High Court Won't Review Case on Diagnostic Method Patents

By Dana A. Elfin

The U.S. Supreme Court's refusal to hear a case involving what diagnostic tests are eligible for patenting means continued uncertainty for biotechnology investors.

The high court declined to review an appeals court's decision invalidating three Cleveland Clinic Foundation patents on methods to test for arterial damage. The U.S. Court of Appeals for the Federal Circuit said the patents merely cover the observation of a natural phenomenon and weren't eligible for patent protection.

The high court's failure to take up the Cleveland Clinic's petition for review in the *Cleveland Clinic Foundation v. True Health Diagnostics* case means an already murky area of patent law will remain murky for now. It also means continued obstacles for biotechnology innovators.

Difficult to Obtain Patents

The Cleveland Clinic case illustrates the difficulties in getting patents on medical diagnostic methods. The tests detect the presence of an enzyme the body releases when there is arterial damage or inflammation.

The continued lack of clarity in the area "impacts technology, investment and the commercialization of inventions," Kevin E. Noonan, a biotechnology patent attorney with McDonnell Boehnen Hulbert & Berghoff LLP in Chicago told Bloomberg Law June 11.

"The Supreme Court has no idea there's a problem or that there's anything for them to review," Noonan said.

Noonan chairs his firm's Biotechnology & Pharmaceuticals Practice Group. He is a founding author of the Patent Docs weblog focusing on biotechnology and pharmaceutical patent law, and he is a Bloomberg Law advisory board member.

Prior Guidance Enough?

But Andrew M. Alul, a patent litigator with Taft Stettinius & Hollister LLP in Chicago, said the high court may have felt there was enough guidance on whether a patent covers patent ineligible subject matter after its decisions in *Mayo Collaborative Services v. Prometheus Labs., Inc.*, and *Alice Corporation Pty. Ltd. v. CLS Bank International*.

"Cleveland Clinic was essentially arguing that the Federal Circuit misapplied Mayo and Alice, but the Supreme Court rarely grants certiorari for alleged misapplications of a properly stated rule of law," Alul said.

The second issue Cleveland Clinic raised in support of Supreme Court review was whether ineligible subject matter challenges should be decided at the pleading stage, without the benefit of claim construction or discovery, Alul said.

But the Supreme Court may have felt the Cleveland Clinic case "was a bad case factually to deal with this issue," Alul said. The two lower courts found Cleveland Clinic hadn't presented any proposed constructions of disputed claim terms or expert testimony that would have changed the analysis, he said.

Safe Harbor Still Fuzzy

The high court also refused to take up Classen Immunotherapies Inc.'s invitation to review a case involving whether Perrigo PLC subsidiary Elan Pharmaceuticals Inc.'s provision of information on the safety and efficacy of its muscle relaxant to the FDA infringed a Classen patent.

The Hatch-Waxman Act's safe harbor is important to companies on both sides of pharmaceutical patent litigation because it can exempt from infringement liability any activity that's "reasonably related to the development and submission of information" to the Food and Drug Administration. The harbor is typically used by generic companies that perform certain activities prior to the market launch of their products.
