

Litigation Alert: *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*—The Federal Circuit Holds 35 U.S.C. § 271(f) Inapplicable to Method Claims

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On August 19, 2009, the Federal Circuit, sitting *en banc*, limited the reach of 35 U.S.C. § 271(f), holding that the statute does not apply to method claims. The Federal Circuit's decision in *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*, F.3d (Fed. Cir. 2009) (*en banc* in part) (Lourie, J.), reversed its earlier holding in *Union Carbide Chemicals Plastics Technology Corp. v. Shell Oil Co.*, 425 F.3d 1366 (Fed. Cir. 2005). In overturning a relatively new precedent, the Federal Circuit explained that the language and legislative history of Section 271(f), as well as the presumption against extraterritorial application of U.S. law, militated against applying the statute to method and process claims.

Section 271(f) provides a cause of action for patent infringement when the “components” of a patented invention are “supplied” for assembly abroad. Congress enacted the statute in response to the Supreme Court's decision in *Deepsouth Packing Co., Inc. v. Laitram Corp.*, 406 U.S. 518 (1972), which held that a manufacturer who shipped unassembled parts of a patented shrimp deveining machine abroad was not liable for patent infringement because “it is not infringement to make or use a patented product outside of the United States.” Section 271(f) thus legislatively closed the loophole exposed by the *Deepsouth* court.

In *Cardiac Pacemakers*, the patentee Cardiac filed suit against St. Jude, alleging infringement of patents covering implantable cardioverter defibrillators (“ICDs”). These are small devices that detect and correct potentially fatal abnormal heart rhythms. After a complex procedural history consisting of several appeals, both sides filed motions for summary judgment in the United States District Court for the Southern District of Indiana, including a motion by St. Jude to limit damages. The district court granted St. Jude's motion in part and denied it in part. Significantly to the discussion here, the district court held that, pursuant to *Union Carbide*, Cardiac's potential damages included the sale

of infringing ICDs supplied from the United States to other countries. The parties appealed the district court's holdings with respect to Section 271(f) and other issues. The only claim at issue on appeal was method claim 4 of U.S. Patent No. 4,407,288.

In considering the lower court's application of Section 271(f) to claim 4, the Federal Circuit focused first and foremost on the language of the statute, and in particular the words “component” and “supplied.” The Court conceded that a method or process claim has “components” in the form of the steps of the process, but it rejected Cardiac's argument that an apparatus for performing a method was a “component” of that method. This meant that for Section 271(f) to apply to process claims, a patentee would have to show that some intangible step of the process was “supplied” to other countries. The Federal Circuit, however, closed off this route, interpreting “supplied” to mean the physical transfer of an object. In light of this interpretation, the Court concluded that “because one cannot supply the step of a method, Section 271(f) cannot apply to method or process patents.”

The Federal Circuit's reading of “supplied” was perhaps influenced by the Supreme Court's recent decision in *Microsoft Corp. v. AT&T Corp.*, 550 U.S. 437 (2007), which centered about AT&T's patent for digitally encoding and compressing recorded speech. AT&T asserted both method and apparatus claims against Microsoft, which eventually admitted that installation of its Windows software on a computer rendered it capable of performing as the apparatus covered by AT&T's patent. The question on appeal was whether Microsoft infringed pursuant to Section 271(f) by sending to computer manufacturers outside the United States a master version of Windows, which would then be copied and installed on computers for sale to users abroad. The Supreme Court held that Microsoft did not subject itself to liability pursuant to Section 271(f) because the actual software installed on foreign-made computers to form the patented product

was not the physical version of Windows supplied by Microsoft, but copies made from masters. Thus, *Microsoft* appeared to tie the concept of “supplying” under Section 271(f) to the notion of tangibility.

The *Cardiac Pacemakers* Court also supported its conclusion with the legislative history of Section 271(f), noting that the statute is geared towards closing the loophole that allowed infringers to ship an unassembled patented product abroad for later assembly. Observed the Court, the “legislative history of Section 271(f) is almost completely devoid of any reference to the protection of method patents.”

Finally, the Court held that extending Section 271(f) to method claims is prohibited by the presumption against extraterritoriality. The Court explained that in “light of the complete absence of any Congressional intent to protect patented methods under Section 271(f) and the explicit Congressional purpose of overruling *Deepsouth*’s holding, the presumption [against extraterritoriality] compels us not to extend the reach of Section 271(f) to method patents.” By so holding, the Court applied the reasoning of *Microsoft*, where the Supreme Court explained that the presumption applies even to statutes with an international reach, and indicated that the scope of such laws should be no broader than specifically set out in the statute. Indeed, in *Microsoft*, the Supreme Court found that the presumption argued in favor of holding that Microsoft’s conduct fell outside the purview of Section 271(f) because the statute did not specifically define “supplied” to encompass duplicates made abroad.

In light of its holding that Section 271(f) does not cover methods or the devices that may be used to practice a claimed method, the Federal Circuit reversed, concluding that St. Jude is not liable for infringement of claim 4 of the ’288 patent under Section 271(f). Judge Newman was the sole dissenter. She argued that the Court’s holding ran afoul of statutory text, legislative history, precedent and statutory purpose. In Judge Newman’s view, the “statute is aimed at evasion of United States patents, and is not limited to any particular class of patentable subject matter.”

As a practical matter, *Cardiac Pacemakers* will likely have limited impact. Most patents include corresponding apparatus and method claims. Thus, so long as the exported item is a “component” of the claimed apparatus, the patentee can still recover damages for exports of that component. However, where there are only method claims, *Cardiac Pacemakers* should operate to limit export damages. This may be of particular interest to biotechnology companies—method claims may be the only claims available to protect certain diagnostic kits or assays. The issue presented by *Cardiac Pacemakers* is also likely to be of significant interest to software companies who may be “supplying” software code outside the United States.

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