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CoreValve Asks High Court To Define Patent Enablement

By **Erica Teichert**

Law360, Washington (May 07, 2013, 7:42 PM ET) -- CoreValve Inc. urged the U.S. Supreme Court on Monday to clarify the Federal Circuit's prior art enablement doctrine, alleging the court adopted three battling standards and erroneously upheld Edward Lifesciences Corp.'s $73.9 million infringement award over catheter heart valve technology.

In November, the Federal Circuit upheld Edwards' jury award and affirmed the company's patent-in-suit was both valid and infringed, but instructed a judge to review his denial of an Edwards' post-trial request for an injunction blocking CoreValve from making infringing devices used to treat patients with aortic valve stenosis. The court said the judge's decision to deny the injunction relied heavily on a statement made by CoreValve, representing that it planned to move its manufacturing operations to Mexico, which would effectively avoid the infringing activity.

But CoreValve — a Medtronic Inc. unit — claimed in its petition for writ of certiorari that Edwards' U.S. Patent Number 5,411,552 doesn't cover catheter heart valve technology in the first place, nor did the company have any evidence to prove its invention could work in human patients.

“In return for exclusive patent rights, the inventor must disclose how to make and use the claimed invention,” the petition said. “The Federal Circuit has departed from this court's enablement precedents and instead has advanced irreconcilable standards that too often authorize patents that do not enable the claimed invention. These patents improperly foreclose others from developing innovative products that actually work.”

In addition, CoreValve maintained that the appeals court has adopted three different standards for proving patent enablement, and that “doctrinal disarray” makes it extremely difficult to defend against prior art.

“The Federal Circuit's exclusive appellate jurisdiction over patent disputes precludes further vetting of these important issues by other courts of appeals,” the petition said. “Thus, this court is the only forum available to address the Federal Circuit's departures from the Patent Act and this court's precedents.”

While one of the three standards is the high court's standard, which requires disclosing the full scope of the patent for patent enablement, another Federal Circuit standard requires a single embodiment be disclosed. The third, according to CoreValve, contains a “laundry list of factors” to prove enablement.

“Unfortunately, the Federal Circuit has undone this court's clear and straightforward application of the statutory enablement requirement and generated confusion and uncertainty over its meaning,” CoreValve said.

Last month, Edwards asked a Delaware federal judge to award it additional damages and a permanent injunction against CoreValve, as it has continued to manufacture its Generation 3 transcatheter heart valves, or THVs, causing additional harm to the company.

CoreValve also refuses to participate in any accounting of its THV sales, and thus damages due, since the '552 patent originally expired in May, despite Edwards having applied for a patent term extension and having been granted an interim extension through at least May 2014, Edwards alleged.

The case was originally filed in 2008, with the jury ruling in Edwards' favor in April 2010. U.S. District Judge Gregory M. Sleet denied all post-trial motions by both Edwards and CoreValve, prompting them to appeal to the Federal Circuit.

The patent-in-suit is U.S. Patent Number 5,411,552.

CoreValve is represented by Jeffrey W. Sarles, James R. Ferguson, Melissa A. Anyetei, Emily C. Rossi and Donald M. Falk of Mayer Brown LLP.

Counsel information for Edwards was not immediately available.

The case is CoreValve Inc. et al. v. Edwards Lifesciences AG et al., case number 12-1325, in the U.S. Supreme Court.

--Additional reporting by Daniel Wilson and Scott Flaherty. Editing by Andrew Park.