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Del. Court Sides With Alvogen In Novartis Patent Row

By **Aaron Vehling**

Law360, New York (June 24, 2014, 6:40 PM ET) -- A Delaware federal judge on Tuesday tossed out a lawsuit Novartis AG brought against Alvogen Group Inc. over a generic version of the Exelon dementia treatment patch, signing off on the argument that the drug lacked a key ingredient and thus did not infringe Novartis' patents.

Novartis had accused Alvogen of infringing two patents when the generic-drug maker sought federal approval of an Abbreviated New Drug Application, but U.S. District Judge Richard G. Andrews granted Alvogen's motion for summary judgment, saying Novartis failed to prove that the generic Exelon patches included an antioxidant, which every claim of the two patents requires.

Alvogen said its motion that because Novartis could not meet its burden of proving that "each and every element of the claims of the [patents] are present in the ANDA products" the court should grant summary judgment of noninfringement.

A Novartis spokesperson told Law360 in a statement Tuesday that the company "strongly believes in defending the intellectual property rights and patents of all our products and will continue to take appropriate actions as necessary to defend and enforce our intellectual property."

A representative for Alvogen was not available Tuesday for comment.

Novartis **filed its suit** against Alvogen in January 2013 as part of a series of lawsuits against generic-drug makers such as Par Pharmaceutical Inc. and Watson Laboratories Inc. over their own ANDAs for a generic Exelon patch.

The Exelon patch, which was introduced in 2007 as the first patch used to treat dementia, is prescribed to patients with mild to moderate dementia related to Alzheimer's and Parkinson's diseases, according to the original complaint.

Alvogen had sought to make and sell a rivastigmine transdermal system in 4.6 milligram and 9.5 milligram doses, the suit said.

When Novartis submitted its initial infringement contentions in May 2013, it identified all ways in which Alvogen's generic patch met each element of each asserted claim, but stopped short when it came to identifying an antioxidant, according to Alvogen's memorandum in support of its summary judgment motion.

The drugmaker requested samples of the generic drug for testing to support its allegations. When Alvogen proffered four interrogatories related to the antioxidant

limitations, Novartis said it would produce information in support of their infringement claims by the May 2 deadline, Alvogen's filing said.

But at a March meet-and-confer, Novartis admitted it did not have any further supporting evidence beyond what was disclosed in the infringement contentions and interrogatory responses, according to court filings. It said it could not prove Alvogen had infringed on the antioxidant limitation of the asserted claims, the filing said.

When the deadline arrived, Novartis did not provide an export report and on May 3, 2014 provided Alvogen with a covenant not to sue. That triggered Alvogen's summary judgment pursuit.

A parallel lawsuit involving a 13.3 mg, 24-hour version of the patch was dismissed as part of Novartis' covenant not to sue, according to Alvogen's court filing.

Novartis has had some recent success litigating infringement of the two Exelon patents. A Delaware federal judge handed Novartis a win in June, finding that Watson had **ripped off** some of the functions and materials of its dementia treatment. Par's litigation was decoupled from the Watson lawsuit because it involved different invalidity defenses.

A day later, fresh off that win, **Novartis slapped Mylan Pharmaceuticals Inc.** with a patent infringement suit over its plans to make and market its own generic version of the patch.

The patents-in-suit are U.S. Patent No. 6,355,031 and U.S. Patent No. 6,316,023.

The plaintiffs are represented by Michael P. Kelly and Daniel M. Silver of McCarter & English LLP and Nicholas N. Kallas and Filko Prugo of Fitzpatrick Cella Harper & Scinto.

The defendants are represented by Dominick T. Gattuso of Proctor Heyman LLP and by Chad A. Landmon, Thomas K. Hedemann and Thara L. Russell of Axinn Veltrop & Harkrider LLP.

The case is Novartis Pharmaceuticals Corp. et al. v. Alvogen Pine Brook Inc. et al., case number 1:13-cv-00052, in the U.S. District Court for the District of Delaware.

--Additional reporting by Ben James and Kat Greene. Editing by Richard McVay.

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