Edwards Lifesciences – More than an *eBay* Redux

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Judge Proust's objection to the majority's treatment of *eBay* will attract notice, but other issues also warrant attention.

Edwards Lifesciences AG v. CoreValve, Inc. 2012 WL 5476839 (Fed. Cir. 2012) (CoreValve II), as well as the district court's opinion, 2011 WL 446203 *11 (D.Del. 2011) (CoreValve I), are notable for their of discussion of remedies, and particularly of injunctions. Yet both courts' rejection of an argument that animal tests are inadequate to establish utility also warrants mention.

As the Federal Circuit points out, the issue has been repeatedly laid to rest. *CoreValve II* at *3. Nearly two decades ago, In re Brana held, "one who has taught the public that a compound exhibits some desirable pharmaceutical property in a standard experimental animal has made a significant and useful contribution to the art, even though it may eventually appear that the compound is without value in the treatment in humans." 51 F.3d 1560, 1566 (Fed.Cir. 1995). Likewise, Scott v. Finney held, "Testing for the full safety and effectiveness of a prosthetic device is more properly left to the [FDA]." 34 F.3d 1058, 1063 (Fed.Cir.1994).

Indeed, as Judge Baldwin wrote soon after Brenner v. Manson, 383 U.S. 519 (1966), "The most important consequence of the grant of a patent in this case is that it would tend to encourage the assignee… to do further work…. This is the kind of investment the patent system was intended to encourage." In re Anthony, 414 F.2d 1383, 1398 n. 15 (CCPA 1969) (quoting appellant with approval). In other words, requiring FDA approval before patents could issue would eliminate sometimes-modest assurance of ability to recoup the substantial cost of clinical trials needed to obtain such approval.

In *CoreValve I*, several remedies receive extended attention. Despite approving a substantial damage award, the court writes, “Although the jury found that CoreValve’s infringement of the asserted claim was willful, the court finds that the issue was sufficiently close that enhanced damages are not warranted.” *Id*. at *12.

The discussion of attorney fees and costs ties to complaints of defendant’s “repeatedly attempt[ing] to revisit claim construction months after the court issue[d] its *Markman* order. … Such actions serve no constructive purpose. In the future, parties who engage in such conduct may face sanctions.” *Id*. at 9 (note omitted). Overall, however, the court finds, “The defendants' conduct in this case does not rise to a level of bad faith or vexatious litigation that warrants an award of attorneys’ fees and costs.” *Id*. at *13.

Following protracted discussion centering on eBay, Inc. v. MercExchange, LLC, 547 U.S. 388 (2006), the court also refuses a permanent injunction. *Id*. at *14-16. It does, however, grant an accounting with respect to “devices made, used, sold, offered for sale, imported or supplied in or from the United States.“ *Id*. at *16.

On the first *eBay* factor, allegations of irreparable harm are found to be undercut because domestic sales were precluded by lack of FDA approval and because defendant claimed that it could move manufacturing operations “almost immediately” to Mexico. *Id*. at 15.

Regarding the second, the court writes, “As with the other *eBay* factors, the burden for establishing the inadequacy of legal remedies falls on the plaintiff.” *Id*. (citing *eBay,* 547 U.S. at 391). The court then finds that, although Edwards was a practicing entity, licensing another in a significantly overlapping field supported the notion that an ongoing royalty would satisfy its needs. *See id*. at n. 15.

Ultimately, tying back to discussion of the first factor, “The court fails to see what hardship Edwards would suffer if CoreValve were permitted to continue manufacturing its product in the United States, as opposed to in Mexico, that could not be compensated through remedies at law.” *Id*. at *16. One must wonder, however, whether a faltering economy and reluctance to move jobs outside the country played a large role.

At the Federal Circuit, CoreValve pursued a variation on this theme by also “argu[ing] that the criteria for award of lost profits were not met, stating that it ‘could have manufactured its device overseas’.” *CoreValve II* at *7. Unimpressed, the court notes, “Whether or not CoreValve could have avoided infringement, it did not do so, although it was notified as early as 2005 of Edwards' position, and the record showed CoreValve's familiarity with the patents and the inventors.” *Id*.

Although it approves most of the findings below, that court, apparently unmoved by the threat to move jobs elsewhere, finds inadequate support for denying an injunction. One fact of consequence was FDA approval apparently secured after the district court’s opinion. In light of that, the court agrees that Edwards’ presence in the U.S. market would be overwhelmed by a much larger firm, Medtronic, CoreValve’s successor in interest. *Id*. at *7. Another was the district court’s indisputable error in finding that Edwards had licensed its invention. *Id*. at *8. The case was therefore remanded. *Id*. at *9.

Providing guidance, *CoreValve II* states, “Absent adverse equitable considerations, the winner of a judgment of validity and infringement may normally expect to regain the exclusivity that was lost with the infringement. … The Court in *eBay* did not hold that there is a presumption against exclusivity on successful infringement litigation.” *Id*. at *7. It also cites with approval the observation, “Courts awarding permanent injunctions typically do so under circumstances where plaintiff practices its invention and is a direct market competitor.” *Id*. at *8 (quoting

Advanced Cardiovascular Sys. v. Medtronic Vascular, Inc., 579 F.Supp.2d 554, 558 (D.Del.2008)).

As mentioned, Judge Proust objects: “To the extent that one reads ‘[a]bsent adverse equitable considerations…’ as creating the presumption of an injunction once the plaintiff prevails, … that is not the law.” *Id*. at *10 (concurring and quoting the majority). In that regard, she cites *eBay’s* statement that plaintiffs must demonstrate that four factors predicate to an injunction have been met. *Id*. (citing 547 U.S. at 391). It might sometimes make a difference, but Edwards seems to face little difficulty.