

The Core Valve compulsory license on patent to treat aortic stenosis

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On February 7, 2011, a federal judge in Delaware rejected a request for an injunction to prevent the continued infringement of United States Patent No. [5411552](#), for "Valve prosthesis for implantation in the body and a catheter for implanting such valve prosthesis." The patent in question relates to the [CoreValve](#) device, which is used to treat [Aortic valve stenosis \(AS\)](#), a disease of the heart valves in which the opening of the aortic valve is narrowed.

This case, *Edwards Lifesciences v CoreValve*, was notable for several reasons.

1. The compulsory licensing of the patent involves a medical technology -- at a time when the Obama Administration is trying to block mention of compulsory licensing of medical patents at a UN high level meeting on non-communicable diseases.
2. At least for now, the compulsory license will be used exclusively for manufacturing and exporting the infringing medical device. This is an example of how a compulsory license issued under Part III of the TRIPS is not bound by the restrictions on exports under a compulsory license granted under Article 31 of the TRIPS (31.f), or even the 30 August 2003 Decision of the WTO to implement Para 6 of the Doha Declaration on TRIPS and Public Health.
3. The decision to order the compulsory licensing of the invention was in part to avoid the relocation of the manufacturing from the United States to Mexico. That is, the compulsory licensing of the patent saved U.S. manufacturing jobs that would have otherwise gone to a country with no patent for the invention.

The patent, originally obtained by three Danish inventors, was apparently assigned to Edward Lifesciences AG and Edwards Lifesciences LLC, the plaintiffs in the infringement action. Edward Lifesciences (AG and LLC) had earlier won a jury verdict that CoreValve, Inc. and Medtronic CoreValve, LLC ("CoreValve") were infringing the patent. Edward Lifesciences sought an injunction.

As noted by the Judge:

a plaintiff seeking a permanent injunction must satisfy a four-factor test before a court may grant such relief." eBay Inc. v. MercExchange, L.L.C, 547 U.S. 388, 391 (2006). A plaintiff must demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction

In rejecting the request of the injunction, Judge Gregory M Sleet wrote:

Since the court is denying Edwards' request for a permanent injunction, the parties may, of course negotiate a license regarding the patent-in-suit. As the Federal Circuit has stated:

In most cases, where the district court determines that a permanent injunction is not warranted, the district court may wish to allow the parties to negotiate a license amongst themselves regarding future use of a patented invention before imposing an ongoing royalty. Should the parties fail to come to an agreement, the district court could step in to assess a reasonable royalty in light of the ongoing infringement. Pace LLC v. Toyota Motor Corp., 504 F.3d 1293, 1315 (Fed. Cir. 2007).

With regard to the export of the infringing product, the Court noted:

Edwards' allegations of irreparable harm are undercut because CoreValve's infringement stems not from sales of the accused product, all of which occurred outside the United States, but rather from the manufacturing of the accused product in the United States.[13] Thus, Edwards must establish that CoreValve's manufacturing operations in the United States are continuing and will continue to cause irreparable harm if not enjoined. Edwards, however, does not appear to dispute that CoreValve would be able to move its remaining manufacturing operations to Mexico almost immediately if the court enjoined it from continuing to manufacture its products in the United States.[14] (See, e.g., D.I. 402 at 1 ("Even now, CoreValve admits that it has been moving off shore to Mexico since January 2010 and could immediately ramp up manufacturing there."); id. at 7-8; D.I. 357 at 15.) Thus, CoreValve would remain in the market with little or no interruption even if the court were to enjoin its infringing manufacturing operations in the United States, and an injunction thus would not affect the alleged harm.

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