

Lilly Loses Bid To Escape \$20M Cialis Patent Verdict

By **Dani Kass**

Law360, New York (August 28, 2017, 6:37 PM EDT) -- Eli Lilly & Co. on Friday lost a post-trial attempt to invalidate a German pharmaceutical company's patent when a Texas federal court denied a motion for judgment or a new trial, leaving Lilly to pay \$20 million for infringing the patent when marketing the erectile dysfunction drug Cialis to treat enlarged prostates.

U.S. Circuit Judge William C. Bryson, sitting in district court, spent 79 pages breaking down the patent invalidation claims Lilly made in a June 15 motion, concluding that U.S. Patent Number 8,791,124 is valid and that Erfindergemeinschaft UroPep GbR had sufficiently proven so during the jury trial. That jury in April had upheld the patent's validity but said Lilly's infringement wasn't willful.

The patent itself involves phosphodiesterase inhibitors, a type of enzyme blocker, to treat prostate disease. More specifically, it deals with inhibiting the enzyme PDE5 to treat benign prostatic hyperplasia, or BPH.

Among the many technical questions raised and rejected by the court, Lilly asked whether the patent application was detailed enough, including whether it disclosed the number of species related to a genus.

"None of the cases cited by Lilly support Lilly's argument that a disclosure must include some absolute number of species to support any patent claim to a genus," Judge Bryson said. "Those cases instead show that patent claims may be invalidated based on the failure to disclose any, or more than one, species in a nascent area where knowledge of the art has nothing to add to the disclosure."

Lilly also said it's not clear if all of the genus' compounds inhibit PDE5 to treat BPH, but Judge Bryson said the drugmaker didn't support the argument sufficiently.

Judge Bryson then upheld the jury's decision to rely on the testimony of UroPep's expert over Lilly's when handling some of the more technical questions. UroPep expert Andrew Bell's "testimony was detailed, credible and supported by public research," the researcher had previously worked at Pfizer Inc., and he discovered a selective inhibitor for PDE5, the opinion states.

Among many other claims, Lilly didn't show that using a PDE5 selective inhibitor to treat BPH was obvious, the judge said.

“At the time of the invention, it was not known that PDE5 was even present in the prostate,” the opinion states. “Furthermore, other research showed that PDE5 was not particularly relevant in the bladder, which, like the prostate, is part of the urogenital tract. It was the inventors of the ’124 patent who performed experiments and discovered that PDE5 was present and functionally relevant in prostatic tissue. Based on that discovery, they used the knowledge in the prior art to come up with a novel method of treating BPH.”

Since the jury returned with the \$20 million verdict in late April, Judge Bryson has entered a final judgment for that same amount and ordered Lilly to pay some \$106,000 in attorneys' fees and costs. However, the verdict has been stayed while Lilly appeals to the Federal Circuit, where Judge Bryson is a senior judge.

“Lilly disagrees with the judge’s latest rulings refusing to overturn the jury’s verdict,” the company said in a statement, adding that it will appeal.

UroPep attorneys Nosson Knobloch and John Hughes of Bartlit Beck Herman Palenchar & Scott LLP said in a statement they "are pleased that the court has upheld the validity of UroPep’s patent against Eli Lilly’s post-trial challenge. ... The court’s detailed and well-reasoned opinion will make it exceedingly difficult for Eli Lilly to overturn this decision on appeal.”

The patent-in-suit is U.S. Patent Number 8,791,124.

UroPep is represented by Melissa R. Smith of Gillam & Smith LLP, and Adam K. Mortara, J. Scott McBride, Benjamin J. Whiting, John M. Hughes and Nosson D. Knobloch of Bartlit Beck Herman Palenchar & Scott LLP.

Lilly is represented by Jon B. Hyland, Todd G. Vare, Jeff M. Barron and Felicia J. Boyd of Barnes & Thornburg LLP.

The case is Erfindergemeinschaft UroPep GbR v. Eli Lilly and Co. et al., case number 2:15-cv-01202, in the U.S. District Court for the Eastern District of Texas.

--Editing by Breda Lund.