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# Immediate Actos Appeal Will Resolve Uncertainty, Takeda Says

By Mike Leonard

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- Judge let end payer, direct purchaser suits move forward
  - Novel ruling requires immediate review, drugmaker says
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Takeda Pharmaceutical Co. Ltd. asked a Manhattan federal judge to let it immediately appeal two rulings greenlighting claims that the drugmaker delayed generic competition for the diabetes medication Actos by misrepresenting its patents to regulators.

“Prompt appellate review is necessary to address a controlling question of law that could obviate the need for prolonged, costly, and complex litigation, and resolve industry-wide uncertainty,” the company wrote in its Nov. 22 motion.

Both proposed antitrust class actions accuse Takeda of bottlenecking the generic approval process by gaming the Hatch-Waxman Act, which awards six months of generic exclusivity to companies that get brand-name drug patents invalidated.

The company allegedly mischaracterized two patents covering only delivery methods as formulation patents.

Relying on those claims, the Food and Drug Administration forced other pharmaceutical companies to challenge the patents, rather than letting them “carve out” non-infringing methods of using their generics, the lawsuits say.

Takeda allegedly responded by filing infringement suits, then using the potential of a yearslong delay to force settlements.

The suits were filed in the U.S. District Court for the Southern District of New York on behalf of “end payers” like union pension funds and “direct purchasers” like pharmacies.

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After the U.S. Court of Appeals for the Second Circuit revived it, Abrams let it proceed in early October on the limited theory that Takeda tricked the FDA into requiring the patent challenges.

The judge reached a similar conclusion a week later in the direct purchaser case. Takeda should face liability for alleged false statements to the FDA, not based on the settlements, she said.

Takeda now wants to take both rulings straight to the Second Circuit.

The decisions confronted an issue of first impression, according to the company's motion: whether brand-name drugmakers can list method-of-use patents as drug patents, the alleged act of gamesmanship that triggered the claims against Takeda.

An immediate appeal would clarify "the critical balance Congress sought to strike between the intellectual property rights of innovators and the interests of would-be generic competitors," Takeda says in its motion.

Takeda is represented by Munger, Tolles & Olson LLP. The direct purchasers are represented by Hagens Berman Sobol Shapiro LLP and Nussbaum Law Group PC. The end payers are represented by Hilliard & Shadowen LLP, Shepherd, Finkelman, Miller & Shah LLP, and 13 other firms.

The case is *In re Actos Direct Purchaser Antitrust Litig.*, S.D.N.Y., No. 15-cv-3278, motion for leave to file interlocutory appeal filed 11/22/19.

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