and infusion set. In a February 2018 opinion, Jackson granted Medtronic's motion for summary judgement in part and denied in part.

Pending Patent Petitions

The Supreme Court has taken up several pharma-related product liability disputes over the years, from Wyeth v. Levine (2009), in which the court ruled that manufacturers are required to update their label to warn of newly discovered risks unless barred by the FDA, to Pliva, Inc. v. Mensing (2011) and Mutual Pharmaceutical Co., Inc. v. Barlett (2013), in which it found that generic drug makers cannot be sued for failure to warn or alleged design defects based on the adequacy of label warnings since under FDA's regulation they must have the same labeling as the brand name drugs.

And in 2019 in Merck Sharp & Dohme Corp. v. Albrecht, the court found that judges rather than juries must decide whether FDA rejected a drug manufacturer's request to add a warning to its labeling. (Also see "*Ruth Bader Ginsburg's Impact On Pharma, From Patents To The First Amendment*" - Pink Sheet, 21 Sep, 2020.)

The high court has also heard a number of patent cases, including seven interpreting the America Invents Act and the machinations of the US Patent and Trademark Office's Patent Trial and Appeal Board. In the most recent case, the court ruled last year in United States v. *Arthrex, Inc.* that PTAB judges were unconstitutionally appointed and that to overcome this problem the PTO director has the discretion to review the board's final decisions in inter partes review (IPR) proceedings. (Also see "*US Supreme Court Gives PTO Director Chance To Impact Outcome Of Patent Disputes*" - Pink Sheet, 21 Jun, 2021.)

Mylan Pharmaceuticals Inc. had petitioned the court to hear another case involving the PTAB. It sought review of the *NHK-Fintiv* rule, which arose from two board decisions, that allows the board to deny institution of an IPR when there is parallel infringement litigation in district court.

In January, the court denied Mylan's petition asking it to determine whether the law categorically precludes appeal of all board decisions not to institute inter partes review. (Also see "*USPTO Faces Growing Pressure To Enter Battle Over Drug Pricing*" - Pink Sheet, 23 Sep, 2021.)

There are likely to be further petitions concerning PTAB proceedings. A bipartisan group of 11 members of Congress recently sent a letter to Drew Hirshfeld, who has been performing the duties of the PTO director, objecting to the PTO's policies on discretionary denials of IPR petitions and the decline in their institution.

One petition pending before the court concerns patent eligibility under Section 101 of the Patent Act, which could have implications for the pharmaceutical industry. The case, American Axle & Manufacturing Inc. v. Neapco Holdings LLC, involves a new process for making a quieter automobile driveshaft. Last May, the court asked the Solicitor General to file a brief expressing the views of the United States.

Jay noted that Section 101 has been a hot issue in the diagnostic and pharmaceuticl space and people will be interested in what happens with the case. "Justice Breyer was keenly interested in 101 and skeptical about patents being used to cover abstract ideas," he said. While Jackson hasn't focused on patents "she will be taking the seat of a judge who spent alot of time thinking about IP."

Jay said a few other pending petitions involve issues of interest to pharma. They include PersonalWeb Technologies, LLC v. Patreon, Inc. concerning the Federal Circuit's patent specific preclusion doctrine, Olaf Sööt Design, LLC v. Datronics, Inc. involving a claim construction issue, and Apple Inc. v. Qualcomm Inc. about a licensee's standing to challenge a patent covered by a license agreement that covers multiple patents. The court invited the Solicitor General to file a brief in all three cases.

Teva Pharmaceuticals USA Inc. also announced that it plans to file a petition for Supreme Court review of its "skinny label" dispute with *GlaxoSmithKline plc*. Last month, the US Court of Appeals for the Federal Circuit declined *en banc* review of a split panel decision that Teva's labeling for a generic version of Coreg (carvedilol), which carved out the patented indication, induces infringement of GSK's patents. (Also see "*Generic Manufacturers Face Uphill Climb After Federal Circuit's 'Skinny Label' Decision*" - Pink Sheet, 15 Feb, 2022.)

Given the attention the case has received and the arguments made in amicus briefs, the case has a chance of being taken up by the Supreme Court. A group of 14 law professors asked the Federal

Circuit to grant *en banc* review to resolve questions about how inducement of patent infringement interacts with other laws and policies. (Also see "*'Skinny Label' Litigation: Generic Firms Rethinking Strategy, May Pursue Legislation*" - Pink Sheet, 24 Jan, 2022.)

This is not a partisan issue and Jackson's appointment to the court would not likely influence the outcome.