Threading the Needle Between Divided Infringement Issues and Patentable Subject Matter

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Personalized medicine is an emerging approach to medical practice that carries the promise of effective, individualized treatment. Investment required to bring these life-saving innovations to market are traditionally secured through appropriate patent protection. Recently, this has become challenging due to patent law developments in the areas of divided infringement and patentable subject matter.

Innovative personalized medicine diagnostics can include methods for data gathering and data analysis. Data gathering may be separated from subsequent analysis, e.g., drug sensitivity or disease prognosis. These steps can be performed by different parties, which can give rise to issues of divided infringement.

The legal standard for joint infringement of patent claims is currently unsettled. 35 U.S.C. Section 271(a) governs direct infringement: "whoever without authority makes, uses, offers to sell or sells any patented invention ..." Direct infringement requires an entity to perform each and every element of the claimed invention. *Warner-Jenkinson Corp. v. Hilton Davis Corp.*, 520 U.S. 17 (1997).

Divided infringement occurs when the actions of multiple entities are combined to perform every step of a claimed method. Prior to 2007, courts were willing to find a defendant liable for direct infringement when two entities' actions were combined to infringe the claim, and the defendant instructed the other entity to perform the infringing steps. *Shields v. Halliburton*, 493 F. Supp. 1376 (W.D. La. 1980); *Mobil Oil Corp. v. W.R. Grace & Co.*, 367 F. Supp. 207 (D. Conn. 1973).

More recently, courts have required that an entity control or direct each step of the process performed by another entity to find joint infringement. *MuniAuction, Inc. v. Thomson Corporation LLC*, 532 F.3d 1318 (Fed. Cir. 2008); *BMC Resources, Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1380 (Fed. Cir. 2007).

Now, a stricter legal standard for joint infringement - an agency relationship or a contractual obligation - has been proposed in *Akamai Technologies, Inc. v. Limelight Networks, Inc.*, 629 F.3d 1311 (Fed. Cir. 2010), and *McKesson Technologies Inc v. Epic Systems Corp.*, 2011 U.S. App. LEXIS 7531 (Fed. Cir. 2011).

In *Akamai*, the patents at issue included methods for a content delivery service that delivers a webpage from a content provider domain and stores embedded objects for the webpage on a separate server. Akamai's competitor, Limelight, practiced some of the claimed steps, but Limelight's customers performed the remaining steps for "tagging" and "serving" the embedded objects. Although a jury found Limelight liable, the district court rejected the jury verdict and found that Limelight had not directed or controlled its customers' actions.

The Federal Circuit affirmed the district court and held that "there can only be joint infringement when there is an agency relationship between the parties who perform the method steps or when one party is contractually obligated to the other to perform the steps."

In *McKesson*, the patent at issue covered an electronic method of communication between healthcare providers and patients involving personalized web pages. McKesson alleged that Epic induced infringement by licensing its MyChart software to health care providers, who subsequently instructed patients to use the software. The patient performed the step of "initiating a communication," and the provider performed the remaining claimed steps. McKesson argued that the doctor-patient relationship was special, something more than an "arms length cooperation."

The district court determined that Epic was not liable because it did not directly perform the initiating step and did not exercise control or direction over another who performed the step. A split panel of the Federal Circuit affirmed: "In this case, nothing indicates that MyChart users are performing any of the claimed method steps as agents for the MyChart providers. ... Nor is there anything indicating that MyChart users were contractually obligated to perform any of the claimed method steps on behalf of the MyChart providers."

These decisions, now vacated, were granted en banc rehearing. Oral arguments were heard, and a decision is expected later this year.

Petitioners for *Akamai* have proposed a less restrictive concerted action standard: "a person is subject to liability when he or she does a tortuous act in concert with the other or pursuant to a common design." Brief for Plaintiff-Appellant on Rehearing En Banc at 23. *Akamai Technologies, Inc. v. Limelight Networks, Inc.*, 629 F.3d 1311 (Fed. Cir. 2010).

The Federal Circuit may affirm the existing standard in *Akamai* and *McKesson*. If the Federal Circuit adopts a concerted action standard, it will be beneficial for patent holders, but can increase exposure to litigation and curtail commercial transactions. Applicants should take care to draft method claims that recite actions performed by a single entity. For instance, a step for diagnosing a patient, typically performed by a physician, should not be included in a claim reciting steps performed by a laboratory.

Method claims drafted to avoid divided infringement, for example, by claiming only the data analysis and not the data collection steps, can give rise to patentability issues under the patent law's eligible subject matter statute, 35 U.S.C. Section 101.

The Supreme Court has interpreted the broad language of this statute to exclude the patenting of abstract ideas, physical phenomena, and laws of nature. *See Gottschalk v. Benson*, 409 U.S. 63 (1972); *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). Recent cases have interpreted the scope of Section 101's exceptions.

In *Bilski v. Kappos*, 130 S. Ct. 3218 (2010), the Court rejected the "machine or transformation" test as the sole way for determining patent-eligibility of business method claims and held that the "concept of hedging" was an unpatentable abstract idea.

Courts have since addressed the law of nature exception in life science cases.

In *Classen Immunotherapies, Inc. v. Biogen Idec, et al.* (Fed. Cir. 2011), the Federal Circuit distinguished between claims directed to a law of nature and those directed to the application of that law.

In *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S.Ct. 1289 (2011), the Supreme Court held unpatentable as directed to a law of nature claims covering the relationship between concentrations of certain metabolites in the blood and the likelihood that a thiopurine drug dosage would prove ineffective or cause harm.

In *Assn. for Molecular Pathology v. Myriad Genetics, Inc.* (Fed. Cir. 2011), the Federal Circuit held isolated DNA molecules to be patent eligible, but invalidated claims to certain methods of analyzing or comparing *BRCA1* and *BRCA2* genes. After petitions for writ of certiorari were made, the Supreme Court GVR'd the case for reconsideration in view of *Prometheus*.

Adding steps using a computer or machine may not easily overcome the barrier of patent-eligibility. Some courts have considered this to be "post solution activity." In *Parker v. Flook*, 437 U.S. 584 (1978), the Supreme Court stated, "The notion that post-solution activity, no matter how conventional or obvious in itself, can transform an unpatentable principle into a patentable process exalts form over substance."

In *Smartgene, Inc. v. Advanced Biological Laboratories, SA, et al.*, 2012 U.S. Dist. LEXIS 44138 (D. D.C. 2012), a patent for guiding the selection of a treatment regimen for a patient was patent ineligible because the claims tracked the abstract mental processes of a doctor treating a patient. In dicta, the court stated that the recitation of a computing device "does not impose any meaningful limit on the scope of the

claims" and amounted to "insignificant postsolution activity." However, the court suggested that this may be resolved by claiming a "particular" type of machine or showing that the computing device is necessary to carry out the method.

Thus, the bar for patentable subject matter is rising. Applicants should draft claims that add additional physical steps that go beyond reciting a "law of nature" or include a particular application of the process. Reciting the use of a particular type of machine or showing specificity about how the machine is necessary may help, but this could be considered "post solution activity."

Thus, in satisfying the requirements under Section 101, applicants can face a divided infringement problem. On the other hand, in attempting to avoid divided infringement, claims may be interpreted as a law of nature or an abstract idea.

It is critical that patent laws evolve in a manner that does not allow gaming of the territory between Section 101 and divided infringement. For the U.S. to retain its competitive edge, it is important that the laws do not set up an untenable conflict for applicants who seek protection for their inventions.

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