MB MCNEILL|BAUR
Intellectual Property Law

US Supreme Court Provides New Hurdles for Personalized Medicine

Bloomberg BNA, World Intellectual Property Report
September 2014

AMELIA FEULNER BAUR, PHD
610.667.2014
amelia.baur@mcneillbaur.com

By Amelia Feulner Baur, PhD

The US Supreme Court has provided the personalized medicine and diagnostics communities with yet an-other hurdle to protecting diagnostic-type inventions, whose patents often involve situations of divided infringement. In *Limelight Networks, Inc. v. Akamai Technologies, Inc.,* S.C., 12-786, 06/02/14[1] (*Akamai*), a unanimous court found that induced infringement of a patent under 35 USC § 271(b) cannot exist where no single actor has directly infringed the patent under 35 USC § 271(a) or any other statutory provision.

In short, the court found that infringement of a multi-step method claim could only occur where a single party performed each step, or where all steps were directed or controlled by that single actor — encouraging, aiding, or urging another actor was not sufficient for a finding of liability under § 271(a). This holding could have major implications for the enforcement of method claims in the personalized medicine and diagnostic fields, as well as in other areas, where method steps are typically performed by multiple actors.

I. Procedural History

Akamai Technologies, Inc., the exclusive licensee of US Patent 6,108,703 ("the '703 patent") first brought action in the US District Court for the District of Massachusetts, alleging that Limelight Networks, Inc. in-fringed the '703 patent, which claims methods for delivering electronic data to internet users using a "content delivery network" (CDN).

In particular, the '703 patent allows internet providers to contract with Akamai to store content on Akamai's servers instead of their own, wherein Akamai delivers the stored content to the internet user directly. Importantly, the '703 patent claims include a step called "tagging", which Akamai performs, and which allows for more efficient distribution of content to the end user. Akamai maintained that Limelight infringed the '703 patent by providing a similar service to internet providers, where the only difference between Akamai's and Limelight's methods involved tagging — Akamai tags the content itself, whereas Limelight requires its customers to do their own tagging. The controversy involved "divided infringement" because more than one party was performing the alleged act of infringement (i.e. Limelight and its customers).

Akamai's complaint alleged infringement under two theories — direct infringement under 35 USC § 271(a), and in the alternative, indirect infringement under § 271(b).

Under its direct infringement claim, Akamai argued that Limelight directly infringed the '703 patent by performing each step of the claimed method and by instructing customers to "tag" and by providing instructions and assistance with the process. Under its indirect infringement claim, Akamai alleged that Limelight was liable for the acts of itself and its customers by "causing, urging, encouraging, or aiding" customers to perform the only step it was not itself performing. Akamai prevailed in the District Court under its theory of direct infringement (35 USC § 271(a)). Thereafter, the Federal Circuit decided *Muniauction, Inc v. Thomson Corp*, Fed. Cir., 07/14/08[2] (*Muniauction*), which clarified that for a finding of direct infringement under § 271(a), a single defendant must be found to exercise "control or direction" over the entire process such that every step is attributable to the controlling party, i.e. the "mastermind".[3] Limelight requested reconsideration, and the District Court granted Limelight's motion, concluding that *Muniauction* precluded a finding of direct infringement under § 271(a) because Limelight did not control or direct its customers' tagging, and therefore it did not exercise "control or direction" over every step of the method claimed in the '703 patent.

Although a panel for the Federal Circuit affirmed the District Court's reversal in favor of Limelight, an en banc Federal Circuit disagreed and reaffirmed infringement. However, instead of addressing *direct* infringement under § 271(a), the en banc court found Limelight liable for infringement on a theory of *induced* infringement under § 271(b).

The en banc court explained that § 271(b) liability arises when a defendant carries out some steps of a claimed method and *encourages* others to carry out the remaining steps — regardless of whether the "encouraged other" was acting under the direction or control of the defendant. The en banc court found that inducement under § 271(b) could be found in the absence of direct infringement under § 271(a).

In essence, the en banc court found indirect infringement under § 271(b) where the defendant encouraged others to perform certain claimed method steps, but where this encouragement did not rise to the level of "exercise and control" as necessary for a finding of direct infringement under § 271(a). The en banc court's holding provided for the possibility of indirect infringement under § 271(b) in the absence of direct infringement under § 271(a).

In June 2014, the Supreme Court reversed the en banc court's finding of infringement, and explained that induced infringement under § 271(b) (or § 271(c)) may arise *only* if there is direct infringement under § 271(a).[4]

The court emphasized that a method patent claim cannot be infringed unless all of the steps are carried out—"'Each element contained in a patent claim is deemed material to defining the scope of the patented invention'[5], and a patentee's rights extend only to the claimed combination of elements, and no further."[6]

Because *Muniauction* held that all method steps must be performed as claimed in the patent by the same defendant (either directly or by directing and controlling others who performed them), and because Limelight did not perform, direct, or control the tagging step, it could not be liable for infringement under § 271(a). As such, there could also be no liability for induced infringement

under § 271(b). The Supreme Court declined to comment on the § 271(a) standard laid out in *Muniauction*, but remanded the matter to the Federal Circuit, whom on remand "will have the opportunity to revisit the § 271(a) question if it so chooses."[7]

Unless *Muniauction* is reconsidered and overturned, a method claim can be infringed only if each of the claimed steps is either:

(a) Performed by a single actor; or

(b) Performed by multiple actors, where a controlling party exercises "control or direction" over the entire process such that every step is attributable to the controlling party.

II. Implications for Method Claims in Personalized Medicine and Diagnostics

Personalized medicine refers to the tailoring of medical treatment to the individual characteristics of each patient.[8] Recent advances in genomics and molecular biology have led to a growth in the number of personalized-medicine-type inventions, including, for example, inventions relating to the detection of genetic markers that allow individuals to be classified as responders or non-responders to various treatments, methods of assessing an individual's risk for certain diseases, and methods for tailoring treatment based on individual responses to treatment regimens.

These types of inventions have one thing in common—they all pertain in some way to nature. That is, because they are based on an individual's inborn characteristics, they are in some way related to a natural phenomenon, a natural product, or a law of nature. Thus, a careful consideration of the recent Supreme Court precedent in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, S.C., 10-1150, 03/20/12[9] (*Prometheus*) and in *Association for Molecular Pathology v. Myriad Genetics,* S.C., 12-398, 06/13/13[10] (*Myriad*) is necessary prior to and during prosecution of such claims.

A typical invention in the field of personalized medicine involves the discovery of a new biomarker. For example, a scientist discovers that if a certain gene or protein is detected in an individual, that individual will suffer from X disease. *Prometheus* makes clear that a simply stated method of detecting biomarker and correlating biomarker with X disease, without more, is not patent eligible under 35 USC § 101. The claimed method is considered a law of nature/natural phenomenon.

Post-*Prometheus*, a claim relating to the discovery of a biomarker must include elements or steps that transform the discovered relationship between the biomarker and disease into a patent-eligible *application* of a natural law. One solution has been to recite not only a method of detecting the biomarker and diagnosing disease, but also a step for treating the patient after diagnosis. This claim is no longer a mere recitation of a natural phenomenon, but rather is an application of that natural phenomenon, patent eligible under § 101. However, post-*Akamai*, will such a claim have value?

A claim involving a multi-step process, like the detection and treatment steps discussed above, will almost certainly involve more than one actor — e.g. a laboratory technician detecting the biomarker, and a doctor interpreting the results, diagnosing the disease, and prescribing the treatment. Under *Akamai*, divided infringement can be found only where one actor exercises direction and control over each and every step, an unlikely scenario in this and other personalized medicine-related hypotheticals.

Akamai, when considered in connection with *Prometheus* and *Myriad* present hurdles to not only patent procurement, but also to patent enforcement. On the procurement side, § 101 case law and US Patent and Trademark Office guidance makes it difficult to obtain patent protection for a simply stated diagnostic or correlative method. To obtain patent protection, applicants will likely need to add method steps that transform their correlative findings into something more than the natural phenomenon. These added steps require consideration of enforcement of these claims — do the added steps result in a scenario of divided infringement? Will it be possible to enforce the claim under *Akamai*, where one actor must control and direct all steps?

III. Considerations Moving Forward

A. Procuring Personalized Medicine Type Claims

Applicants seeking to obtain patent protection for personalized medicine type inventions should carefully consider not only § 101 case law, but also developments in the divided infringement area, including *Akamai* and *Muniauction* and the cases that are sure to follow and clarify these decisions. Multiple claims should be drafted and presented to the patent office ranging from broad to narrow—a so-called "layering" strategy. A broad claim may recite, for example, a particular method to detect the natural correlation, whereas successively narrower claims may recite, for example, particular reagents to be used in these methods, or a particular ordering of steps to be following while performing those methods. While the patent office incentivizes applicants to reduce the number of independent and dependent claims by charging excess claim fees for presenting more than three independent and greater than twenty total claims, applicants should not shy away from providing many claims, each with an incremental "layer" of detail.

The layering should define and shape the patent eligible subject matter associated with the discovery, and will result in a claim set that will hopefully withstand the test of time. That is, with evolving case law, applicants run the risk of presenting too narrow a claim to meet today's guidance, whereas one must consider the possibility of that guidance changing to permit a somewhat broader claim. Layering assists not only during patent prosecution to work out the line of patent eligibility, but also should result in a comprehensive claim set that patentee can later rely on to allege infringement.

B. Enforcing Personalized Medicine Type Claims

Yet *Akamai* is not bad news for all. Third parties may use *Akamai's* guidance to avoid infringement of known competitor's patents. For example, when providing a service involving multiple parties, the provider typically wishes to maintain control of each and every step of that service. To this end, when subcontractors are needed, the service provider may draft agreements evidencing their control over that party. But is this wise? Considering *Akamai*, a service provider wishing to avoid infringement of known patents may wish to be less specific in the agreements with subcontractors. Being vague as to who directs and controls the subcontractors actions may be evidence of a lack of direction and control required by *Akamai* and *Muniauction* for a finding of direct infringement. Taken further, the agreement may be drafted with explicit language defining the role of the provider and subcontractor, where the agreement makes clear that the subcontractor may use their own know-how in providing their complement service. These agreements will surely be a focus in litigation in determining divided infringement. Careful

consideration during drafting and execution may result in a stronger non-infringement defense, where potential litigation can be anticipated in advance.

IV. Conclusions

Professionals with interests in personalized medicine have become leaders in advocacy efforts regarding 35 USC § 101, and should now rally their efforts regarding divided infringement. Recent Supreme Court case law in both of these areas has created significant hurdles to patenting and enforcing valuable intellectual property, and lobbying and advocacy efforts should continue. In the meantime, § 101 and divided infringement should be considered in concert when considering both patent procurement and litigation strategies.

Notes

[1] 134 S Ct 2111 (2014).
[2] *Muniauction, Inc v. Thomson Corp*, 532 F 3d 1318 (2008).
[3] Ibid at 1329.
[4] 134 S Ct 2111 (Slip Op at 5), citing *Aro Mfg Co v. Convertible Top Re-placement Co*, 365 US 336, 341 (1961) ("our case law leaves no doubt that inducement liability may arise 'if, but only if, [there is]. . .direct infringement' ").
[5] *Warner-Jenkinson Co v. Hilton Davis Chemical Co*, 520 US 17, 29 (1997).
[6] 134 S Ct 2111 (Slip Op. at 5).
[7] Ibid (Slip Op at 10).
[8] *Priorities for Personalized Medicine*, President's Council of Advisors on Science and Technology, September 2008, p 1, www.whitehouse.gov/files/documents/ostp/PCAST/pcast_report_v2.pdf.
[9] 132 S Ct. 1289 (2012).
[10] 133 S Ct 2107 (2013).