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Generics Cos. Urge Fed. Circ. To Upend Depomed Patent Win

By **Bryan Koenig**

Law360, Washington (September 4, 2018, 9:44 PM EDT) -- A group of generic-drug makers urged a Federal Circuit panel Tuesday to nix patents upheld, and found infringed, for Depomed Inc.'s opioid painkiller Nucynta, arguing that the patents cover follow-on developments that offered no improvement on an older invention or would have been obvious for others to try.

Actavis Inc. and Alkem Laboratories Ltd., along with West-Ward Pharmaceuticals International Ltd. and parent Hikma Pharmaceuticals USA Inc., played different roles in the challenge to a New Jersey federal judge's decision to uphold the validity of the patents and find they were infringed by generic-drug applications aimed at Nucynta.

U.S. District Judge Claire C. Cecchi upheld the validity of U.S. Reissue Patent Number 39,593 and U.S. Patent Numbers 7,994,364 and 8,536,130 in September 2016 following a bench trial and issued years-long blocks on generic competition that do not begin to expire until 2025, while Alkem will be barred until 2028 from marketing tapentadol hydrochloride, the scientific name for Nucynta.

The problem with the validity finding for West-Ward and Hikma, an attorney for the companies said in oral arguments, is that the '364 patent built on an older patent but added nothing "useful," as required.

"Improvement has to be new and useful" to warrant patent protection, Latham & Watkins LLP's Robert J. Gajarsa told the panel.

When the panel pushed back, saying patents typically just require something new rather than an improvement, Gajarsa held firm, arguing that the '364 patent is being used to extend Nucynta's exclusivity born from an older patent, the '593, which runs out in 2022 while the '364 expires in 2025. He said the two patents cover pharmacologically identical drugs, with the only difference that the newer '364 is more stable in the sense that it can be stored at room temperature.

"It doesn't have any utility," said Gajarsa, who argued that Judge Cecchi had specifically refused to decide whether the stability change affected patentability, finding instead that no improvements were needed. Gajarsa also argued that any utility from a tweak must be explicitly laid out, which he said had not been done in the current case.

An attorney for Depomed, which acquired U.S. Nucynta rights from German pharmaceutical giant Grunenthal GmbH via Johnson & Johnson, argued that the patent is not about improving anything.

“The crystalline structure is brand new crystalline structure,” said Gibson Dunn & Crutcher LLP’s Michael A. Sitzman.

Sitzman argued further that the stability increase is an important improvement, allowing the older version to be swapped for one more easily stored.

Sitzman also had to contend with assertions from Imron T. Aly, a Schiff Hardin LLP attorney representing Alkem, who argued that the ‘364 patent would also have been obvious for other drugmakers.

Aly’s assertions of obviousness trace to a 1995 article by Stephen Byrn that explained how to perform “screens” looking for “polymorphs” — drug compounds that can be shaped into different crystalline structures, like the ones found in Nucynta. While Aly admitted that neither Byrn nor anyone else laid out the definitive process for looking for polymorphs, he argued that the article provided enough of a “low-hanging fruit” starting point that it would inevitably have led to the patented technology.

Circuit Judge Richard G. Taranto picked up on the path from Byrn to the technology when it was Sitzman’s turn. But when Judge Taranto asked if, given U.S. Food and Drug Administration pressure to find any polymorphs that may exist, any outcome might be rendered obvious, Sitzman argued that there are many unknowns when it comes to polymorphs.

Byrn is “helpful,” Sitzman said, “but it’s not the answer book.”

“There are so many variables out there,” continued Sitzman, who argued that unpredictability meant there was no “reasonable expectation” that the patented invention would be yielded, meaning it cannot be obvious.

Another major point of contention was the labeling of the drugs, which is particularly important as Depomed and Grunenthal pursue their own appeal of the lower court finding that Actavis and Roxane Laboratories Inc., another generics maker, would not infringe the ‘130 patent, which runs out in 2028.

That argument is based around the labeling of Nucynta’s generic and brand versions, with the brandmakers assailing lower-court findings that the proposed generic versions tweaked their labeling to avoid infringement. Depomed contends the generic labels will induce the drug’s use for treating polyneuropathic pain, which is covered by the brand label.

“That’s just not true,” countered Michael E. Joffre of Sterne Kessler Goldstein & Fox PLLC.

Joffre is representing Actavis as it opposes Depomed’s cross-appeal. He argued that there is no “encouragement” of that particular use by doctors, asserting that the only thing that matters “is what is in the label.”

Sitzman countered that every expert, from either side of the issue, testified in the lower court that the labels included the treatment of polyneuropathic pain. “That evidence was undisputed in the record,” he told the panel.

Circuit Judges Jimmie V. Reyna, Richard G. Taranto and Raymond T. Chen sat on the panel.

The patents-in-suit are U.S. Reissue Patent Number 39,593 and U.S. Patent Numbers 7,994,364; and 8,536,130.

Grunenthal and Depomed are represented by Michael A. Sitzman of Gibson Dunn & Crutcher LLP. Depomed is also represented by Timothy P. Best, Jaysen S. Chung and Christine L. Ranney of Gibson Dunn & Crutcher LLP. Grunenthal is also represented by Linda A. Wadler, Krista E. Bianco of Finnegan, Henderson, Farabow, Garrett & Dunner LLP.

Alkem is represented by Imron T. Aly, Neil Lloyd, Jason G. Harp, Brooke Clason Smith and Ahmed M.T. Riaz of Schiff Hardin LLP.

West-Ward Pharmaceuticals International Ltd. and Hikma Pharmaceuticals USA Inc. are represented by Robert J. Gajarsa, Terrence J. Connolly, Kenneth G. Schuler and Gregory K. Sobolski of Latham & Watkins LLP.

Actavis Elizabeth LLC is represented by Michael E. Joffre and William H. Milliken of Sterne Kessler Goldstein & Fox PLLC.

The case is Grunenthal GmbH v. Alkem Laboratories Ltd., case number 17-1153 in the U.S. Court of Appeals for the Federal Circuit.

--Additional reporting by Dani Kass, Suevon Lee and John Kennedy. Editing by Peter Rozovsky.

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