

FEDERAL CIRCUIT REVIEW

INFRINGEMENT

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This issue will focus on infringement under 35 U.S.C. § 271 of the patent statute. In the past few years, the Supreme Court and Federal Circuit refined the standards for direct, indirect, and joint infringement through decisions such as *Grokster* and *BMC Resources*. This issue will explore the effects of those important decisions on more recent Federal Circuit cases. The concept of infringement will also be analyzed in the context of the Hatch-Waxman safe harbor as it applies to drug research tools. Finally, this issue will examine a decision defining what constitutes an “infringing use” of a claimed invention.

DIRECT AND INDIRECT INFRINGEMENT

In *Ricoh Company, Ltd. v. Quanta Computer Inc.*, the Federal Circuit addressed direct and indirect infringement of method claims. 550 F.3d 1325 (Fed. Cir. 2008). Ricoh owned various patents claiming methods of writing and formatting data onto optical discs. Quanta manufactured notebook computers containing optical disc drives accused of infringement. Quanta sold its computers to distributors who, in turn, resold them to consumers. The patent owner alleged that the manufacturer directly infringed its method patents by selling software embedded in optical disc drives that instructed the drives to perform the claimed methods. The patent owner also asserted that the manufacturer was liable for contributory infringement for selling computers containing the accused optical disc drives to resellers. Finally, the patent owner accused the manufacturer of active inducement of infringement by providing instructions and other forms of encouragement to consumers to perform the claimed methods of writing and formatting data onto optical discs.

The district court granted summary judgment dismissing all infringement claims as a matter of law, holding that (1) the sale of software does not constitute an act of direct infringement of a method claim under § 271(a); (2) there was no contributory infringement under § 271(c) because the optical disc drives were capable of substantial non-infringing uses, such as reading data from discs as opposed to writing data; and (3) there was no induced infringement under § 271(b)

because the patent owner failed to present evidence that the manufacturer communicated any encouragement to infringe to the customers who purchased and used the computers. The patent owner appealed to the Federal Circuit.

DIRECT INFRINGEMENT

An accused infringer commits an act of direct infringement under 35 U.S.C. § 271(a) if it “makes, uses, offers to sell, or sells any patented invention, within the United States, or imports into the United States any patented invention.” It is well established, however, that the sale of a device that performs a claimed method is not a sale of a “patented invention” under § 271(a) and thus not an act of direct infringement. *See, e.g., NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1317 (Fed. Cir. 2005); *Joy Technologies, Inc. v. Flakt, Inc.*, 6 F.3d 770, 773 (Fed. Cir. 1993). The Federal Circuit has yet to address the question of whether it is ever possible to “sell” or “offer to sell” a claimed method.

In *Ricoh*, the patent owner did *not* argue that the sale of the accused optical disc drives was an act of direct infringement of its method claims. Instead, the patent owner argued that the sale of embedded *software* that instructs the drives to perform the claimed methods constitutes a sale of the patented method under § 271(a). The Federal Circuit disagreed.

Citing *NTP* and *In re Kollar* (286 F.3d 1326 (Fed. Cir. 2002)), the Federal Circuit reaffirmed that “a process is nothing more than the sequence of actions of which it is comprised” and that a process “has to be carried out or performed” to constitute an act of direct infringement under § 271(a). *Ricoh*, 550 F.3d at 1335. Software, on the other hand, is a “set of instructions that directs hardware to perform a sequence of actions.” *Id.* (citing *Microsoft Corp. v. AT&T Corp.*, 550 U.S. 437 (2007)). Because software is not itself a sequence of actions, but rather a set of instructions that directs hardware to perform a sequence of actions, selling software cannot constitute an act of direct infringement of a method claim. *Id.* The Federal Circuit left undecided the larger question of whether it is ever possible to “sell” or “offer to sell” a patented method under § 271(a) — “because the allegedly infringing sale in this case was the sale of software (*i.e.*, instructions to perform a process rather than the performance of the process itself), we need not determine whether a process may ever be sold as to give rise to liability under § 271(a).” *Id.*

CONTRIBUTORY INFRINGEMENT

A party contributorily infringes a method claim under 35 U.S.C. § 271(c) if it offers to sell, sells, or imports into the United States a “material or apparatus for use in practicing a patented process, constituting a material part of the invention,” that is “not a staple article or commodity of commerce suitable for substantial non-infringing use.”

In *Ricoh*, the parties agreed that the accused optical disc drives included components and software that did not infringe the method claims, such as the components and software that allowed the drives to read data from optical discs. Nevertheless, the patent owner argued that the manufacturer was still liable for contributory infringement because the accused drives contained separate components and software that could be used only to perform the claimed method of writing and formatting data to optical discs.

The Federal Circuit recognized that this case presented “an important, and previously unresolved, question concerning the scope of liability for contributory infringement, the construction of § 271(c), and the interpretation of *Sony Corp. of America v. Universal City Studios, Inc.*, 464 U.S. 417 (1984), and *Metro-Goldwyn-Mayer Studios, Inc. v. Grokster, Ltd.*, 545 U.S. 913 (2005).” *Ricoh*, 550 F.3d at 1336. Looking first at the language of § 271(c), the Federal Circuit held that it incorporated “the core notion that one who sells a component especially designed for use in a patented invention may be liable as a contributory infringer, provided that the component is not a staple article of commerce suitable for substantial noninfringing use.” *Id.* at 1337. In the present case, the Federal Circuit noted that the manufacturer would be liable for contributory infringement if it sold or imported into the United States a bare component — e.g., a microcontroller and associated software — that had no use other than practicing the patented methods. *Id.* Merely embedding an infringing component into a larger product with some additional, separable feature does not allow a manufacturer to escape liability as a contributory infringer. *Id.* “If we were to hold otherwise, then so long as the resulting product, as a whole, has substantial non-infringing use *based solely on the additional feature*, no contributory liability would exist despite the presence of a component that, if sold alone, plainly would incur liability.” *Id.* (emphasis in original).

The Federal Circuit found this conclusion to be consistent with the Supreme Court’s holdings in *Grokster* and *Sony* as well as its prior decision, *Hodosh v. Block Drug Co.*, 833 F.2d 1575 (Fed. Cir. 1987), for which the dissent in *Ricoh* relied on. The Federal Circuit vacated the summary judgment of no contributory infringement and remanded for further proceedings.

INDUCED INFRINGEMENT

Under 35 U.S.C. § 271(b), a party that “actively induces infringement of a patent shall be liable as an infringer.” To prove active inducement, a patent owner must prove that the alleged inducer intended to infringe the patent-in-suit. In *Ricoh*, the question before the Federal Circuit was whether the patent owner must present evidence that the manufacturer’s efforts to encourage infringement was successfully communicated to customers who directly infringe the patent. Relying on *Grokster*, the Federal Circuit held that a patent owner is *not* required to show such evidence. *Ricoh*, 550 F.3d at 1341-42 (citing *Grokster*, 545 U.S. at 935).

Because the district court discounted the patent owner's evidence of inducement on purely legal grounds, the Federal Circuit remanded to the district court to determine the factual sufficiency of that evidence as it impacts the various parties involved in the manufacture, sale, and distribution of the accused optical drives.

Cases Referenced

Hodosh v. Block Drug Co., 833 F.2d 1575 (Fed. Cir. 1987)

In re Kollar, 286 F.3d 1326 (Fed. Cir. 2002)

Joy Technologies, Inc. v. Flakt, Inc., 6 F.3d 770 (Fed. Cir. 1993)

Metro-Goldwyn-Mayer Studios, Inc. v. Grokster, Ltd., 545 U.S. 913 (2005)

Microsoft Corp. v. AT&T Corp., 550 U.S. 437 (2007)

NTP, Inc. v. Research In Motion, Ltd., 418 F.3d 1282, 1317 (Fed. Cir. 2005)

Ricoh Company, Ltd. v. Quanta Computer Inc., 550 F.3d 1325 (Fed. Cir. 2008)


Sony Corp. of America v. Universal City Studios, Inc., 464 U.S. 417 (1984)

JOINT INFRINGEMENT

The statutory concepts of contributory and induced infringement do not capture all situations in which multiple parties participate in the infringement of a single claimed method. Sometimes it is necessary to invoke the principle of joint infringement when two or more parties collectively perform all of the claimed steps of a claimed invention, while no one party performs all of the steps individually.

In 2007, the Federal Circuit addressed the issue of joint infringement in *BMC Resources, Inc. v. Paymentech, L.P.* 498 F.3d 1373 (Fed. Cir. 2007). It held that direct infringement under 35 U.S.C. § 271(a) requires "a party to perform or use each and every step or element of a claimed method or product." *Id.* at 1378. Furthermore, indirect infringement under 35 U.S.C. § 271(b) or (c) requires that at least one party commit an act of direct infringement. *Id.* at 1379. Nevertheless, the Federal Circuit noted that in agency law, vicarious liability is imposed when a liable party controls the conduct of the acting party. *Id.* Accordingly, parties may be liable for joint infringement if one party is the "mastermind," imposing "control or direction" over the entire process. *Id.* at 1381. If the cooperation occurs at mere "arms-length," then there is no direct infringement and no liability for joint infringement. *Id.*

The Federal Circuit recently revisited joint infringement in *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318 (Fed. Cir. 2008). The patent-in-suit was directed to electronic methods for conducting auctions over an electronic network, such as the Internet, using a web browser. The accused infringer originally operated an auction system over a proprietary computer network. When the accused infringer modified its system to allow bidders to operate over the Internet using a web browser, the patentee filed suit for patent



infringement. Both parties agreed that no single actor performed all of the steps of the asserted method claims. The issue was whether the accused infringer sufficiently controlled or directed the bidders such that it could be held liable for joint infringement.

The Federal Circuit re-affirmed that “control or direction” is the applicable standard for joint infringement post-*BMC Resources*. *Muniauction*, 532 F.3d at 1329. It then held that the method claims-in-suit were *not* jointly infringed because the accused infringer did not control or direct the bidders to operate the auction over the web-based system on its behalf. *Id.* at 1330.

It is important to note that many patent claims requiring joint infringement could be remedied by proper claim drafting. “A patentee can usually structure a claim to capture infringement by a single party.” *BMC Resources*, 498 F.3d at 1381. However, courts will not unilaterally restructure the claims on behalf of the patent holder. Instead, the patent holder “must bear the cost” of its failure to construct claims that are suitable for direct infringement. *Id.* (citation omitted).

Cases Referenced

BMC Resources, Inc. v. Paymentech, L.P., 498 F.3d 1373 (Fed. Cir. 2007)

Muniauction, Inc. v. Thomson Corp., 532 F.3d 1318 (Fed. Cir. 2008)

HATCH-WAXMAN SAFE HARBOR AND RESEARCH TOOLS

The Hatch-Waxman Act provides for a safe harbor that immunizes competitors from infringement for activities undertaken for the sole purpose of obtaining FDA regulatory approval. In *Proveris Scientific Corp. v. Innovasystems, Inc.*, the Federal Circuit considered whether the safe harbor also applied to research tools that are used by third parties for the development and submission of information to the FDA. 536 F.3d 1256 (Fed. Cir. 2008).

The patentee held claims directed to an apparatus for characterizing aerosol sprays used in various drug delivery devices such as inhalers and nasal spray pumps. Spray characterization plays an important role in the FDA regulatory approval process for makers of products that use this delivery method. The accused manufacturer made and sold a spray analyzer apparatus that measured certain parameters of nasal drug delivery devices. The manufacturer argued that its activities were protected by the safe harbor because it had offered to sell the analyzer solely to pharmaceutical companies and the FDA.

The Federal Circuit noted that the Hatch-Waxman Act sought to eliminate the *de facto* patent term extension that resulted from FDA pre-market approval requirements by providing a safe harbor. *Id.* at 1260-61. Under 35 U.S.C. § 271(e)(1), competitors are

immunized from claims of infringement of a “patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.” The determinative issue was whether the accused manufacturer’s spray analyzer apparatus was a “patented invention” that was “reasonably related.”

In *Eli Lilly & Co. v. Medtronic, Inc.*, the Supreme Court held that the safe harbor was not limited to drugs but also extended to medical devices such as defibrillators. 496 U.S. 661, 664 (1990). Thereafter, in *AbTox, Inc. v. Exitron Corp.*, the Federal Circuit adopted the broader holding that the phrase “patented invention” may include any medical device. 122 F.3d 1019, 1028-29 (Fed. Cir. 1997). In *Telectronics Pacing Systems v. Ventritex, Inc.*, the Federal Circuit held that demonstrating an implantable defibrillator at a conference was “reasonably related” to FDA approval because it “facilitated the selection of clinical trial investigators.” 982 F.2d 1520, 1525 (Fed. Cir. 1992). The Supreme Court later held in *Merck KGaA v. Integra Lifesciences I, Ltd.* that “reasonably related” activity does not require actual submission of information to the FDA so long as there is a “reasonable basis for believing that a patented compound may work.” 545 U.S. 193, 198-99 (2005).

In *Proveris Scientific*, however, the Federal Circuit distinguished those past decisions on the ground that the accused spray analyzer was not itself subject to the FDA pre-market approval process, even though it was used in the development of FDA regulatory submissions. 536 F.3d at 1266. The manufacturer was not seeking FDA approval of the analyzer in order to enter the market to compete with existing patent holders. The Federal Circuit further noted the patentee could not receive a patent-term extension because the claimed invention was not subject to FDA pre-market approval. *Id.*

The Federal Circuit, therefore, held that the Hatch-Waxman safe harbor did *not* apply to the spray analyzer and affirmed the district court’s judgment of infringement.

Cases Referenced

AbTox, Inc. v. Exitron Corp., 122 F.3d 1019 (Fed. Cir. 1997)

Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661 (1990)

Merck KGaA v. Integra Lifesciences I, Ltd. 545 U.S. 193 (2005)

Proveris Scientific Corp. v. Innovasystems, Inc., 536 F.3d 1256 (Fed. Cir. 2008)

Telectronics Pacing Systems v. Ventritex, Inc., 982 F.2d 1520 (Fed. Cir. 1992)

INFRINGEMENT USE

In *Medical Solutions, Inc. v. C Change Surgical LLC*, the Federal Circuit considered whether displaying an accused device at a trade show was an infringing use of a claimed invention.

541 F.3d 1136 (Fed. Cir. 2008). The device at issue was an apparatus that controlled the temperature of surgical tools. At a trade show, the accused infringer exhibited a prototype of its apparatus, staffed its booth with representatives, and distributed brochures about the apparatus. The representatives also demonstrated the functionality of various internal components of its accused surgical apparatus.

The patent holder originally alleged infringement under 35 U.S.C. § 271(a) of the patent statute based on an “offer to sell” and “use” of its patented invention. The district court rejected both arguments. Applying traditional contracts analysis, the district court ruled that there was no “manifestation of willingness to enter into a bargain” by the accused infringer at the trade show because it never disclosed price terms for its device. *Medical Solutions I*, 468 F. Supp. 2d 130, 134-35 (D.D.C. 2006). The patent holder subsequently abandoned the “offer to sell” argument and advanced its “use” claim to the Federal Circuit.

The Federal Circuit examined the totality of the circumstances in determining that the accused infringer’s display of the apparatus was not an infringing use. The Federal Circuit noted that in *NTP, Inc. v. Research In Motion, Ltd.*, it relied on the ordinary dictionary definition of “use” as “to put into action or service.” *Medical Solutions*, 541 F.3d at 1141 (citing *NTP*, 418 F.3d at 1317). None of the activities at the trade show fell within this definition. There was no proof that the accused apparatus was ever used to heat medical items at the trade show. The closest evidence indicated that representatives demonstrated how the surgical apparatus could have been operated had it been properly loaded. Absent evidence of the device being put into service, the patent holder failed to make a *prima facie* case of infringing use. *Id.*

The Federal Circuit sidestepped the larger issue of whether a demonstration of an accused device is an infringing “use.” It recognized that some lower courts have held that “the mere demonstration or display, . . . even in an obviously commercial atmosphere” is sufficient to establish an act of infringement, while others have concluded that a demonstrative display “hardly qualifies” as using the device for its intended purposes. *Id.* at 1141 n.4. But here, because the accused infringer never fully demonstrated the functionality of its device at the trade show, the Federal Circuit did not need to reach an answer to this more fundamental question. *Id.* at 1141.

Cases Referenced

Medical Solutions, Inc. v. C Change Surgical LLC, 541 F.3d 1136 (Fed. Cir. 2008)

Medical Solutions, Inc. v. C Change Surgical LLC, 468 F. Supp. 2d 130 (D.D.C. 2006)

NTP, Inc. v. Research In Motion, Ltd., 418 F.3d 1282 (Fed. Cir. 2005)

CONTACT INFORMATION

If you have any questions, please contact the authors of this newsletter listed below or the Willkie attorney with whom you regularly work.

John DiMatteo

(212) 728-8299

jdimatteo@willkie.com

Michael W. Johnson

(212) 728-8137

mjohnson1@willkie.com

Ketan Pastakia

(212) 728-8713

kpastakia@willkie.com

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WILLKIE FARR & GALLAGHER LLP

787 Seventh Avenue

New York, NY 10019-6099

Tel (212) 728-8000

Fax (212) 728-8111

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