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IP FRONTIERS

Court asked to correct course on patent eligibility

The U.S. Court of Appeals for the Federal Circuit, the appellate court responsible for interpreting and applying the Patent Act subject to review by only the Supreme Court, is currently considering several cases with profound implications for patenting medical diagnostic, biotechnological and other inventions in the life sciences. At issue is the requirement known as "patent eligibility," which the Supreme Court has mandated of all inventions on which patenting is sought.

In several recent cases on this issue, the Supreme Court gave only faint guidance as to the line between patent-eligible and -ineligible inventions, leaving it to the Federal Circuit and lower courts to further clarify the distinction in subsequent cases. The Federal Circuit is currently attempting to do just that, at the urging of not only the parties to appeals it is hearing but also trade associations, legal scholars, and other third parties seeking certainty in this important are of patent law.

By TEIGE P. SHEEHAN
Daily Record Columnist

For inventors currently wondering whether innovative applications of their discoveries are eligible for patenting, the best answer for now appears to be: Wait and see.

There are numerous legal requirements that need to be satisfied before an inventor will be granted a patent. The invention needs to be "novel," meaning it does not already exist anywhere in the world. It needs to be "non-obvious," meaning another person of skill in the relevant technological field would not have been motivated to create the invention by combining together multiple pieces of known but previously disconnected items of information.

And the patent must be limited in scope to what the inventor can demonstrate she actually has and can also enable others to perform. These patentability requirements, enacted by Congress and substantially developed by the courts, function to make sure an inventor cannot appropriate from the public domain more than she deserves on the basis of what she has created.

In contrast to these patentability requirements, patent eligibility had received relatively less attention by courts until the Supreme Court's reinvigorated interest in it over the past five years. Under this doctrine, certain inventions, no matter how novel, non-obvious, or possessed and enabled by an inventor, are not eligible for patenting because they "pre-empt" subject matter that should remain free for all people's use, particularly "abstract ideas, laws of nature, and natural phenomena."

In the 1980s, the Supreme Court stated that an invention may be patent eligible when viewed as a whole even if some of its individual elements are patent ineligible and other individual elements are patent eligible but not new when viewed in isolation. In other words, taking ineligible subject matter like a natural phenomenon and adding previously known material or steps to it in a new way can result in a patent-eligible invention.

The reason for this is that all inventions ultimately consist of components that follow natural, physical laws combined with previously known information. In other words, no invention could ever be patented if each of its component parts had to be new individually.

In a more recent case, however, the Supreme Court found an invention ineligible for patenting because, in the court's view, it amounted to no more than an instruction to doctors to apply a law of nature (related to determining how much of particular type of drug to administer patients). Language the court used in that decision seems somewhat incongruous with the rule that eligibility is determined by examining an invention as a whole and does not require every individual aspect of an invention to be new.

Consequently, since then courts and the U.S. Patent and Trademark Office have been finding increasing numbers of inventions patent ineligible even though they would long have been considered eligible, interpreting the Supreme Court as now requiring that every aspect of an invention be new in order to for it to be eligible for patenting.

One such case is Ariosa v. Sequenom, a patent infringement action currently on appeal to the Federal Circuit. The inventors of the patent at issue in that case discovered that the blood of a pregnant woman contains genetic material from the fetus she is carrying. Building on this discovery, they patented a method for prena-

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tal screening using a blood test, significantly safer than previous methods, like amniocentesis, which pose health risks to the fetus.

Although the new test revolutionized prenatal care, a trial court held that it was ineligible for patenting because the presence of fetal genes in pregnant women's blood was a natural phenomenon and, beyond that, the invention included only previously known steps applied to this natural phenomenon. The patentee has appealed this decision to the Federal Circuit.

Although there are 12 active Federal Circuit judges, appeals are typically decided by a panel of just three. Here, a three-member panel affirmed the trial court's conclusion that the invention is ineligible for patenting, although one member of the panel strongly expressed his view that this invention deserves to be patented and lamented the confusion the Supreme Court has created on this issue. Because of the exceptional importance of the patent-eligibility matter in this case and the widespread uncertainty in this area for the past few years, the patentee has asked the full bench of all twelve active judges to come together and rehear the appeal.

Numerous third parties, from trade associations, bar associations, companies, and patent scholars, have also weighed in to urge the full Federal Circuit to decide this question. For example, the Intellectual Property Owners Association, a trade association representing businesses with significant patent and other intellectual property interests, argues that the panel erred in its eligibility assessment by inappropriately breaking the invention down into its individual parts, rather than analyze the invention as a whole as required, thereby missing the forest for the trees. (The author wrote the brief IPO submitted to the Federal Circuit supporting the patentee's request that the full court rehear the appeal.)

It also argued that the panel inappropriately disregarded evidence submitted by the patentee that other groups had made use of the existence of fetal genes in pregnant women's blood with methods that did not infringe the patent, meaning the natural phenomenon remained available for use by others so was not "pre-empted" by the patent.

If the Federal Circuit grants the request that the full bench rehear the appeal, it may invite still more input to advise it on how to more appropriately assess patent eligibility. And this is not the only patent-eligibility appeal currently before the Federal Circuit for which a decision from the full bench has been requested. Furthermore, a handful of additional cases with questions of patent eligibility at issue are currently before three-member Federal Circuit panels, while still others are percolating up through the lower courts and may soon reach the Federal Circuit on appeal.

Thus, inventors considering applying for patents in the medical diagnostic, biotech or related life sciences space and wondering whether they have an invention that is eligible for patenting may do well to wait on the Federal Circuit to provide needed some needed clarification, given that this question currently remains in flux.

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