

# Medinol stent gets FDA approval

• By YEHEZKEL LAING

The US Food and Drug Administration (FDA) has approved Medinol's Nirflex stent, the company announced Sunday.

Medinol is suing Boston Scientific of the US, alleging it stole several patent rights and is using the technology to produce its own stents.

Medinol said the FDA's approval will open up a large market for its products in the US, and give it the chance to compete with Boston Scientific. However, as the court case with Boston Scientific has not yet started, Boston Scientific is still free to sell its own stent with the allegedly stolen technology.

In June, a German court found Boston Scientific guilty of infringing the patents of Medinol. It ruled that Boston Scientific, a former distributor

for Medinol and the world's third-largest maker of stents, had sold a stent called Express, which infringed on two of seven Medinol patents. A court in Holland recently came to the same decision.

A stent is a short tube used to keep open a formerly blocked passageway, such as an artery or a bile duct, especially after the artery-clearing procedure known as angioplasty.

A stent can cost more than \$1,000. The US market for Medinol's technology is estimated at \$4 billion.

Founded in 1992, Jerusalem-based Medinol is a world leader in stent design and manufacture. In 1996, while still a start-up, it entered into a venture with Boston Scientific to distribute a range of Medinol's NIR stents worldwide after it won approval to sell them in Europe.

By 2000, Boston Scientific had bought 22 percent of Medinol, and the two companies entered into negotiations concerning the remaining 78%. The marketing agreement between them ended in 2001, and talks broke off after Boston Scientific declined to meet Medinol's asking price.

In April 2001, Medinol filed suit in the US District Court for the Southern District of New York alleging intellectual property theft, breach of contract, and fraudulent filings. Boston Scientific claimed the suit was a ploy by Medinol to inflate the price of its planned acquisition for an estimated \$1.5b. to \$2b. The case has yet to be decided.

In September, Medinol signed a new US distribution agreement with W.L. Gore and Associates; a private medical implants maker.