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Federal Circuit Patent Bulletin: *Cleveland Clinic Found. v. True Health Diagnostics, LLC*

June 19, 2017

"A party that provides a service, but no 'material or apparatus,' cannot be liable for contributory infringement."

On June 16, 2017, in *Cleveland Clinic Found. v. True Health Diagnostics, LLC*, the U.S. Court of Appeals for the Federal Circuit (Lourie, Reyna,* Wallach) affirmed the district court's judgment that U.S. Patents No. 7,223,552, No. 7,459,286, and No. 8,349,581, and No. 9,170,260, which related to methods for testing for myeloperoxidase (MPO) in a bodily sample, were not invalid under 35 U.S.C.§ 101 as patent-ineligible subject matter, and that U.S. Patent No. 9,170,260, which related to treating a patient that has cardiovascular disease, was not infringed contributorily or by inducement. The Federal Circuit stated:

Section 101 of the Patent Act defines patent eligible subject matter: Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title. The Supreme Court has long held that there are certain exceptions to this provision: laws of nature, natural phenomena, and abstract ideas. To determine whether a claim is invalid under § 101, we employ the two-step Alice framework. In step one, we ask whether the claims are directed to ineligible subject matter, such as a law of nature. While method claims are generally eligible subject matter, method claims that are directed only to natural phenomena are directed to ineligible subject matter. If the claims are directed to eligible subject matter, the inquiry ends.

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Practice Areas

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The claims of the testing patents are directed to multistep methods for observing the law of nature that MPO correlates to cardiovascular disease. Moreover, the testing patents' specifications similarly instruct that the inventions are "based on the discovery that patients with cardiovascular disease have significantly greater levels of leukocyte and [MPO]," and they do not purport to alter MPO levels in any way. Cleveland Clinic's invention thus involves "seeing" MPO already present in a bodily sample and correlating that to cardiovascular disease. Because the testing patents are based on "the relation [between cardiovascular disease and heightened MPO levels that] exists in principle apart from human action," they are directed to a patent-ineligible law of nature. . . . Cleveland Clinic has not created a new laboratory technique; rather, it uses well-known techniques to execute the claimed method. The specifications of the testing patents confirm that known testing methods could be used to detect MPO, and that there were commercially available testing kits for MPO detection. Because the claims of the testing patents are directed to a natural law, we turn to the second step of the Alice framework.

In Alice step two, we examine the elements of the claims to determine whether they contain an inventive concept sufficient to transform the claimed naturally occurring phenomena into a patent-eligible application. We must consider the elements of the claims both individually and as an ordered combination to determine whether additional elements transform the nature of the claims into a patent-eligible concept. "To save a patent at step two, an inventive concept must be evident in the claims." We conclude that the practice of the method claims does not result in an inventive concept that transforms the natural phenomena of MPO being associated with cardiovascular risk into a patentable invention. . . . Cleveland Clinic does not purport to derive new statistical methods to arrive at the predetermined or control levels of MPO that would indicate a patient's risk of cardiovascular disease. . . . The claims, whether considered limitation-bylimitation or as a whole, do not sufficiently transform the natural existence of MPO in a bodily sample and its correlation to cardiovascular risk into a patentable invention. . . .

Contributory infringement occurs if a party sells, or offers to sell, a material or apparatus for use in practicing a patented process, and that "material or apparatus" is material to practicing the invention, it has no substantial non-infringing uses, and it is known by the party "to be especially made or especially adapted for use in an infringement of such patent." A party that provides a service, but no "material or apparatus," cannot be liable for contributory infringement.

True Health provides MPO testing services. The only "material or apparatus" that Cleveland Clinic claims True Health sells are lab reports documenting the results of True Health's testing services. We agree with the district court that the "lab reports attached to the complaint reflect the manner in which defendant reports the results of the service it provides." They are not a "material or apparatus." Accordingly, it was not an abuse of discretion for the district court to dismiss Cleveland Clinic's contributory infringement claims and deny leave to amend.

"Whoever actively induces infringement of a patent shall be liable as an infringer." "However, knowledge of the acts alleged to constitute infringement is not enough." The mere knowledge of possible infringement by others does not amount to inducement; specific intent and action to induce infringement must be proven. It is undisputed that True Health does not sell or prescribe lipid lowering drugs to patients. Cleveland Clinic

argues that True Health's lab reports are sufficient to create the reasonable inference that a doctor who ordered such a report would rely on the results and would administer a lipid lowering agent where the results indicated the patient had a cardiovascular disease risk. Cleveland Clinic alleges no facts that suggest any connection between True Health and doctors that may prescribe lipid lowering drugs. Cleveland Clinic thus falls short of showing "specific intent and action" on behalf of TrueHealth to induce infringement of the '260 patent. It was not an abuse of discretion for the district court to dismiss Cleveland Clinic's induced infringement claims and deny leave to amend.