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Medical Device Manufacturer Not Liable for Inducing Customers' Patent Infringement

By: Courtland Merrill

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The District of Minnesota recently found a medical device manufacturer did not indirectly infringe a competitor's patents even though customers allegedly used the defendant's accused product in an infringing manner, but did so in a way that differed from the product's instructions for use. In *QXMedical, LLC v. Vascular Solutions, LLC*, 408 F. Supp. 3d 996, 1012-1014 (D. Minn. 2019), the federal district court ruled that Roseville, Minnesota device manufacturer QXMedical was not liable for indirect infringement even though the company's guide extension device was capable of use—and in fact was allegedly used by cardiologists—in a way that directly infringed, where the device's instructions for use affirmatively told customers not to use the device in an infringing manner.

The case provides an example of how induced-infringement claims can be avoided where a medical device has both infringing and non-infringing uses, without changing the device itself, by changing the instructions to prescribe only legitimate, non-infringing uses.

Induced-Infringement Claims Failed Where Instructions for Use Instructed Users Not to Infringe. Vascular Solutions accused QXMedical of infringing patent claims requiring insertion of a guide extension into a guide catheter not more than “one French” size—0.0131 inches—smaller than the diameter of the extension. To avoid infringement, QXMedical changed the instructions for use sold with its accused guide extension device, without changing the device itself, to prescribe use only with a guide catheter at least 0.014 inches larger, and

outside the scope of the patents' claims.

There was no medical reason for the change to the instructions. The accused guide extension was cleared for use with the FDA, and could be used, with commonly available, smaller-sized guide catheters in a manner that would otherwise infringe Vascular Solutions' patents. However, many larger-sized guide catheters are available on the market for use with QXMedical's guide

extension in ways that legitimately avoided infringement of the one-French claims.

The court dismissed Vascular Solutions' claim for direct infringement because QXMedical itself did not make or sell a one-French size smaller guide catheter required to complete the “system” or practice the “method” covered by the claims. Vascular Solutions alleged that QXMedical nonetheless indirectly infringed the one-French size claims by inducing doctors to perform cardiology procedures using QXMedical's guide extension with available smaller-sized guide catheters in a way that directly infringed.

Inducing infringement requires proof that a defendant acted affirmatively to encourage another's direct infringement with knowledge that the induced acts constitute patent infringement. See 35 U.S.C. § 271(b). The lawful promotion of non-infringing uses, however, does not constitute an intent to induce infringing uses.¹

Vascular Solutions argued that QXMedical intended to induce doctors' use with smaller guide catheters in a way that would infringe because QXMedical tested and certified to the FDA that its device could be used with guide catheters smaller than the size prescribed in the instructions for use. Vascular Solutions argued doctors were not required to follow the instructions for use sold with QXMedical's device and, in at least one actual instance, did not follow those instructions. The district court, nonetheless, granted QXMedical summary judgment of non-infringement on Vascular Solutions' induced-infringement claim because, despite the product's capabilities, QXMedical's instructions



promoted only non-infringing uses.

The district court concluded that, because QXMedical's instructions for use specifically instruct customers not to use the accused guide extension device with a smaller-sized guide catheter, the instructions specifically instructed doctors not to infringe. Given the instructions, the court concluded QXMedical could not be found to have affirmatively acted with the specific intent necessary to be liable for inducing doctors' use with smaller-sized guide catheters.

¹*Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 933 (2005) (discussing *Sony Corp. of Am. v. Universal City Studio, Inc.*, 464 U.S. 417 (1984)); *Takeda Pharm. U.S.A., Inc. v. W. Ward Pharm. Corp.*, 785 F.3d 625, 630 (Fed. Cir. 2015); *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1305-06 (Fed. Cir. 2006).

BIO: Courtland Merrill is a trial attorney at Anthony Ostlund Baer & Louwagie P.A. His practice focuses exclusively on business and intellectual property disputes. Courtland has successfully tried patent cases and various other intellectual property disputes before juries and argued before the U.S. Court of Appeals for the Federal Circuit. Courtland currently represents QXMedical in litigation. He may be reached at cmerrill@anthonyostlund.com.