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EXPERT ANALYSIS

Diagnostic Method Patents — Not All Hope is Lost

By Eldora L. Ellison, Esq., and David W. Roadcap, Esq.
Sterne, Kessler, Goldstein & Fox

Diagnostic methods are a central part of personalized medicine because they allow doctors to determine a patient's particular disease or condition. As more specialized treatments become available for cancer, genetic disorders and other ailments, the identification of particular conditions becomes ever more important. But even as researchers and companies create sophisticated and informative diagnostic methodologies, an important question remains: What patent protection is available for these innovations?

Recent case law relating to medically related method patents has left many patent applicants scratching their heads as to how to obtain valid and enforceable patents for various types of diagnostic methods and methods of treatment. One difficulty relates to the eligibility of diagnostic claims under Section 101 of the Patent Act, which provides that any useful process, machine, manufacture, or composition of matter is subject to patent protection. Naturally occurring phenomena cannot be patented.

The U.S. Court of Appeals for the Federal Circuit recently determined in *Ariosa Diagnostics v. Sequenom Inc.* that the diagnostic claims at issue were ineligible because they were directed to a naturally occurring phenomenon.[1] The court questioned whether "the claim contains an inventive concept sufficient to 'transform' the claimed naturally occurring phenomenon into a patent eligible application." It held that it did not.

In an effort to avoid patent eligibility issues, many applicants have sought to show that they are claiming "significantly more" than a natural law or other ineligible concept by combining treatment steps with diagnostic steps.

Adding steps to patent claims increases the risk that split infringement could occur and that enforcing the patent would be difficult. The recent decisions in *Akamai Technologies v. Limelight Networks* and *Eli Lilly & Co. v. Teva Parenteral Medicines* provide guidance as to how one can establish direct infringement, even when different parties perform subsets of the claim limitations.[2]

This commentary reviews the current state of the law relating to diagnostic method claims and method of treatment claims, and it explores strategies for obtaining patent claims that may withstand Section 101 challenges while avoiding split infringement limitations.

ELIGIBILITY OF DIAGNOSTIC PATENTS

A key factor to consider for diagnostic patents is that such methods, by definition, detect what is occurring in a patient. As such, the gathered information reflects a natural condition, and patents relating to that information may thus raise concerns relating to patent eligibility.

The well-known and extensively discussed *Mayo Collaborative Services v. Prometheus Laboratories* and *Association for Molecular Pathology v. Myriad Genetics* cases provide guidance as to the scope of

eligible subject matter for diagnostic claims.[3] The Federal Circuit's recent decision in *Ariosa* also examines the question.

These cases stand for the proposition that even if a method is new, non-obvious and revolutionary, it may not be patent-eligible if the claims are directed to detecting a natural phenomenon using conventional and routine methodology. Of course, methods for diagnosing a condition are based on detection of a natural phenomenon, such as the presence of a given genetic marker or the expression level of certain proteins in a diseased state.

Given this fact, how can innovators seek patent protection for novel and non-obvious methods that are rooted in assessing a natural phenomenon?

One possible solution is to ensure that the experimental techniques associated with a diagnostic method are neither routine nor conventional. The techniques can be significant because, in an effort to show patent ineligibility, patent examiners and accused infringers often dissect diagnostic method claims into "conventional and routine" techniques layered on top of a natural phenomenon.

Patent owners may view this approach as contrary to the general principle of assessing the claim as a whole, as well as conflating obviousness and novelty with a distinct statutory requirement. But given the possibility of encountering such an approach in prosecution or during litigation, one way to shore up the eligibility of a diagnostic claim is to differentiate the claimed techniques from those in the prior art.

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For example, a method might include improvements to a technology or a new combination of steps, such as detecting a new combination of biomarkers that had not previously been shown to be useful in combination for diagnosing a particular condition. The difficulty with this strategy is that many diagnostic methodologies are based on well-known underlying techniques because those techniques are the most efficient and informative (such as polymerase chain reaction, antibody-based detection and DNA sequencing).

The Federal Circuit's recent *Ariosa* decision provides one example of the dissection approach to assessing patent eligibility. The court's decision has garnered much attention and caused concern for patent owners. Though the patentees in *Ariosa* revolutionized the prenatal genetic testing industry by developing a non-invasive fetal genetic diagnostic technique, the Federal Circuit held the claims were ineligible. The rationale for the decision was that "[t]he method at issue here amounts to a general instruction to doctors to apply routine, conventional techniques when seeking to detect [cell free fetal DNA]."[4]

Another potential solution to diagnostic method patent eligibility issues is to incorporate elements of patient treatment into the claims. By including treatment of a particular disease, use of a particular drug, or performance of a particular medical activity as additional steps, the method claims become further distanced from the base natural phenomenon.

The Federal Circuit has signaled that adding an "administering" step can alleviate eligibility concerns.[5] But introducing such a step comes at a cost. When claims pair treatment and diagnostic tests, there is an increased risk of split infringement, making it difficult to enforce the patent because performance of different steps may be divided between doctors, patients, diagnostic laboratories and other parties.

SPLIT INFRINGEMENT OF METHOD PATENTS

The recent high-profile *Akamai v. Limelight* series of decisions has altered the rules for dealing with cases where multiple parties perform different steps of a claimed method. In those cases, the central issue was created by the fact that the accused infringer performed some of the claimed method steps while the accused infringer's customers performed the remainder. Initially, the Federal Circuit held that there was induced infringement because the accused infringer instructed its clients on how and when to perform their portion of the method.[6]

The Supreme Court reversed the Federal Circuit and held there was no induced infringement because "liability for inducement must be predicated on direct infringement."[7] The high court

noted "the possibility that the Federal Circuit erred by too narrowly circumscribing the scope of Section 271(a) [direct infringement]."[8]

On remand, the Federal Circuit clarified the circumstances under which a party can be held to directly infringe even when it does not perform all steps of a claimed method. According to the Federal Circuit, the basic consideration is whether the actions of others are "attributable" to the entity in question. The tests for such attribution are drawn from "general principles of vicarious liability," which focus on whether the "entity directs or controls the acts of another."

In previous cases, courts had been willing to attribute actions only in two narrow circumstances: when the accused infringer controls or directs a third party (via agency or contractual relationship), and in the case of a joint enterprise in which the actions of the two parties can be attributed to each other.

In *Akamai*, however, the Federal Circuit added a new theory of attribution based on control by conditional or incentivized participation. Specifically, the court said that "liability under Section 271(a) can also be found when an alleged infringer conditions participation in an activity or receipt of a benefit upon performance of a step or steps of a patented method and establishes the manner or timing of that performance."[9]

The *Akamai* decision indicates that courts may flexibly interpret when actions are attributable to an accused infringer. This new flexible approach has already affected cases in the pharmaceutical and biotechnology industries.

In *Eli Lilly v. Teva*, the claims at issue covered methods of co-administering the cancer therapeutic Alimta with folic acid and vitamin B-12 to reduce the drug's side effects. According to the manufacturer's prescribing information provided with Alimta, doctors should administer vitamin B-12 via injection while instructing patients to take folic acid orally. The question before the district court was whether a patient's self-administration of folic acid could be attributed to a doctor.

Citing *Akamai*, the court held that the patient's actions were attributable because patients were incentivized to receive the benefit of the medication and because the doctor controlled the manner and timing of administration.[10] Thus, the doctor's actions were held to constitute a direct infringement that was induced by the defendants.

While the full scope of relationships to which this new theory of attribution will be applicable remains to be seen, it is clear that the previously strict limits on attribution of method steps have been loosened. Relationships between parties performing multiple steps must be considered and analyzed to determine whether any party will be in control of all steps of the claimed method.

PROSECUTION OF DIAGNOSTIC METHODS

Given the relevant case law, it is apparent that many potential method patents are caught between the rock of subject matter eligibility and the hard place of split infringement. But careful applicants can navigate a path between the two issues.

Applying three basic guidelines can aid in avoiding eligibility issues when prosecuting diagnostic method patents under the current case law.

First, to minimize the risk of eligibility problems, applicants may seek to avoid triggering words that may imply abstract ideas or natural phenomenon. For example, claims whose sole central premise is to "obtain," "detect," "identify" or "diagnose" a certain set of conditions could raise red flags. Instead, applicants may seek to frame the claims in terms that are more detailed and focused on the technology employed rather than abstract concepts.

Claims that recite novel and non-obvious detection methodology, such as a new antibody or new detection reagent, will help focus the patent analysis on the new material rather than the natural phenomenon associated with the diagnostic method. Similarly, the claims may benefit from reciting a composition that did not previously exist, such as a biological complex that is formed when carrying out the diagnostic test.

Even if a method is new, non-obvious and revolutionary, it may not be patent-eligible if the claims are directed to detecting a natural phenomenon using conventional and routine methodology.

Second, the claims should have meaningful steps beyond recognizing a natural phenomenon. A common way of ensuring this guideline is met is by including an "administering" step when possible. Alternately, an applicant can include multiple additional steps. Though each step may involve only well-known techniques, the claim as a whole may amount to significantly more than the natural phenomenon when the steps are viewed in combination.

In either case, clearly articulating in the specification how the claimed method is an improvement over the prior art will aid in demonstrating that the claims recite "significantly more" than what was known in the art at the time of the invention. And expert testimony relating to the significance and inventiveness of the methodology accompanying the purported natural phenomenon may prove useful in rebutting ineligibility arguments. Providing such expert testimony during prosecution may also produce the benefit of creating a bigger hurdle for a potential challenger to overcome later.

Third, in drafting claims, care should be given to avoid preempting all uses of a natural phenomenon. Including alternative embodiments in the specification or discussing other methods known in the art may be useful in demonstrating that the inventive concept does not have a preclusive effect on all approaches of a natural phenomenon. Again, expert testimony may be useful.

Claims may contain enough additional steps to minimize eligibility concerns while maximizing the chance that — from an infringement viewpoint — a single party controls the entire method where multiple parties perform various steps. One consideration when drafting claims with an eye towards minimizing the risk of split infringement is to consider who could be performing each task in real-world situations.

Drug administration will almost certainly be performed by a doctor or the patients themselves. And diagnostic tests will likely be carried out by a hospital laboratory, a doctor's office or a company dedicated to such testing. Will the actions of such parties be attributable to the party performing the other steps, such as a doctor? Certain relationship pairs may become commonly associated with a "controlling" relationship, such that claims involving both parties performing steps will not encounter split infringement problems.

As seen in *Eli Lilly*, patients' actions performed under doctor's orders can be attributed to a doctor in an infringement analysis. The incentivized or conditional control theory underlying such attribution may be applicable to other relationships, such as the one between a doctor and a laboratory technician. If so, then drafting claims that include steps likely to be split between these parties may be useful. One might pursue claims that recite ordering or receiving a certain test result, in an effort to better capture the relationship that exists between a doctor and a diagnostic laboratory. But the case law continues to be shaped, and such infringement theories remain largely untested. Therefore, prosecuting a variety of claim structures may be desirable.

Another reason to approach diagnostic method claim drafting with caution is that the rules regarding diagnostic patents vary significantly in different countries. For instance, adding treatment steps to diagnostic patents could be problematic in Europe, where Article 53(c) of the European Patent Convention forbids patents that claim "diagnostic methods practised on the human or animal body."

In China, the situation is complicated by Article 25 of the Chinese Patent Law, which states that "[p]atent rights shall not be granted for ... methods for the diagnosis or treatment of diseases," while in Canada, the promise doctrine may endanger claims to diagnostic methods that claim utility beyond that shown in the specification.

Given the complex international landscape with regard to diagnostic patents, it may be most prudent to present a variety of types of claims in Patent Cooperation Treaty applications and then select targeted approaches when entering the national phase of the application process.

Lastly, all parties should remember that the law regarding patent eligibility and diagnostic patents remains in flux. Some stakeholders have even advocated for legislative action to confirm diagnostic method patent eligibility, or to at least provide greater clarity in the interpretation of

Section 101. This uncertainty provides another reason to present a variety of claims in method patent applications. Applicants may also hedge against future developments by maintaining pending continuation applications so they can update the claims as the law evolves.

NOTES

[1] *Ariosa Diagnostics Inc. v. Sequenom Inc.*, 788 F.3d 1371 (Fed. Cir. 2015).

[2] *Akamai Techs. v. Limelight Networks*, 797 F.3d 1020 (Fed. Cir. 2015) (*en banc*); *Eli Lilly & Co. v. Teva Parenteral Meds.*, No. 1:10-cv-01376, 2015 WL 5032324 (S.D. Ind. Aug. 25, 2015).

[3] *Mayo Collaborative Servs. v. Prometheus Labs.*, 132 S. Ct. 1289 (2012); *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303 (Fed. Cir. 2012).

[4] *Ariosa*, 788 F.3d at 1377.

[5] *Classen Immunotherapies Inc. v. Biogen Idec*, 659 F.3d 1057, 1068 (Fed. Cir. 2011) (holding that administration of a vaccine "moved the ... claims through the coarse filter of Section 101").

[6] *Akamai Techs. v. Limelight Networks*, 692 F.3d 1301, 1306 (Fed. Cir. 2012).

[7] *Limelight Networks v. Akamai Techs.*, 134 S. Ct. 2111, 2117, 2119 (2014).

[8] *Id.* at 2119.

[9] *Akamai,* 797 F.3d at 1023.

[10] *Eli Lilly,* 2015 WL 5032324, *14-16.

Eldora L. Ellison, Esq., Ph.D. (L), is a director in the biotech/chemical and litigation practice groups at **Sterne, Kessler, Goldstein & Fox** in Washington. Over the course of her 21-year career, Ellison has gained extensive experience in *inter partes* patent matters, building on a strong foundation in patent prosecution. **David W. Roadcap**, Esq., Ph.D. (R), is an associate in the firm's biotechnology/chemical group in Washington. He has extensive experience in the preparation and prosecution of patents and in litigation.