

Endo Patent Decision Appeal May Shift Life Sciences Investment

By Dana A. Elfin

The outcome of an upcoming oral argument involving Endo Pharmaceuticals Inc.'s patent on a claimed new treatment method for an existing opioid drug could shift the landscape for life sciences investment.

Branded drugmaker Endo Pharmaceuticals Inc. and generic maker Teva Pharmaceuticals USA Inc. are set to present dueling arguments at the U.S. Court of Appeals for the Federal Circuit Dec. 6 over whether certain method of treatment claims for already approved drugs are eligible for patents.

The question of what's an abstract idea or law of nature that can't be patented is a major topic in life sciences and the invalidation of a patent has huge financial consequences for litigants. So how the appeals court interprets the area of law in this case could reverberate throughout the industry. If Endo loses its appeal, it could push drug companies to shift their research and development efforts away from exploring new uses for existing drugs.

Endo is trying to convince the Federal Circuit to undo a district court ruling finding an allegedly new way of using its opioid painkiller Opana ER to treat pain in patients with reduced kidney function wasn't patentable because it claimed an unpatentable law of nature.

Opana ER is an extended-release opioid used to relieve moderate to severe pain. The Food and Drug Administration approved it in 2006.

Endo argues the district court got its patentability decision wrong by failing to properly differentiate between method of treatment claims and claims directed to abstract ideas or laws of nature. But the generic challengers argue Endo's patent claims "present an open-and-shut case of patent ineligibility" and say the ruling shouldn't be disturbed.

Outcome Has Implications

"The reality is if Endo loses, then I think you would see a drop-off in investment in new uses for old drugs because there's no payoff," Michael Risch, associate dean of faculty research and development and professor of law at Villanova University School of Law, told Bloomberg Law Dec. 5. Risch focuses on intellectual property law, with an emphasis on patents and trade secrets.

How the Endo case comes out could shift innovators' research efforts, Melissa Brand, associate counsel and director of intellectual property policy at the Biotechnology Innovation Organization, told Bloomberg Law Dec. 5. BIO is a trade association representing the biotechnology industry.

If the district court's decision on Endo's claims not being patent-eligible stands, it's possible innovators will be discouraged from investing resources into new ways of using already existing drugs or new ways of using those drugs more safely, she said. And those methods "have value to patients," Brand said.

And, if the Federal Circuit upholds the district court's decision, "the brand-name industry is going to feel it'll be a lot harder to patent new uses for old drugs," Andrew M. Alul, an intellectual property lawyer with Taft Stettinius & Hollister LLP in Chicago, told Bloomberg Law Dec. 5. Alul's practice focuses on pharmaceutical drug patent litigation and regulatory litigation.

"We certainly have Endo crying, 'If you find our claims ineligible for patent protection, then just about every other method of treatment patent out there is going to be invalidated and that would essentially destroy the pharmaceutical industry.'"

But Alul said, "I think it's an exaggeration that it will spell the death knell for pharmaceutical method of treatment patents."

Patent eligibility questions have been roiling the life sciences community since 2012, when the U.S. Supreme Court found a diagnostic method claim patent ineligible in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.* The *Mayo* ruling and its progeny have made it more difficult for life sciences companies to protect their intellectual property.

But it's not impossible.

In fact, the Federal Circuit recently decided *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals Int'l Ltd.*, in which it found Vanda's personalized method of treatment claims relating to schizophrenia drug Fanapt (iloperidone) didn't run afoul of prohibitions against patenting a law of nature even though it was related to a natural phenomenon.

In its briefing papers, Endo argues the claims the Federal Circuit found patentable in the *Vanda* case are indistinguishable from its method of treatment claims for Opana. But Teva says the Endo claims don't cover a new method and don't include any inventive step beyond a natural law.

Drug Industry Is Watching

However the Federal Circuit comes out in the Endo case, the pharmaceutical industry will be watching.

“Cases like Endo are going to be important to give us a sense of where this is headed,” Hans Sauer, BIO's deputy general counsel and vice president for intellectual property, told Bloomberg Law.

Meanwhile, even the *Vanda* case is likely to continue. It's likely West-Ward, the losing party in the *Vanda* case, will ask the U.S. Supreme Court to take another look at the case. It has until Dec. 27 to file a petition with the high court.

Dechert LLP represents Endo Pharmaceuticals. Endo is based in Ireland, with its U.S. headquarters in Malvern, Pa.

Goodwin Procter LLP represents Teva and Barr Laboratories Inc. Teva is based in Israel with U.S. headquarters in North Wales, Pa.

Holland & Knight LLP and Kirkland & Ellis LLP represent Actavis LLC, Actavis South Atlantic LLC, and Teva.

The case is *Endo Pharmaceuticals Inc. v. Amneal Pharmaceuticals LLC*, Fed. Cir., No. 2017-01240, oral argument 12/6/18.

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