IP Alert: Divided Infringement and Subject-Matter Eligibility: Are Mixed Diagnostic and Therapeutic Method Claims Viable and Valuable?

Divided Infringement and Subject-Matter Eligibility: Are Mixed Diagnostic and Therapeutic Method Claims Viable and Valuable?

By Sarah A. Kagan

Until recently, diagnostic assay developers wanting to protect their innovations with patents have faced a Hobson's choice: claim a treatment step to gain subject-matter eligibility but do so at the risk of creating downstream enforcement problems of divided infringement. Fortunately, new

decisions on induced infringement from the Court of Appeals for the Federal Circuit may provide a path forward for some diagnostic inventions.

Diagnostic assay developers have been reluctant to cast their inventions as involving a treatment step, even while suspecting that a treatment step may make their patent claims subject-matter eligible. Their reluctance stems from the projected difficulty in enforcing a claim whose steps would be practiced by distinct entities (i.e., divided infringement). For example, a commercial laboratory may perform a diagnostic step, and a physician may perform a treatment step. Who would be infringing a claim with one of each type of steps?

To directly infringe, a party must perform all steps of a method. Muniauction, Inc. v. Thomson Corp., 532 F. 3d 1318 (Fed., Cir. 2008). However, Akamai Technologies, Inc. v. Limelight Networks, Inc., 797 F.3d 1020, 1022 (Fed. Cir. 2015) (en banc) broadened the circumstances under which acts of multiple parties could be attributed to a single actor. If one party directs or controls the actions of another, that party can be considered as the one performing the acts. Similarly, if parties form a joint enterprise, that joint enterprise can be considered to have performed the separate acts of the distinct parties.

The Akamai court set a test for directing and controlling. A directing or controlling party must condition participation in an activity or receipt of a benefit on the second party's performance of a patented method step. Additionally, the party must establish the manner or timing of performing the patented method step.

Earlier this year the Federal Circuit considered a case of divided infringement in which physicians were found to have met the test of "direct or control." Eli Lilly Co. v. Teva Parenteral Medicines, 845 F.3d 1357 (Fed. Cir. 2017). The patent claim required administering three substances, two of which the physician administers to patients and one of which patients self-administer. The court found that the physicians' prescriptions were the means of direction or control for patients to administer a substance to themselves. Thus the court found a direct infringer: individual physicians.

As a practical matter, however, rather than suing thousands of individual physicians, the patentee, Eli Lilly, sued Teva for inducing physicians to directly infringe. Establishing liability for induced infringement requires proof that the accused infringer actively encouraged the infringing acts. In this case, the court found that Teva's proposed product label encouraged or recommended infringement, establishing intent to induce infringement.

Given the Eli Lilly holding, diagnostic assay developers may be a bit more optimistic that adding a treatment step to their diagnostic methods will not amount to trading a subject-matter eligibility problem for a divided infringement problem. Indeed, the Eli Lilly holding suggests that it may be possible to find a direct infringer of a mixed diagnostic/therapeutic method. Further Eli Lilly

suggests that it may be possible to use a drug label instruction that includes a diagnostic or monitoring assay as an aid in proving infringement.

Whether any particular mixed assay and treatment method will be held subject-matter eligible, however, remains an open question, and neither the Supreme Court not the Federal Circuit has provided much guidance on this point. The claim struck down in Mayo Collaborative Servs. v. Prometheus Labs. Inc., 566 US 66, 757-77 (2012) was a mixed assay and treatment claim, in which a drug was administered and levels of metabolite were assayed. The U.S. Patent and Trademark Office's May 2016 Life Sciences Example 29 presents a different type of mixed assay and treatment claim in which a subject is tested and if a certain result is obtained, treated with a drug. While the Patent and Trademark Office considers this hypothetical claim to be subject-matter eligible, the Federal Circuit has not yet considered the eligibility of this type of claim.

Although the Federal Circuit considered a mixed diagnostic/therapeutic method claim in Cleveland Clinic v. True Health Diagnostics, LLC 859 F.3d 1352 (Fed. Cir. 2017), it did not reach its eligibility. Not surprisingly, the Federal Circuit affirmed that claims of three related patents that contained solely diagnostic testing steps were subject-matter ineligible. Claims of a fourth patent that contained mixed assay and treatment steps were not challenged by the accused infringer for lack of subject-matter eligibility. We do not know how the Federal Circuit would treat them.

Cleveland Clinic failed in its attempt to pin inducement to infringe on diagnostic laboratory True Health. The court found no "specific intent and action" to induce infringement. Although the Federal Circuit did not analyze it in this manner, the facts did not show that one actor was directing or controlling another actor. In the absence of such facts, there was no underlying direct infringement for the induced infringement.

Cleveland Clinic failed to prove that a diagnostic laboratory induced infringement, while Eli Lilly succeeded in proving that a drug vendor induced infringement. Eli Lilly pointed to the physician as the direct infringer controlling the steps performed by different actors. Eli Lilly was aided in its inducement assertion by the proposed drug label of the accused infringer, which taught administration of the three substances, but Cleveland Clinic had no drug label to show specific intent of the alleged inducer. Cleveland Clinic's difficulty suggests that overcoming the obstacle of divided infringement may not be as easy for a mixed diagnostic and therapeutic method claim as it was for a solely therapeutic method claim.

Posted: October 19, 2017