Exploring Viability Of 'Diagnose And Treat' Method Claims

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The enforceability of single claims that cover the steps of both diagnosing and treating a patient is discussed in view of Cleveland Clinic Foundationv. True Health Diagnostics LLC[1], which held that the claims in U.S. Patent No. 9,170,260[2] were not infringed under either contributory infringement or induced infringement.

Patentability of Medical Diagnostic Method Claims

The 2012 U.S. Supreme Court Mayo decision[3] effectively limited patentable processes in the field of medical diagnostics[4] with a potential impact on the development of personalized medicine in the U.S.[5] While the impact on diagnostic method claims was profound, method of treatment claims were largely unaffected. In May 2016 the U.S. Patent and Trademark Office issued “Subject Matter Eligibility Examples: Life Sciences” patenting guidelines taking into account the 2012 Mayo decision and other relevant Supreme Court decisions. The guidelines included examples of combination methods that could be considered as still patentable by the USPTO . One such example was a method claim directed to separate steps of diagnosing and treating a patient (Example 29, Diagnosing and Treating Julitis, Claims 5 and 6 of the USPTO guidelines) — what we call herein a “diagnose and treat” claim.

This format has proven to be a successful strategy for obtaining patentable claims[6]. However, at the time the guidelines were released, some of us in the patent prosecution community were concerned that while such claims overcome subject matter rejections, they might be unenforceable where the diagnostic step and treatment step are performed by different actors. This is because of the difficulty of proving direct infringement[7] of a method claim where different actors are performing the method steps. It remains the case that attributing performance of method steps by multiple actors to a single party requires a persuasive case, and is still fraught with uncertainty, although the Federal Circuit recently offered an encouraging decision for patent owners with two actor method claims in Eli Lilly & Co. v. Teva Parenteral Medicines Inc.[8].

Enforceability of “Diagnose and Treat” Method Claims

In Cleveland Clinic Foundation, a claim consistent with the May 2016 USPTO guidelines, i.e., a

diagnosing and treating claim in which there are different actors performing the method steps, was considered by the Federal Circuit.

As background, in October 2015, the USPTO issued U.S. Patent No. 9,170,260[2], assigned to The Cleveland Clinic Foundation, with claims directed to performing a diagnosis and subsequently treating a patient. Claim 1 recites:
A method for administering a lipid lowering agent to a human patient based on elevated levels of myeloperoxidase (MPO) mass and/or activity comprising:

(a) performing an enzyme linked immunosorbent assay (ELISA) comprising contacting a serum or plasma sample with an anti-MPO antibody and a peroxidase activity assay to determine MPO activity in the serum or plasma sample;

(b) selecting a patient who has elevated levels of MPO mass and/or activity compared to levels of MPO mass and/or activity in apparently healthy control subjects; and

(c) administering a lipid-lowering agent to the selected human patient.

The patent owners, namely, Cleveland Clinic Foundation and Cleveland Heartlab Inc. accused a diagnostics company, True Health Diagnostics LLC, of infringement of the '260 patent and three other patents that claimed methods for testing for myeloperoxidase. True Health Diagnostics was allegedly detecting MPO in samples, as stated in the claim, and then sending a lab report with the results to doctors who were treating the patients with lipid-lowering agents, as stated in the claim. The U.S. District Court for the Northern District of Ohio found that Cleveland Clinic failed to state a claim of contributory or induced infringement of the '260 patent (and also opined that the claims of the three testing patents — which did not recite method of treatment claims — were not directed to patent-eligible subject matter). These decisions were affirmed by the Federal Circuit. The contributory and induced infringement positions are discussed below in regard to the '260 patent claim.

Contributory Infringement

Contributory infringement occurs when a party "offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use ..."[9] The district court found, and the Federal Circuit affirmed, that True Health's testing service and laboratory reports were not "material and apparatus" that could form the basis for contributory infringement. The Federal Circuit further indicated that "[a] party that provides a service, but no 'material or apparatus,' cannot be liable for contributory infringement." Thus, even in the "information age," where information can underlie a business, and economies, in much the same way physical products dominated in prior times, diagnostic reports are not considered a material by the Federal Circuit, at least in the context of the '260 patent claims. With this

ruling, it is difficult to see how a patented method claim directed to separate steps of diagnosis and treatment of a patient, where a diagnostic report is provided to the doctor, could be found enforceable against a diagnostic testing company under a theory of contributory infringement.

Induced Infringement

Induced infringement occurs when a party "actively induces infringement of a patent ..."[10]. In the present case, citing DSMU Med. Corp.[11], the Federal Circuit indicated that "[t]he mere knowledge of possible infringement by others does not amount to inducement; specific intent and action to induce infringement must be proven." The district court found, and the Federal Circuit affirmed, that Cleveland Clinic did not allege facts sufficient to show the specific intent to induce a third party to infringe. The Federal Circuit indicated that "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 True Health to induce infringement of the '260 patent." In other words, to prevail under induced infringement, Cleveland Clinic needed to establish a clear nexus between the diagnostic testing company actions and the subsequent actions of the health care provider. Nevertheless, since the Federal Circuit only stated that the alleged facts were insufficient, the issue of whether "diagnose and treat" claims can be enforced under a theory of induced infringement has not yet been resolved.

Direct Infringement Requirement of Induced Infringement

The Federal Circuit in Cleveland Clinic did not broach the issue of direct infringement. Notably, as written, claim 1 of the '260 patent involves, at least on its face, two actors: (1) the diagnostic lab performing the ELISA test, and (2) the medical professional administering a lipid-lowering agent. Like claims 5 and 6 of Example 29 of the USPTO guidelines, the different steps would be expected to be performed by different parties. The "wet" steps of the diagnostic procedures would likely be performed by a testing laboratory and the treatment steps would be performed by a physician or health care facility. However, there can be no inducement of infringement without an underlying act of direct infringement,[12] and direct infringement occurs where all steps of a claimed method are performed by or attributable to a single entity.[13]

In Eli Lilly & Co.[8], the Federal Circuit upheld a district court decision that found direct infringement of method of treatment claims by physicians, even though the actions of both physicians and patients were required by the claims, and no single actor performed all steps. The Federal Circuit held defendant generic drug companies liable for inducing that infringement. It should be noted, however, that the claims under consideration in Eli Lilly & Co. were treatment claims and not "diagnose and treat" claims. In Cleveland Clinic the Federal Circuit only stated that the facts were insufficient to show inducement and did not directly speak to the problem of divided infringement invoked by the claim in question.

Practice Considerations

Given the problems of divided infringement, patent practitioners could draft combination "diagnose and treat" claims such that the steps are attributable to a single entity. An example of such a claim is one having the following format:

A method of treating disease X in a subject comprising:

a) receiving an identification of the subject as having marker Y in a specific cell type, wherein marker Y has been identified by a method comprising specified steps A and B; and

b) administering a specified treatment to the subject identified as having marker Y in a specific cell type.

With a single actor, the showing of the required underlying direct infringement is easier than the two-actor scenario. Claims of this type, where one actor performs both the gerund steps (e.g., (a) receiving and (b) administering), but is not required to perform the diagnostic laboratory steps themselves, have been patented. To our knowledge, however, such claims have not yet been subjected to judicial review for infringement.

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[1] Cleveland Clinic Foundation v. True Health Diagnostics LLC 859 F.3d 1352 (Fed. Cir. 2017).

[2] U.S. Patent No. 9,170,260 B2, Hazen et al., issued Oct. 27, 2015, Myeloperoxidase, a risk indicator for cardiovascular disease.

[3] Mayo Collaborative Services v. Prometheus Laboratories Inc. 132 S. Ct. 1289 (2012).

[4] See e.g., Amos B. and Miller A.D. (2017) Differing diagnoses for European and U.S. patents. Nature Biotechnology 35(4): 334-335; Noonan, K. (2016) Diagnostic patents at risk after Federal Circuit decisions. Nature Reviews 15: 377; Thomas J.R. (2017) Patentable Subject Matter Reform, Congressional Research Service, 1-17.

[5] Ledford, H. (2016) U.S. personalized-medicine industry takes hit from Supreme Court. Nature 536 (Issue 7617): 382.

[6] Miller A.D. and Amos B (2017) Successful Strategies for Diagnostic Method Patents. Journal of Commercial Biotechnology 23(1): 60–64.

[7] 35 U.S.C. §271(a).

[8] Eli Lilly & Co. v. Teva Parenteral Medicines Inc., Appeal No. 2015-2067 (Fed. Cir. Jan. 12, 2017).

[9] 35 U.S.C. §271(c).

[10] 35 U.S.C. §271(b).

[11] DSU Med. Corp. v. JMS Co., 471 F.3d 1293 (Fed. Cir. 2006) (en banc).

[12] Limelight Networks Inc. v. Akamai Techs. Inc., 134 S. Ct. 2111 (2014).

[13] Akamai Technologies Inc. v. Limelight Networks Inc., 797 F.3d 1020 (Fed. Cir. 2015) (en banc).