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Patents/Eligibility

Comparing U.S. and EPO Approaches to Diagnostic Patents

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Medical diagnostics innovators should be aware of divergent patent practices at the U.S. Patent and Trademark Office (PTO) and at the European Patent Office (EPO) as to subject matter eligibility.

Diagnostic tools are a necessary precursor to personalized medicine, which customizes assessment and treatment for an individual patient. Recently, this industry has experienced significant growth, accounting for more than 25 percent of new drug approvals in the United States in 2015. But research and development in this industry requires accurate diagnostic tests that identify medical risks and efficacy for specific patients. Such diagnostics cannot be commercialized without patent protection.

To encourage discovery, the U.S. excludes inventions directed to certain judicially identified categories. But innovators in the United States still face uncertainty over how such an eligibility analysis will be applied to diagnostics. In contrast, the exception for European patents is motivated solely by the need to enable medical practitioners to treat patients. This exception has been interpreted narrowly, and remains static.

Taken together, these disparate perspectives complicate cross-jurisdictional patenting, particularly as U.S. jurisprudence continues to evolve.

Ray of Light for Diagnostics in U.S.: Limiting Ariosa

The U.S. Supreme Court's two-step analysis in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.* has thus far

discouraged the PTO from granting patent protection for most diagnostics inventions.

The analysis itself is now familiar: at step one, the question is whether the claim is directed to one of the judicially identified, patent-ineligible subjects, one of which is natural phenomena. If the answer is no, the claim is patent eligible. If the answer is yes, the question then is whether any additional elements, either individually or as an ordered combination, transform the claim into patent-eligible subject matter.

In the wake of *Mayo*, the Supreme Court and U.S. Court of Appeals for the Federal Circuit have yet to find a diagnostic claim patent eligible. Until they do, the extent of diagnostic claims' patentability is unknown.

But despite this uncertainty, a novel approach applied by the Federal Circuit in the *Enfish* and *CellzDirect* cases, along with a series of district courts that follow, offer some hope that *Ariosa Diagnostics, Inc. v. Sequenom, Inc.* and *Mayo* will be limited to their facts.

Ariosa illustrates the difficulty that diagnostic claims face following *Mayo*. Sequenom discovered a noninvasive way to test for fetal characteristics using known laboratory techniques to determine the presence of a substance in maternal serum. It applied for a patent, including claims reciting detection of a naturally occurring substance by (1) amplifying the substance from maternal serum and (2) detecting the presence of the substance in the sample.

The Federal Circuit concluded that Sequenom's claims were directed to a natural phenomenon because they began and ended with the naturally occurring substance.

The court then determined that, because the process steps were well-known in the art, the claims lacked an inventive concept that transformed the phenomenon into a patent-eligible application. In particular, the court noted that the patent did not claim the discovery of the presence of this particular substance in maternal serum.

Then, in *Enfish, LLC v. Microsoft Corp.*, the Federal Circuit reframed the *Mayo* step one analysis in the context of a computer implementation, asking whether the claims were directed to an abstract idea, and thus meriting step two consideration, *or* to an improvement in computer capabilities, in which case the claim is eligible. In this way, the court shifted focus to the uniqueness of the claimed approach to a problem, and away from mere abstractness.

Following these decisions, the diagnostics industry sought and enforced patents on inventions ancillary to the diagnostic method itself. For example, claims were now focused on new laboratory techniques, treatment based on diagnostic steps, or products used in diagnostic tools. Where possible, practitioners emphasized technological innovation in the specification and claims, and in litigation. To date, these approaches have met with some success.

In *Rapid Litigation Management Ltd v. Cellzdirect, Inc.*, the Federal Circuit applied its *Enfish* reasoning to a life science patent ancillary to diagnostic tools. The patent concerned the cryopreservation of hepatocytes, a type of liver cell used in testing, diagnosis, and treatment of patients.

At step one, the court asked whether the claims were directed to a natural law or to a new laboratory technique. Defendants alleged that the claims merely involved a natural law—the ability of hepatocytes to survive multiple freeze-thaw cycles. But because the end result of the claim was a preparation of hepatocytes with an improved viability over prior techniques, the court concluded that the claims were directed to a new technique and therefore patent eligible.

For thoroughness, the court analyzed the claims under step two, determining that the claimed process contained an inventive concept because it was far from conventional, even if the individual steps were routine.

Despite some progress, uncertainty remains. At least one divided Federal Circuit panel concluded that the *Enfish* step-one approach was not appropriate in every case. And the one district court case to squarely address the subject, *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, rejected the application of *Enfish* to a diagnostic patent.

So, although *Enfish* has not provided absolute clarity to the industry under step one, district courts have found diagnostic claims patent eligible at step two. For example, in *Vanda Pharmaceuticals Inc. v. Roxane Labs., Inc.*, specific genotyping tests, applied in a "highly specified" way, amounted to an inventive concept. In *Oxford Immunotec Ltd. v. Qiagen, Inc.*, the court concluded that a diagnostic test for tuberculosis taught an inventive concept because "there was no *in vitro* diagnostic test for tuberculosis in common use before plaintiff developed its test." And in *Idexx Labs., Inc. v. Charles River Labs., Inc.*, the court concluded that a method of diagnosing disease in a rat population described a "specific solution to a problem which afflicted the field of the invention."

Notably, the patents in all three cases were issued before *Ariosa*, so any changed approach to drafting specifications and claims based on that decision could not have accounted for this shift. If any of these decisions are appealed, practitioners may gain some additional clarity as to the contours of patentability for diagnostic claims.

Recent PTO Guidance Adds to Confusion

In May 2016, the PTO issued examples for subject matter eligibility for life sciences inventions, and subsequently issued a memorandum affirming that these examples were consistent with *Ariosa* and *Cellzdirect*.

Example 29 mirrors claim 25 in *Ariosa* by specifying a method of detection involving the introduction of a substance to a sample. Here, the substance may be man-made or from nature. The PTO concludes that the claim is not directed to a natural law because measuring a response to an introduced substance is not directed to a natural law, citing *Mayo*.

But the PTO does not compare the exemplary method of detection to claim 25 in *Ariosa*, which specified a cat-

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egory of methods of detection. Therefore, the PTO appears to distinguish between diagnostic claims with methods of detection involving addition of a substance to a sample and methods of detection based solely on mechanical means. This distinction could lead to undesired pressures on R&D and appears divorced from the motivation for the judicial exceptions themselves.

Contrary European Approach

In contrast, Europe's analysis of diagnostic claims is more settled. Article 52 of the European Patent Convention (EPC) established the eligibility requirements for an invention: it must be new (novel), involve an inventive step (nonobvious) and be susceptible to industrial application (useful).

Article 53(c) specifies a narrow exception from patent eligibility for "methods for treatment of the human . . . body . . . and diagnostic methods practised on the human . . . body." To fall within this exception, a method must include an examination, a comparison, a finding of any significant deviation, and a decision. Such steps may be implied in other steps or be essential to the invention, even if not explicitly claimed. The motivation for the Article 53(c) exception is to free medical activities from restraint by patent laws, in contrast to the United States where the stated intention of the judicial exceptions is to prevent preemption of an area for further discovery.

The European Patent Office has construed this exception narrowly, permitting claims covering the treatment of body tissues or fluids after they have been removed from the human body (so long as they are not returned to the same body). But the addition of any method step constituting treatment of a human body with therapy has rendered the entire claim ineligible.

Conclusion

Although *Enfish*, *Cellzdirect*, and subsequent district court decisions could mark the emergence of a body of case law setting forth the scope of patent-eligible diagnostic claims, uncertainty remains in the U.S. In the interim, practitioners seeking patent protection in both the U.S. and Europe should be aware of the differences in approach when developing their prosecution strategies and should attempt to obtain claim sets that find some common ground between them, such as through highly specific solutions to particularly diagnostic problems.