

Bayer Urges Fed Circ. To Reinstate Contraceptive Patent

By **Daniel Wilson**

Law360, Washington (April 5, 2016, 6:15 PM ET) -- A Bayer unit on Tuesday asked the Federal Circuit to reinstate an invalidated contraceptive patent allegedly infringed by Warner Chilcott's Lo Loestrin Fe tablets, saying a lower court improperly excluded evidence that would have cleared up purportedly vague patent terms.

A district court had wrongly ignored expert evidence showing that terms in a disputed patent clause, deemed by the court to be indefinite, would provide clear indications to a "person skilled in the art," or PSA, about the specific benefits of the contraception regimen covered by the patent-in-suit, Matthew Ford of Bartlit Beck Herman Palenchar & Scott LLP, representing Bayer Intellectual Property GmbH, told the three-judge panel at oral argument.

The dispute involves U.S. Patent Number 5,980,940, covering an oral contraceptive regimen in which two different hormone combinations are taken at set time points throughout the dosing schedule, a process used with Bayer's Yaz contraceptive, and which Bayer argued had been infringed by Lo Loestrin Fe.

Bayer sued its rival in Delaware district court, but the court in April 2015 invalidated the patent and granted summary judgment to Warner Chilcott Co. LLC, based on indefiniteness in a so-called whereby clause. The clause claimed that the patented regimen had "high contraceptive reliability, low incidence of follicular development, and satisfactory cycle control, with reliable avoidance of intracyclic menstrual bleeding and undesirable side-effects."

These words of degree — high, low, satisfactory and reliable — offered no specific measurements or standards against which to draw comparisons, the court found, rejecting what it said was an attempt by Bayer to "reargue claim construction" with new evidence prior to the ruling.

But Ford argued Tuesday that although the district court had not deemed extrinsic expert evidence necessary for claim construction, and thus Bayer hadn't introduced it at that stage, it had not waived the right to use such evidence for further considerations once past claim construction, and the district court was mistaken when it excluded that evidence.

This expert evidence shows that the disputed whereby clause would make it reasonably clear to a PSA that the terms deemed by the court to be indefinite were meant to be looked at in comparison to other similar products on the market at the time of the patented regimen's creation in 1995, according to Ford.

"[The expert] said a person of ordinary skill in the art knows reliability is high when the reliability is comparable to other marketed oral contraceptives," he said.

The whereby clause demonstrates specifically how the patent is different from earlier prior art, Ford said, showing that the contraceptive regime can effectively use a low dose of the hormone estrogen, reducing side effects, without an otherwise expected drop in effectiveness, Ford claimed.

Warner Chilcott's counsel, Covington & Burling LLP attorney Christopher Sipes, argued, however, that Bayer had waived its chance to use expert evidence during claim construction, and that the patent was clearly too vague on the intrinsic evidence alone.

All the terms in the whereby clause are subjective and there is no specific comparison product or regimen listed, or any other "objective boundary," to pin down specifics, Sipes claimed.

For instance, the phrase regarding avoidance of side effects does not state specifically how the patented regimen performs regarding a number of common side effects associated with oral contraceptives, such as headaches, breast tenderness and cardiovascular effects, which can vary not only in their level of incidence, but also their degree of severity, he noted.

"Every one of the five [disputed] terms has variance ... there are manifold issues of degree," he said.

The patent-in-suit is U.S. Patent Number 5,980,940.

Circuit Judges Kimberly A. Moore, Sharon Prost and Kara F. Stoll sat on the panel for the Federal Circuit.

Bayer is represented by Matthew R. Ford and Sharon Desh of Barlit Beck Herman Palenchar & Scott LLP.

Warner Chilcott is represented by Christopher N. Sipes and Eric R. Sonnenschein of Covington & Burling LLP.

The case is Bayer Intellectual Property GmbH et al. v. Warner Chilcott Co. LLC et al., case number 15-1716, in the U.S. Court of Appeals for the Federal Circuit.

--Additional reporting by Kurt Orzeck. Editing by Kelly Duncan.

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