FEDERAL CIRCUIT DECLINES TO FOLLOW U.S. PATENT & TRADEMARK OFFICE § 101 GUIDANCE AND HOLDS DIAGNOSTIC METHOD PATENT CLAIMS INVALID

Date: 13 May 2019

U.S. IP Litigation, IP Procurement, and Pharma & Biopharma Litigation Alert

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INTRODUCTION AND BACKGROUND

On April 1, 2019, in *Cleveland Clinic Foundation v. True Health Diagnostics, LLC ("Cleveland Clinic II"),* [1] the Federal Circuit Court affirmed the district court's decision holding claims invalid under § 101 and dismissing for failure to state a legally cognizable claim. Specifically, the Federal Circuit held that Cleveland Clinic's patent claims were directed to a natural law and, therefore, ineligible subject matter under 35 U.S.C. § 101. [2] The claims at issue [3] were directed to diagnostic methods for determining a patient's risk of cardiovascular disease ("CVD") by detecting plasma levels of myeloperoxidase ("MPO") in patients with CVD and comparing those results to MPO concentrations of healthy subjects. [4] The patents at issue claim priority to a parent patent [5] that the Federal Circuit previously held "invalid under § 101 as directed to the ineligible natural law that blood MPO levels correlate with atherosclerotic CVD" [6] *("Cleveland Clinic I*"). [7]

DISTRICT COURT

After the district court ruled that the parent patent's asserted claims were ineligible, [8] but before the *Cleveland Clinic I* decision, Cleveland Clinic filed a new complaint alleging infringement of the patents at issue [9] against True Health. True Health moved to dismiss under Rule 12(b)(6). [10] Less than two months after the Federal Circuit's decision in *Cleveland Clinic I*, the district court applied the *Alice* two-part test [11] and held the asserted claims patent ineligible as directed to a natural law under § 101. [12] The district court dismissed Cleveland Clinic's complaint for failure to state a claim, and Cleveland Clinic then appealed.

FEDERAL CIRCUIT ANALYSIS

Cleveland Clinic argued that unlike the claims held ineligible in *Cleveland Clinic I*, the "claims at issue are not directed to assessing a test subject's risk of having atherosclerotic CVD by comparing a subject's MPO levels to a control group, but rather to techniques for detecting elevated levels of MPO in the blood of patents having CVD." [13] Agreeing with the district court, the Federal Circuit found this distinction "overly superficial." [14] The court explained that under *Alice/Mayo* step 1, the claims are directed to a natural law. "The claims are not directed to

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new techniques," but only apply known methods to detect MPO levels in plasma. The only other step is comparing the detected MPO levels to standard MPO levels to determine whether they are elevated. [15] As the court held in *Cleveland Clinic I*, "the claims are directed to the patent-ineligible natural law that blood MPO levels correlate with risk of atherosclerotic CVD." [16] Citing *Flook*, [17] the Federal Circuit reasoned that "rephrasing of the claims does not make them less directed to a natural law." [18]

Regarding step two of the *Alice/Mayo* [19] framework, again the Federal Circuit stated that the patents disclose that the claimed immunoassay for determining MPO levels was a known technique, and there were no significant adjustments for measuring blood MPO levels. [20] Therefore, the Federal Circuit concluded that "the claims contain no additional inventive concept." [21]

Cleveland Clinic also argued that the district court "improperly resolved factual disputes against it at the pleadings stage," but the Federal Circuit rejected this argument. [22] The court explained that the "specification and prosecution history [were] clear that the [claimed] method use[d] a known technique in a standard way to observe a natural law [thus] [t]here [was] no reason to task the district court with finding an inventive concept that the specification and prosecution history concede [did] not exist." [23]

Additionally, Cleveland Clinic argued that the district court erred by not granting *Skidmore* deference [24] to subject matter eligibility guidance published by the U.S. Patent and Trademark Office ("PTO"). [25] The Federal Circuit did not agree, asserting "we are not bound by [the PTO's] guidance . . . especially regarding the issue of patent eligibility and . . . the distinction between claims directed to natural laws and those directed to patent-eligible applications of those laws . . . ." [26]

CONCLUSION

In *Cleveland Clinic II*, the Federal Circuit affirmed the district court's judgement finding the asserted claims invalid under § 101. The court held that the claims "only recite applying known methods to detect MPO levels . . . compar[e] them to standard MPO levels, and reach[] a conclusion [which] is simply another articulation of the natural law that blood MPO levels correlate with atherosclerotic CVD." [27] As the court found in *Cleveland Clinic I*, the claims are directed to a natural law, "contain no additional inventive concept," and are therefore patent ineligible under § 101. [38]

Although this decision is nonprecedential, the evolution of how courts conduct a § 101 analysis continues with *Cleveland Clinic II*. The Federal Circuit explained that reframing a diagnostic method, which is "well-known in the art" and "directed to a natural law," into a different claim preamble is unlikely itself to provide patent eligibility. [29] The Federal Circuit's opinion also suggests that applicants attempting to establish patent eligibility of diagnostic methods may be better served by focusing on the distinctions between standard, known methods and the diagnostic methods claimed, rather than the general field of use or purpose of those claimed methods. [30] Moreover, the decision implies that relying on other court decisions may be more persuasive than citing PTO guidance. [31]

NOTES:

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[1] Cleveland Clinic Found. v. True Health Diagnostics, LLC, Appeal No. 2018-1218 (Fed. Cir. Apr. 1, 2019).
[2] Cleveland Clinic Found. v. True Health Diagnostics, LLC, No. 1:17-cv-00198-LMB-IDD, 2017 WL 3381976 (E.D. Va., Aug. 4, 2017).
[3] U.S. Patent Nos. 9,575,065 and 9,581,597.
[4] *Cleveland Clinic II* at 6–7.
[5] U.S. Patent No. 7,223,552.
[6] *Cleveland Clinic II* at 5.
[7] Cleveland Clinic Found. v. True Health Diagnostics, LLC, 859 F.3d 1352 (Fed. Cir. June 16, 2017), *cert. denied,* 138 S. Ct. 2621 (2018).
[8] Cleveland Clinic Found. v. True Health Diagnostics, LLC, No. 1:15-cv-02331-PAG, 2016 WL 705244 (N.D. Ohio, Feb. 23, 2016).
[9] U.S. Patent Nos. 9,575,065 and 9,581,597.
[10] *Cleveland Clinic II* at 6–7.
[11] Alice Corp. v. CLS Bank Int'l, 573 U.S. 208, 217 (2014).
[12] *Cleveland Clinic II* at 7.
[13] *Id.* at 9–10 (internal quotations and citations omitted).
[14] *Id.* at 10
[15] *Id.*
[16] *Id.*
[17] Parker v. Flook, 437 U.S. 584, 593 (1978).
[18] *Cleveland Clinic II* at 10.
[19] Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66 (2012).
[20] *Cleveland Clinic II* at 11.
[21] *Id.*
[22] *Id.*
[23] *Id.* at 11–12.
[24] Skidmore v. Swift & Co., 323 U.S. 134 (1944).
[25] *Cleveland Clinic II* at 12.
[26] *Id.* at 13.
[27] *Id.* at 10.
[28] *Id.* at 10–11.
[29] *Id.* at 11.
[30] *Id.*
[31] *Id.* at 13.

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