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Life Sciences Cases To Watch In 2014

By **Andrew Scurria**

Law360, New York (January 01, 2014, 10:08 AM ET) -- Pharmaceutical manufacturers in 2014 will be glued to a high-stakes tussle in federal court over the Federal Trade Commission's power to punish pay-for-delay deals, while the U.S. Supreme Court has the chance to put to rest muddied questions on False Claims Act pleading standards and off-label drug promotion.

The next 12 months could also reshape the landscape for patent protection on lucrative genetic diagnostic products and open up device makers to a new breed of tort claims. Here are six cases life sciences attorneys would be wise to follow in 2014.

FTC v. Cephalon

In the wake of the U.S. Supreme Court's landmark FTC v. Actavis ruling last year, the agency is newly emboldened to challenge so-called pay-for-delay agreements restricting generic drug market entry.

A top priority is a Pennsylvania federal lawsuit challenging Cephalon Inc.'s patent settlements with four generic drugmakers related to its narcolepsy drug Provigil. The FTC is claiming Cephalon used licensing agreements to bribe the generic companies into dropping their patent challenges, keeping competing versions of Provigil off the market.

Since FTC v. Actavis did not specify under which circumstances pay-for-delay violates antitrust law, the Cephalon case could establish an important data point for pharmaceutical companies considering patent settlements coupled with licensing transactions, despite being an intensely fact-specific dispute, according to Colin Sandercock of Perkins Coie LLP.

"If there's going to be any guidance from this, it's going to be on that issue — how the court will look at and evaluate the combination of business transactions and simultaneous patent settlements," he said.

A critical question is whether the FTC has the power to ask for disgorgement of hundreds of millions of dollars in profits Cephalon allegedly raked in while the deals were in place. Disgorgement is a controversial and rarely invoked remedy where precedent is sparse, according to Stephen Mahinka of Morgan Lewis & Bockius LLP.

"It's an important case to monitor because when the FTC attempts to get disgorgement, what's to prevent states from trying to do so as well? Because we've always seen the states try to follow what the FTC does," he said.

To get the case to trial, though, the agency must first prove that its case was not mooted by the generic versions of Provigil launched in the course of the litigation, which was put on hold pending the Supreme Court's Actavis decision.

Cephalon is represented by WilmerHale and Conrad O'Brien PC.

The case is Federal Trade Commission v. Cephalon Inc., case number 2:09-cv-02141, in the U.S. District Court for the Eastern District of Pennsylvania.

U.S. ex rel. Nathan v. Takeda

Three cases with U.S. Supreme Court petitions pending, meanwhile, could furnish life sciences attorneys with broad appellate court guidance.

In a closely watched whistleblower suit, the justices have the chance to put to rest a long-simmering question on the proper pleading standards in False Claims Act cases.

The justices are considering reviewing the Fourth Circuit's dismissal of a Takeda Pharmaceutical Co. Ltd. salesman's claims that the company marketed the gastrointestinal drug Kapidex off-label and caused improper Medicare billing.

If the court takes the case, it will likely be to decide whether relators must present a particular example of a false claim, which the Takeda whistleblower admittedly failed to do, in order to survive a Rule 9 motion to dismiss. The issue has split eight circuit courts down the middle.

The Fourth Circuit said that absent a tangible false claim, a purported kickback or off-label scheme would have to allege that false claims were "necessarily" submitted.

That's a tighter requirement than in other circuits, which only require a scheme to plead facts showing a reasonable indicia leading to a strong inference of fraudulent billing. A ruling for the relator could allow a significant number of whistleblower suits to proceed to discovery that wouldn't have survived otherwise, according to Fred Kelly, a Nixon Peabody LLP partner and False Claims Act specialist.

The Supreme Court has not yet granted certiorari in the Takeda case but has asked the Obama administration to weigh in. The solicitor general has previously taken the position that the proper pleading standard is an important, unsettled question of law ripe for Supreme Court review, having said so in a 2010 brief in a False Claims Act suit against Ortho Biotech Inc. The justices passed on that case for procedural reasons.

"If [federal officials] do what they did in 2010, they're going to say that the relaxed standard provides enough specificity for the accused company to figure out what the allegations are and to defend itself," Kelly said. "They want more of these cases brought, so a less stringent standard will result in it being easier for relators to bring these cases so that alleged circumstances of fraud are brought to the government's attention."

The relator is represented by MoloLamken LLP.

Takeda is represented by Patterson Belknap Webb & Tyler LLP and by the Law Offices of Susan R.

Podolsky.

The case is U.S. ex rel. Nathan v. Takeda Pharmaceuticals North America Inc. et al., case number 12-1349, in the U.S. Supreme Court.

U.S. v. Harkonen

A long-running criminal case could allow the justices to clarify the extent to which the First Amendment shields drugmakers from the government's campaign to prosecute off-label marketing.

W. Scott Harkonen, the former CEO of Intermune Inc., is asking the Supreme Court to review the Ninth Circuit's March affirmation of his wire fraud conviction over an allegedly misleading press release that offered his personal interpretation of an inconclusive clinical trial.

The government charged and a jury agreed that data from the trial were insufficient to support Harkonen's conclusions about the drug's effectiveness. His appeal, which argues that the government can't prosecute based on statements of scientific opinion, has drawn support from pharmaceutical trade groups and academics, and could provide more guidance into the scope of the high court's Sorrell v. IMS Health Inc. decision.

In that ruling, the court invalidated a Vermont law that it found infringed on drugmakers' rights to disseminate truthful, nonmisleading marketing speech on their products. Harkonen is arguing that prosecutors' case did exactly what Sorrell prohibits: outlawing certain scientific opinions to tilt public opinion.

"That could be teed up as the next interesting First Amendment case in the area, but there will be more," said Daniel Kracov of Arnold & Porter LLP. "It could help overturn the current framework for the Federal Food Drug and Cosmetic Act regulation of drugs, which is based on what companies say about products."

Harkonen is represented by Mayer Brown LLP.

The case is Harkonen v. United States, case number 13-180, before the U.S. Supreme Court.

Medtronic v. Stengel

A landmark Ninth Circuit ruling recently carved out an exception to the preemption doctrine in medical device injury suits.

Medtronic Inc. is fighting an en banc decision that federal law does not preempt claims that the company failed to alert the FDA to adverse event reports regarding a pain pump that caused a man's paralysis. If the Supreme Court doesn't reverse, a host of tort claims based on failure-to-report allegations could come back into play.

The opinion held that Medtronic's duty under state law to disclose adverse events paralleled its duties under the Medical Device Amendments to the Federal Food, Drug and Cosmetic Act and therefore did not conflict with FDA authority.

The high court has yet to take up the case but is seeking the solicitor general's position. The case will

likely hinge on the scope of its 12-year old decision in Buckman v. Plaintiffs' Legal Committee, which held claims that a device maker lied to the FDA during the premarket process to be preempted. Federal appeals courts have split on whether Buckman also prohibits claims arising from a subsequent failure to report adverse events.

"The question in Stengel is whether failure to report adverse information is something a private plaintiff can assert." said Andrew Campbell of Faegre Baker Daniels LLP. "If the Ninth Circuit ruling is upheld, you could assert a claim for failure to warn based on a failure to report."

If that happens, the FDA could find itself drawn into discovery proceedings in countless personal injury suits, Campbell said.

In a separate issue, Medtronic is asking the justices to rule that "parallel" state law claims must be based on a device-specific FDA directive, not on the broad duties all companies face under the Medical Device Amendments.

Medtronic is represented by Gibson Dunn & Crutcher LLP and Reed Smith LLP.

Stengel is represented by Haralson Miller Pitt Feldman & McAnally PLC.

The case is Medtronic Inc. v. Richard Stengel et ux., case number 10-17755, in the U.S. Supreme Court.

Myriad Diagnostic Genetic Test Suits

Meanwhile, an ever-widening brawl in the federal district courts will shape the competitive landscape for cutting-edge gene-based diagnostic testing technology.

In a suit led by the American Civil Liberties Union, the high court last year struck down patent claims by Myriad Genetics Inc. covering isolated human DNA associated with a higher risk of breast cancer, but the decision hasn't stopped Myriad from launching a half-dozen new suits against competitors over patent claims more closely directed at the diagnostic detection of the BRAC-1 and BRAC-2 gene mutations.

The cases could provide valuable guidance on how far patents in molecular diagnostics can be enforced under the Supreme Court's pronouncements in both the Myriad and the Mayo v. Prometheus decisions, for patent practitioners and for the U.S. Patent and Trademark Office alike, according to Antoinette Konski of Foley & Lardner LLP.

Since Myriad and Prometheus, lower courts have been narrowing the scope of patent-eligible subject matter in molecular diagnostics, notably in an October decision out of California federal court saying that the decisions rendered a Sequenom Inc. patent covering a prenatal DNA test invalid.

A ruling is expected soon on Myriad's bid for an injunction against Ambry Genetics Corp. and Gene By Gene Ltd. An immediate appeal to the Federal Circuit is almost certain to follow.

If the patents are upheld on appeal, the Myriad Supreme Court case could wind up as a pyrrhic victory for competing diagnostics companies, civil libertarians and patient advocates, none of favor stronger patent protections for the life-saving technology.

FTC's LabMD Data Security Suit

Retail pharmacies and health care providers are troubled at the FTC's attempt to bring accusations of inadequate data security against medical testing laboratory LabMD Inc., but the case could have an equally profound impact on drug and device companies if the FTC's authority to bring those claims is upheld, Mahinka said.

"The FTC is saying their authority is over all entities that get personal information," he said.

That would include not just the FTC's previous targets in the health care field — retail pharmacies — but also drug companies that maintain information on users of their products for marketing purposes. LabMD has resisted the administrative suit by claiming that health information security is the exclusive bailiwick of the U.S.Department of Health and Human Services' Office for Civil Rights.

If the judge disagrees, drug makers and distributors could face the prospect of dual investigations brought under different statutes by each entity, plus the millions of dollars in fines that can come with crossing the FTC.

LabMD is represented by Dinsmore & Shohl LLP and by Cause of Action.

The case is In the Matter of LabMD Inc., docket number 9357.

--Editing by Rebecca Flanagan.
