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PATENTS

Improving the Prognosis for Your Diagnostic Method Patents



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Medical diagnostics is a formidable industry, with the global *in vitro* diagnostic market, alone, being worth \$60.2 billion in 2016 and having a predicted worth of up to \$78.4 billion by 2021. See *In Vitro Diagnostics/IVD Market—Forecast to 2021*, MARKET-SANDMARKETS (December 2016).

Because of the significant research and development costs incurred in bringing new diagnostic methods to market, innovators preferably protect their investment through patent protection in key jurisdictions. In recent years, however, patent jurisprudence throughout the world, including in the all-important U.S. market, has made it more difficult to receive patent protection for diagnostic methods. In the United States, cases such as *Ariosa Diagnostics Inc. v. Sequenom Inc.*, 788 F.3d 1371, 115 U.S.P.Q.2d 1152 (Fed. Cir. 2015); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 101 U.S.P.Q.2d 1961 (2012); and *Association for Mo-*

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lecular Pathology v. U.S. Patent & Trademark Office and Myriad Genetics, 689 F.3d 1303, 103 U.S.P.Q.2d 1681 (Fed. Cir. 2012), have resulted in significant confusion and frustration for the medical diagnostics industry and those who wish to protect their investment through medical diagnostics patents.

In May 2016, the U.S. Patent and Trademark Office released the *Subject Matter Eligibility Examples: Life Sciences*, which include seven relevant claim examples relating to the patent eligibility of diagnostic methods. Using these *Guidelines* as a jumping-off point, the primary purpose of this article is to provide patent drafting suggestions to practitioners who are attempting to avoid potential rejections for ineligible subject matter, under 35 U.S.C. § 101, when preparing patent applications related to diagnostic methods.

New Reagents and Targets

As a starting point, diagnostic methods that make use of new and nonobvious reagents can be patent-eligible. For example, methods that are directed towards diagnosing a particular disease using novel monoclonal antibodies have routinely been patented. As a representative example, U.S. Patent No. 8,076,093 contains useful claims that are focused on diagnosing cervical cancer through the use of novel monoclonal antibodies that bind to MCM2.

In the burgeoning field of personalized medicine, diagnostics that have focused on new reagents comprised of novel combinations of genetic markers also constitute patent-eligible subject matter. For example, U.S. Patent No. 8,703,127 recites claims for diagnosing prostate cancer by detecting the presence of a unique plurality of polypeptide biomarkers. Serving as another relevant example, U.S. Patent No. 7,767,395 recites claims for diagnosing sepsis in an individual using the measurement of a unique plurality of biomarker mRNAs.

Not only do novel reagents confer patentability on a diagnostic claim, but the *Guidelines* also reinforce the view that a diagnostic method that uses a known reagent for a new purpose will be patent-eligible. *Guide-*

lines at 13-14. In the case of the third claim example provided in the *Guidelines*, use of a porcine antibody, which was previously used only for veterinary therapeutic purposes, resulted in a patent-eligible claim when subsequently used to detect a specific human protein.

In addition to focusing on new and nonobvious reagents, diagnostic methods that focus on biological targets not previously associated with a disease can also result in patent-eligible subject matter. In the personalized medicine arena, methods that focus on determining the presence or absence of genetic polymorphisms and correlating such polymorphisms to the diagnosis of a particular disease have resulted in issued patents. For example, U.S. Patent No. 8,003,325 recites claims for detecting a group of specific lymphomas based on the detection of a series of three alleles in the B-lymphocyte stimulator gene, which were previously not associated with lymphoma detection.

In sum, when tasked with reviewing an invention disclosure related to a diagnostic method, practitioners should carefully review the disclosure to determine whether the application can focus on new reagents, new uses for known reagents, or new biological targets, all of which can lead to eligible subject matter and issued claims. Additionally, emphasizing and reinforcing the novelty and nonobviousness of the use of such reagents or biological targets in the specification may further demonstrate the patent-eligibility of the claimed diagnostic method.

Addition of a Treatment Step

Another approach for attempting to overcome the hurdles associated with patenting diagnostic methods is through the addition of a treatment or administration step to a diagnostic claim. As shown in a recent example, U.S. Patent No. 9,315,868 for “Diagnostic Method Using PALB2” includes claims that focus on detecting the presence of a mutation in the PALB2 gene, correlating such mutation to a diagnosis of pancreatic cancer, and treating an individual who has been diagnosed based on the mutation detection. The *Guidelines*, and particularly the sixth claim example therein, reinforce the view that an invention that includes a new and nonobvious combination of steps that both accurately diagnose a particular indication and include a step of properly treating such indication is patent-eligible. *Id.* at 15. Additionally, a treatment step reciting a previously unconventional treatment of a diagnosed indication may also confer patentability. *Id.* at 14.

There are potential downsides in relying solely on the addition of a treatment step to obtain diagnostic method claims. First, from a patent infringement perspective, the addition of a treatment step creates new challenges as it becomes unlikely that a single entity will have infringed all of the steps of the method claims. In a typical diagnostic claim that includes a treatment step, the treatment step will be carried out by a medical professional whereas the diagnostic portion may be carried out by a separate entity such as a professional testing company. When faced with this divided infringement scenario, patent owners seeking to enforce their patent will thus need to be creative in attempting to demonstrate that the medical professional’s actions can be attributed to the party that infringed the diagnostic steps.

While it is preferable to have an issued claim that does not result in divided infringement, the Federal Cir-

cuit has put forth a more flexible approach to finding direct infringement by a single party in a divided infringement scenario, and thus, a means to find induced infringement by a party inducing the direct infringement. In *Akamai Technologies, Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020, 116 U.S.P.Q.2d 1344 (Fed. Cir. 2015), the Federal Circuit said, in regard to divided infringement cases, that a party may be held “responsible for others’ performance of method steps in two sets of circumstances: (1) where that entity directs or controls others’ performance, and (2) where the actors form a joint enterprise.” *Id.* at 1022. The court went on to state that an alleged infringer may be deemed to control another party, and therefore direct infringement by a single party may be found in a divided infringement scenario, when the “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.” *Id.* at 1023.

In *Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*, 845 F.3d 1357, 1364–68, 121 U.S.P.Q.2d 1277 (Fed. Cir. 2017), the Federal Circuit applied the divided infringement test from *Akamai* and found that physicians directly infringed Eli Lilly’s method of treatment patent because the physicians performed some of the claimed method steps and directed the patients to perform the remaining claimed steps. The court went on to find that the defendant, a generic drug manufacturer, induced the direct infringement of the physicians. *Id.* at 1369.

Applying the divided infringement test put forth in *Eli Lilly* to claims that include both diagnostic and treatment steps, patent owners seeking to enforce such claims may make the legal argument that a competitor diagnostic testing entity, after performing the diagnostic testing steps, directs and controls the treatment performed by the doctor.

A second issue with relying on a treatment step is that the majority of jurisdictions in the world do not allow claims on a method of medical treatment. As such, while this approach may work in the United States and Australia, it cannot be followed *verbatim* in other important jurisdictions such as Europe and China, where these types of claims are not permitted. Practitioners should work closely with their foreign associate counterparts in these jurisdictions to develop strategies, such as the preparation of “use” and “kit” claims that can result in the patentability of related claims on a world-wide basis.

Claim Language

The *Guidelines* support the view that when it comes to seeking patent protection for diagnostic methods, language matters. The recitation of a preamble such as “A method of diagnosing” immediately brings a patent application into the uncertain realm of potentially ineligible subject matter. In contrast, there are numerous examples of issued patents that essentially cover the same “method of diagnosing,” but have done so in a more nuanced linguistic fashion.

For example, successful drafting and prosecution strategies have been employed around methods for: (a) detecting a patient’s risk to a particular disease, as outlined in U.S. Patent No. 9,441,277; (b) determining if a patient has an increased risk of a particular disease, as outlined in U.S. Patent No 9,353,420; and (c) determin-

ing the presence or absence of a particular genetic abnormality in a patient's biological sample, as outlined in U.S. Patent No. 9,353,414. While these approaches do not necessarily remove the case in question from the issues pertaining to patent-eligible subject matter, the cases are often viewed in a more favorable light and receive more favorable treatment when compared with cases that are unequivocally focused on diagnostic method claims.

Related to the use of claim language is the development of multiple types of independent claims. Relying solely on "method of diagnosis" or "method of treatment-type" claims not only can be a risky proposition in the U.S., but also, as mentioned above, can limit options internationally when attempting to obtain patent protection in other jurisdictions. Accordingly, it is wise for practitioners to provide support for a wide range of independent claim, including "use" and "kit" claims. The importance of including support for these claims directly in the application is underscored by jurisdictions such as China that will not allow an applicant to subsequently introduce medical use claims when the only support in the application as filed is for method of treatment or method of diagnosis-type claims.

Keeping a wide range of independent claim types within an application's arsenal will provide for much

greater flexibility both at home and abroad once prosecution begins.

Conclusion

Against the backdrop of the *Guidelines*, implementing a combination of the foregoing patent drafting strategies should assist patent practitioners in increasing the chances that a diagnostic-related claim will comprise patent-eligible subject matter. Furthermore, drafting the detailed description of the patent application with the foregoing strategies in mind should also result in a disclosure robust with possible claim amendments, which are absolutely essential when arguing against patent-eligible subject matter rejections during prosecution.

Finally, patent jurisprudence related to diagnostic method claims continues to evolve in the U.S. and in other key jurisdictions around the world. Therefore, practitioners prosecuting foreign patent applications are wise to make effective use of foreign counsel early and often to obtain useful claim coverage. Practitioners prosecuting U.S. applications are wise to make use of the liberal PTO continuation practice so that pending applications may benefit from any positive changes to the law.