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Federal Circuit Patent Bulletin: *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*

June 15, 2015

"Where claims of a method patent are directed to an application that starts and ends with a naturally occurring phenomenon, the patent fails to disclose patent eligible subject matter if the methods themselves are conventional, routine and well understood applications in the art."

On June 12, 2015, in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, the U.S. Court of Appeals for the Federal Circuit (Reyna,* Linn, Wallach) affirmed the district court's summary judgment that U.S. Patent No. 6,258,540, which related to a method for detecting a paternally inherited nucleic acid of fetal origin performed on a maternal serum or plasma sample from a pregnant female, was invalid under 35 U.S. C. § 101 for lack of patent eligible subject matter. The Federal Circuit stated:

Section 101 of the Patent Act defines patent eligible subject matter: Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title. The Supreme Court has long held that there are certain exceptions to this provision: laws of nature, natural phenomena, and abstract ideas. [T]he Supreme Court set forth a framework for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts. First, we determine whether the claims at issue are directed to a patent-ineligible concept. If the answer is yes, then we next consider the elements of each claim both individually and "as an ordered combination" to determine whether additional elements "transform the nature of the claim" into a patent-eligible application. The Supreme Court has described the second

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step of this analysis as a search for an "inventive concept"—i.e., an element or combination of elements that is "sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself."

The claims of the '540 patent that are at issue in this appeal are method claims. Methods are generally eligible subject matter. In this case, the asserted claims of the '540 patent are directed to a multistep method that starts with [cell-free fetal DNA] cffDNA taken from a sample of maternal plasma or serum—a naturally occurring non-cellular fetal DNA that circulates freely in the blood stream of a pregnant woman. See, e.g., '540 patent claims 1, 24, 25. It is undisputed that the existence of cffDNA in maternal blood is a natural phenomenon. Sequenom does not contend that Drs. Lo and Wainscoat created or altered any of the genetic information encoded in the cffDNA, and it is undisputed that the location of the nucleic acids existed in nature before Drs. Lo and Wainscoat found them. The method ends with paternally inherited cffDNA, which is also a natural phenomenon. The method therefore begins and ends with a natural phenomenon. Thus, the claims are directed to matter that is naturally occurring. . . .

Because the claims at issue are directed to naturally occurring phenomena, we turn to the second step of Mayo's framework. In the second step, we examine the elements of the claim to determine whether the claim contains an inventive concept sufficient to "transform" the claimed naturally occurring phenomenon into a patent-eligible application. We conclude that the practice of the method claims does not result in an inventive concept that transforms the natural phenomenon of cffDNA into a patentable invention.

[T]ransformation into a patent-eligible application requires "more than simply stat[ing] the law of nature while adding the words 'apply it.'" A claim that recites an abstract idea, law of nature, or natural phenomenon must include "additional features" to ensure "that the [claim] is more than a drafting effort designed to monopolize the [abstract idea, law of nature, or natural phenomenon]." For process claims that encompass natural phenomenon, the process steps are the additional features that must be new and useful. . . .

Sequenom contends that the claimed methods are patent eligible applications of an atural phenomenon, specifically a method for detecting paternally inherited cffDNA. Using methods like PCR to amplify and detect cffDNA was well-understood, routine, and conventional activity in 1997. The method at issue here amounts to a general instruction to doctors to apply routine, conventional techniques when seeking to detect cffDNA. Because the method steps were well-understood, conventional and routine, the method of detecting paternally inherited cffDNA is not new and useful. The only subject matter new and useful as of the date of the application was the discovery of the presence of cffDNA in maternal plasma or serum. . . .

The dependent claims are broad examples of how to detect cffDNA in maternal plasma. The dependent claims are focused on the use of the natural phenomenon in combination with well-understood, routine, and conventional activity. For example, claim 2 identifies the polymerase chain reaction as the amplification technique to be used in the detection method of claim 1. As noted above, this technique was well-understood, routine, and conventional in 1997, as specified by the patent itself. Like claim 1, claims 5 and 8 focus on detecting a specific chromosome within the cffDNA—a natural phenomenon—again, adding no inventive concept to the limitations of claim 1. None of the remaining asserted dependent or independent claims differ

substantially from these claims. Thus, in this case, appending routine, conventional steps to a natural phenomenon, specified at a high level of generality, is not enough to supply an inventive concept. Where claims of a method patent are directed to an application that starts and ends with a naturally occurring phenomenon, the patent fails to disclose patent eligible subject matter if the methods themselves are conventional, routine and well understood applications in the art. The claims of the '540 patent at issue in this appeal are not directed to patent eligible subject matter and are, therefore, invalid.