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Life Sciences Cases To Watch In 2015

By **Jessica Corso**

Law360, New York (January 02, 2015, 5:06 PM ET) -- Life sciences attorneys will need to keep close tabs on a number of cases in 2015, with the ability to prosecute generic-drug manufacturers over outdated labels hanging on a U.S. Supreme Court decision expected to come down this year, and with a New Jersey district court still contemplating how much access a brand-name manufacturer must give to a competitor seeking U.S. Food and Drug Administration approval.

From product liability, to intellectual property, to antitrust, here are six cases that could have a major impact on the life sciences industry in 2015.

Teva Pharmaceuticals USA et al. v. Superior Court of California et al.

The U.S. Supreme Court will potentially decide a landmark case in the life sciences industry this year, after asking the U.S. Solicitor General to weigh in on a product liability dispute in July that once again touches on the question of federal preemption.

Teva Pharmaceuticals USA Inc. is petitioning the court to hear a challenge to a California appellate decision that a generic-drug manufacturer can be held liable for failing to warn consumers of the side effects listed on the equivalent brand-name drug.

Once the solicitor general is asked to weigh in on a dispute, it's generally accepted that the U.S. Supreme Court will take up the case, according to Crowell & Moring LLPpartner Keith Harrison.

Although federal law generally prohibits state-law tort claims from being brought against generics manufacturers following brand-name labeling, Teva, by not updating its label for the generic form of the osteoporosis drug Fosamax, may have opened itself to scrutiny.

"The plaintiffs bar in California is very anxious to try and kick that door open literally and see if they can sue generic manufacturers on product liability claims," Harrison said. "This is going to be a case that is going to further define the scope of federal preemption."

Teva is represented by Jay P. Lefkowitz, Michael D. Shumsky, John K. Crisham and Stephen S. Schwartz of Kirkland & Ellis LLP.

Olga Pikerie is represented by Mark G. Crawford of Skikos Crawford Skikos & Joseph and Mark P. Robinson

Jr. and Kevin F. Calcagnie of Robinson Calcagnie Robinson Shapiro Davis Inc.

The case is Teva Pharmaceuticals USA et al. v. Superior Court of California et al., case number 13-956, in the Supreme Court of the United States.

Teva Pharmaceuticals USA Inc. et al. v. Sandoz Inc. et al.

Generic-drug labeling isn't the only issue Teva has dragged in front of the U.S. Supreme Court this term, with life sciences attorneys anxiously awaiting a ruling that could have major implications for the claims construction process in intellectual property cases.

In October, the high court appeared divided over the pharmaceutical giant's arguments that the Federal Circuit wrongly invalidated five of the patents for Teva's multiple sclerosis drug Copaxone after a district court ruled that Sandoz Inc. and Mylan Inc. had infringed the patents.

Teva is challenging the Federal Circuit practice of reviewing claims construction anew and wants appellate courts to give deference to the original construction set out by district courts, which do a lot of heavy lifting to uncover the facts surrounding the claims.

"Right now the appellate standard for claim construction is de novo review. It's a standard that's been in place for awhile," Nixon Peabody International LLP partner Maia Harris said. "But, if more discretion is given to the district court decision, I think what you're going to see as a practical matter at the district court is more attention paid to the factual sides of our arguments."

With oral arguments heard this past October term, a decision on the future of Federal Circuit patent infringement claim review will likely be seen sometime this year.

Teva is represented by William M. Jay, William G. James II, David M. Hashmall, Elizabeth J. Holland, Steven J. Bernstein, Daryl L. Wiesen, Henry C. Dinger, John C. Englander, Nicholas K. Mitrokostas, Todd Marabella and Jaime A. Santos of Goodwin Procter LLP; Jay P. Lefkowitz, John C. O'Quinn and Jason M. Wilcox of Kirkland & Ellis LLP; and Harvard Law School professor Alan M. Dershowitz.

Sandoz is represented by Deanne E. Maynard, Brian R. Matsui, Marc A. Hearron, David C. Doyle, Anders T. Aannestad, Brian M. Kramer, Elizabeth Cary Miller and James J. Cekola of Morrison & Foerster LLP. Mylan is represented by Carter G. Phillips, Ryan C. Morris, Adam Hallowell and Steven J. Horowitz of Sidley Austin LLP; Eric D. Miller, Shannon M. Bloodworth, David L. Anstaett and Brandon M. White of Perkins Coie LLP; and Evan R. Chesler and Richard J. Stark of Cravath Swaine & Moore LLP.

The case is Teva Pharmaceuticals USA Inc. et al. v. Sandoz Inc. et al., case number 13-854, in the Supreme Court of the United States.

In re: Cuozzo Speed Technologies LLC

In another controversy set to shake up the claims construction process, the Federal Circuit is currently weighing Cuozzo Speed Technologies LLC's suit arguing that the Patent Trial and Appeal Board uses the incorrect standard during America Invents Act proceedings, making it difficult for inventors to hold on to their patents.

The judicial arm of the U.S. Patent and Trademark Office ruled against Cuozzo in November 2013, siding

with Garmin International Inc. that a device alerting drivers to the speed limit wasn't patentable, in the PTAB's first-ever decision under the new inter partes review process.

Cuozzo is now challenging that process in a first-impression case before the Federal Circuit, which heard oral arguments in November 2014, saying that PTAB shouldn't be allowed to apply stricter claims construction standards than in district court litigation.

The case threatens to upend the new IPR standards, and former USPTO director and current Crowell & Moring partner Terry Rea said that both life sciences and non-life sciences attorneys who specialize in IP are waiting with bated breath for the Federal Circuit's decision, which could be handed down in early 2015.

"We're in the new world of PTAB with the America Invents Act," Rea said.

"Everybody is going to be very, very careful how they handle this" case, she added, because it gets to not only the heart of how claims are constructed in front of the PTAB but also whether a decision by the board to review a patent is appealable to begin with.

"We are all getting used to this brave new world right now," Rea said.

Cuozzo is represented by John R. Kasha of Kasha Law LLC and New Jersey-based attorney Timothy Salmon.

The USPTO is represented in-house by Solicitor Nathan Kelley and Associate Solicitors Scott C. Weidenfeller and Robert J. McManus.

The case is In re: Cuozzo Speed Technologies LLC, case number 14-1301, in the U.S. Court of Appeals for the Federal Circuit.

King Drug Co. of Florence Inc. et al. v. SmithKlineBeecham Corp. et al.

In November the Third Circuit heard oral arguments in a suit that could "test the limits" of how the U.S. Supreme Court's groundbreaking Federal Trade Commission v.Actavis Inc. ruling is applied to exclusivity agreements between pharmaceutical competitors, Harrison said.

The nation's highest court ruled in June 2013 that pay-for-delay deals struck between a brand-name manufacturer of a drug and the drug's generic manufacturer can be scrutinized under federal antitrust laws.

The current suit, brought by King Drug Co. of Florence Inc. and Louisiana Wholesale Drug Co. Inc., argues that a nonmonetized patent settlement between GlaxoSmithKline LLC and Teva Pharmaceutical Industries Ltd. postponing production of a generic epilepsy drug falls under the Actavis ruling.

The FTC stood in front of the Third Circuit during oral arguments in November, to back King Drug's contention that a district court's dismissal of the case should be overturned because the Supreme Court intended for the Actavis ruling to apply to all agreements between companies to halt the marketing of a generic — even in cases where no money changed hands.

"The appellees [GSK and Teva] are saying there should be a narrow interpretation of the Supreme Court's decision in Actavis, essentially limiting it to cash payments or other things that can be estimated in a

dollar-type fashion. That's going to be an important issue," Harrison said.

The case was argued for the plaintiffs by Bruce E. Gerstein of Garwin Gerstein & Fisher LLP.

The case was argued for the FTC by in-house counsel Mark S. Hegedus.

The case was argued for Teva by Jay P. Lefkowitz of Kirkland & Ellis LLP.

The case was argued for GSK by Barbara W. Mather of Pepper Hamilton LLP.

The case is King Drug Co. of Florence Inc. et al. v. SmithKlineBeecham Corp. et al., case number 14-1243, in the U.S. Court of Appeals for the Third Circuit.

In re: Suboxone Antitrust Litigation

In a showdown in a Pennsylvania federal court over a brand-name drug manufacturer's ability to extend the life of its patent, Reckitt Benckiser Inc. was told in December that it wouldn't be completely let off the hook for class action allegations that it is preventing generic versions of its opiate addiction treatment Suboxone from coming to market.

The direct purchasers that remain party to the suit are saying that Reckitt is illegally holding on to its exclusivity patent for the drug by tweaking its formula for Suboxone tablets to a film product that performs essentially the same functions in a practice known pejoratively as "product-hopping."

But Stephen Mahinka of Morgan Lewis & Bockius LLP said the suit is not as straightforward as it would seem because this life-cycle management approach —where a manufacturer modifies their formula slightly, thereby extending the life of their original patent — has been common practice in the pharmaceutical industry for years.

Of course, Mahinka said, purchasers and patients who want to keep prices down are unhappy with the practice, but "from the standpoint of the manufacturer of the product that would be going off patent, this is an attempt to come up with a better product and migrate patients to it."

The multidistrict litigation, he said, could have a major impact on how this type of life-cycle management approach is policed and gets at the heart of the innovation-versus-cost debate that is prevalent in the industry.

Reckitt continues to battle the suit in the Eastern District of Pennsylvania.

The direct-purchaser plaintiffs are represented by Bruce E. Gerstein and Joseph Opper of Garwin Gerstein & Fisher LLP; Peter R. Kohn, Sarah A. Westby and Joseph T. Lukens of Faruqi & Faruqi LLP; and Lauren Guth Barnes, Kristen A. Johnson and Thomas M. Sobol of Hagens Berman Sobol Shapiro LLP.

The indirect-purchaser plaintiffs are represented by Jeffrey L. Kodroff and John A. Macoretta of Spector Roseman Kodroff & Willis PC; Kenneth A. Wexler of Wexler Wallace LLP; Michael M. Buchman of Motley Rice LLC; and Marvin A. Miller of Miller Law LLC.

Reckitt is represented by Kevin D. McDonald and Thomas Demitrack of Jones Day.

The case is In re: Suboxone Antitrust Litigation, case number 2:13-md-02445, in the U.S. District Court for the Eastern District of Pennsylvania.

Mylan Pharmaceuticals Inc. v. Celgene Corp.

Another suit that seeks to tackle the divide between consumers seeking cheap drug options and pharmaceutical companies wanting to be paid top dollar for their innovative products is the ongoing district court squabble between Mylan Pharmaceuticals Inc. and Celgene Corp. over access to samples for generic-drug testing.

In that suit, Mylan is accusing Celgene of taking advantage of FDA safety measures — known as risk evaluation and mitigation strategies programs — to deny Mylan access to samples of cancer drugs Thalomid and Revlimid. Mylan says it needs the samples to obtain approval to market a generic version of the drug.

“The prevailing antitrust doctrine is that a company does not have to aid a potential competitor in virtually all circumstances into enabling it to become a new competitor and injure the first company,” Mahinka said.

But now the FTC has stepped in on the side of Mylan, saying in an amicus filing in New Jersey federal court that generic-drug makers should be allowed to sue brand-name companies under antitrust laws for using REMS as an excuse to deny competitors access to the generics market.

“These cases, in many areas, show societal tension between the desire to stimulate and maintain innovation and, on the other hand, to somehow control costs to people and the overall health care system,” Mahinka said.

A pared-down version of Mylan v. Celgene is currently making its way through the District of New Jersey, after U.S. District Judge Esther Salas trimmed certain Sherman Act and New Jersey state claims from the suit late in December.

Mylan is represented by Arnold B. Calmann and Jakob B. Halpern of Saiber LLC; and Michael S. Sommer, Seth C. Silber, Jonathan R. Lutinski, Valentina V. Rucker and Roisin E. Comerford of Wilson Sonsini Goodrich & Rosati PC.

Celgene is represented by Kevin D. McDonald of Jones Day and Daniel R. Guadalupe of Norris McLaughlin & Marcus PA.

The FTC is represented in-house by Markus H. Meier, Bradley S. Albert, James E. Rhilinger, Daniel W. Butrymowicz and Kara L. Monahan.

The case is Mylan Pharmaceuticals Inc. v. Celgene Corp., case number 2:14-cv-02094, in the U.S. District Court for the District of New Jersey.

--Additional reporting by Khadijah M. Britton, Melissa Lipman, Ryan Davis, Matt Fair and Juan Carlos Rodriguez. Editing by Edrienne Su.
