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IP FRONTIERS

High Court considers revisiting issue of patent eligibility

The U.S. Supreme Court is currently deciding whether to take a case that could have a significant impact on patenting inventions in the life sciences, software, and other technological areas. At issue is a doctrine in patent law known as "patent eligibility."

The invention is a method for performing prenatal genetic testing by conducting a blood test a pregnant woman. By avoiding health hazards of older methods of prenatal screening, like amniocentesis, the invention is credited with revolutionizing prenatal testing and providing substantial benefits in health and safety to expectant mothers and their developing newborns.

It was made possible by a discovery by researchers working at Oxford University that copies of fetal genes actually circulate in a pregnant woman's blood. Having made this discovery and developed and patented a method of prenatal genetic testing based on it, Oxford partnered with a genetic testing company, Sequenom, that invested the hundreds of millions of dollars necessary to validate the test, gain regulatory approval, and make it available to the public. In time, Sequenom's competitors began offering a similar test which Sequenom alleged infringed their patent.

The competitors responded with a lawsuit seeking invalidation of the patent on the grounds that the inventors had merely discovered the natural phenomenon of fetal genes being present in pregnant women's blood and that the genetic test based on that discovery merely added routine methodology to that discovery.

As a result, they argued, on the basis of recent Supreme Court decisions, the invention was not eligible for patenting and the patent should be invalidated, which would allow all genetic testing companies to market similar tests.

By TEIGE P. SHEEHAN
Daily Record Columnist

In fact, in four decisions since 2010, the Supreme Court has built up the doctrine of patent eligibility as a basis to prevent patenting of certain types of inventions. There are many legal requirements for obtaining a patent.

The invention must be novel and non-obvious, meaning it must not already exist nor be something that would have been obvious to create by putting together aspects of different, preexisting technologies. And an application for a patent must sufficiently describe the invention, in definite terms, and how to make and use it.

But the requirement of patent eligibility applies even if these other requirements are satisfied. The Supreme Court has stated that laws of nature, abstract ideas, and natural phenomena are excluded from the universe of patent-eligible subject matter, as are inventions that impermissibly "tie up" such excluded subject matter.

The difficulty has been in identifying the difference between, say, a law of nature such as Einstein's E = mc2 or Newton's law of gravity, which all agree are improper subject matter for a patent, and an application of a natural law or phenomenon, which may well be deserving patent protection.

The Supreme Court has acknowledged that all inventions ultimately rely on the natural operation of physical laws such that all inventions ultimately entail their operation, and that applications of abstract ideas, laws of nature, and natural phenomena must therefore remain patent eligible lest the exception swallow the rule.

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And since the 1980s it had held that combining ineligible subject matter with other elements can yield a patent-eligible invention, even if the added elements are not themselves new when viewed in isolation, provided that the entire invention when viewed as a whole constitutes more than just the ineligible subject matter.

But some more recent Supreme Court decisions have sowed doubt as to whether a holistic view of a patent can save if from ineligibility if it contains ineligible subject matter combined with previously known technology, even if these elements are combined to apply the ineligible subject matter in a new, innovative way way.

It is this tension that set the stage for Sequenom's current petition. The Federal Circuit Court of Appeals, the circuit court

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responsible for hearing appeals of patent cases and subject to Supreme Court review, affirmed a judgment that Sequenom's patent was invalid for subject matter ineligibility, but in the process several Federal Circuit judges took the opportunity to voice their disagreement with the Supreme Court's current guidance on this issue.

Although they acknowledged that the invention was a breakthrough, revolutionary, provided a public health benefit, and deserved a patent, and that the protection from copying conferred by a patent is often necessary to protect the financial investment required to bring a scientific discovery out of the laboratory and translate it into a useful application available to the public, several read the Supreme Court's recent rulings as nevertheless requiring the judgment of invalidity. Several also expressed their view that the Supreme Court should revisit its patent-eligibility jurisprudence, such as by taking up this case.

Indeed, recent analyses have documented an adverse impact the Supreme Court's perceived shift in tone is having on biomedical innovation and other areas. For example, in January, the U.S. Patent and Trademark Office published a working paper reporting a study demonstrating the importance obtaining a patent has on the viability of startup companies and their ability to provide innovative products.

Furthermore, this month researchers, including Ronald Hansen, a professor at the Simon Business School at the University of Rochester, have shown that it takes hundreds of millions to billions of dollars of investment to bring new pharmaceuticals through regulatory development, testing, and approval to market, and similar results have also recently been reported for medical diagnostics.

And in April, researchers from the University of Denver Sturm College of Law published a study demonstrating a direct relationship between the Supreme Court's reinvigorated subject matter eligibility jurisprudence and a dramatic increase in refusals by the U.S. Patent and Trademark Office, obliged to follow the Supreme Court's guidance, to grant patents on inventions in the emerging and promising field of personalized medicine (which promises the possibility of medical treatments uniquely tailored to individual patient's) on subject matter ineligibility grounds.

Together these findings suggest that the Supreme Court, with its recent patent-eligibility decisions, is having a demonstrable, harmful impact on biomedical innovation, long a strength of the U.S. economy. Other technologies, such as in the area of software, are also heavily affected. So much so, in fact, that David Kappos, former director of the U.S. Patent and Trademark Office, has called for outright abolition of the U.S.'s subject matter eligibility doctrine, citing the strength of patent systems in Europe and Asia that lack a corresponding rule.

Several private organizations, such as the American Intellectual Property Owner's Association and Intellectual Property Owners Association (IPO), are also considering legislative amendments to the Patent Act to propose to Congress to clarify the confusion over patent eligibility.

In the more near-term, however, the Supreme Court may first decide to yet again step into the patent eligibility arena and grant Sequenom's petition to take up its appeal. Given the remarkable tone of several of the opinions issued by Federal Circuit judges in this case and the significant volume of amicus curiae briefs filed urging the Supreme Court to grant Sequenom's petition (the author wrote such a brief submitted on behalf of IPO), odds for a grant of review may be above average.

In any event, however, no resolution to this issue should be expected soon, as even if the Supreme Court did agree to hear this appeal it would not issue a decision before next year's term. In the meanwhile, stakeholders would do well to keep apprised of developments on this still-shifting area of patent law, perhaps biding their time until an environment develops that is more favorable to protecting their inventions.

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