No. 15-1182

IN THE

Supreme Court of the United States

SEQUENOM, INC,

Petitioner,

v.

ARIOSA DIAGNOSTICS, INC., NATERA, INC., AND DNA DIAGNOSTICS CENTER, INC.,

Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF METABOLON, INC. AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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INTEREST OF *AMICUS CURIAE*[1]

Amicus curiae Metabolon, Inc. ("Metabolon") is a pioneer and leader in the field of metabolomics, which is the study of small molecules and integral technology for understanding the function of biological systems. Metabolon has advanced the field of metabolomics by pioneering and patenting the industry's leading biochemical biomarker discovery and profiling platform. Prior to Metabolon's platform, comprehensive metabolomics studies were prohibitive for most research projects due to the challenge of processing and interpreting metabolite data. Because a single sample could yield hundreds of metabolites and tens of thousands of data points, processing that data was not only time and labor intensive, but also prone to significant error. By contrast, Metabolon's technology allows scientists to quickly identify and measure all of the biochemicals in a biological sample. Through the generation and interpretation of data, Metabolon's method provides a precise understanding of disease etiology and drug action, and advances personalized medicine beyond what genomics and other approaches can promise. Metabolon's expertise is already being embraced by a wide range of pharmaceutical, biotechnology, food and agricultural companies. The technology also has potential applications across multiple research areas, including cancer, metabolic

[1] No counsel for any party authored this brief in whole or in part and no person other than *amicus curiae,* its members, and its counsel made a monetary contribution intended to fund its preparation or submission. All parties have consented to the filing of this *amicus* brief, and their consent letters are on file with the Clerk's office.

and cardiovascular disease, immunology, neurology, and plant and animal biology.

Patent protection is critical to Metabolon to ensure continued partnering with pharmaceutical, biotechnology, food and agricultural companies. Patent protection is also needed to ensure the availability of resources needed to continue the advancement of metabolomics and further define the current state of health and actionable information to advance clinical decision–making and research. Metabolon invests a large percentage of its resources in basic research and licenses its patent portfolio to generate revenue for continued research and development. Metabolon's ability to obtain and license its patents has been negatively impacted by the lower courts' decisions under 35 U.S.C. § 101.

The decision below threatens to destroy the predictability and certainty of the patent system. At a minimum, the biomedical community is now adrift in determining whether or not patents will ever be available in these or related fields. The uncertainty means that members of the biomedical community cannot: (1) confidently invest in research; (2) confidently invest in clinical validation and commercialization of existing patents; or (3) confidently predict that it is better to disclose discoveries through the patent system than it is to keep discoveries a trade secret.

The Federal Circuit's judgment applies an approach to patentable subject matter that is inconsistent with this Court's precedent requiring consideration of the interplay between a natural phenomenon and other claim elements in determining whether a combination of elements transforms the claim into a patent–eligible application of the natural phenomenon. The Federal

Circuit's approach has created confusion and unpredictability as to the scope of patent–eligible subject matter across a wide range of biomedical applications, which threatens to undermine investor confidence in research across numerous fields, including metabolomics. Metabolon urges this Court to grant certiorari and to correct the standard for subject–matter eligibility analysis under 35 U.S.C. § 101 by reestablishing this Court's prior precedent requiring that courts consider any recited natural phenomenon as part of the patent claim as a whole.

Metabolon has no financial interest in the parties to this litigation or in the outcome of this specific case.

SUMMARY OF ARGUMENT

This Court's precedent requires that for a patent–eligibility analysis the claims must be considered as a whole, just as claims are considered as a whole under a 35 U.S.C. § 103 obviousness analyses. *Parker v. Flook*, 437 U.S. 584, 594 n.16 (1978). In turn, to consider a claim as a whole means to consider all claim elements, as well as their interrelationship with each other.

In contravention of this Court's precedent, the Federal Circuit has re–interpreted this Court's decisions in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012), and *Alice Corp. v. CLS Bank International*, 134 S. Ct. 2347 (2014) by limiting patent–eligibility determinations to the patent–eligible claim elements, while ignoring elements that may not be patent eligible in isolation.

The district court in this case found that the patentee's claims recited an "inventive component." *See Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 19 F. Supp. 3d 938, 953 (N.D. Cal. 2013). However, since

the inventive component relied, in part, on a natural phenomenon,[2] the district court and Federal Circuit disregarded the natural phenomenon and erroneously concluded that the remaining claim elements did not confer patent eligibility.

The Federal Circuit's approach to subject–matter eligibility contravenes Supreme Court precedent and conflicts with § 103 by requiring courts to interpret the patent claim in question differently for purposes of subject–matter eligibility under § 101 on one hand and for obviousness under § 103 on the other. This Court should grant certiorari, set aside the Federal Circuit's mistaken interpretation of *Mayo* and *Alice*, and consider the subject–matter eligibility of Sequenom's patent claims in light of the claims as a whole, including the inventive component identified by the district court.

ARGUMENT

I. THE FEDERAL CIRCUIT MISINTERPRETS *MAYO* TO REQUIRE EXCLUSION OF ANY NATURAL PHENOMENON FROM AN INVENTIVE CONCEPT ANALYSIS

The Federal Circuit has misinterpreted this Court's decisions in *Mayo* and *Alice* as authority for disregarding the interplay between a natural phenomenon and other claim elements in determining whether a combination of claim elements transforms the claim into a patent–eligible application of the natural phenomenon. *See Ariosa Diagnostics, Inc. v. Sequenom, Inc*., 788 F.3d 1371, 1377-78 (Fed. Cir.),

[2] For simplicity, a law of nature, a natural phenomenon, and an abstract idea are collectively referred to as a "natural phenomenon."

reh'g denied per curiam, 809 F.3d 1282 (2015). Under the first step of *Mayo*'s framework, the Federal Circuit characterized the Sequenom patent claims as "generally directed to detecting the presence of a naturally occurring thing or a natural phenomenon, cffDNA in maternal plasma or serum." *Ariosa*, 788 F.3d at 1376. In the second step of *Mayo*'s framework, the court ignored the interplay of cffDNA with the other claim elements in its search for an "inventive concept sufficient to 'transform' the claimed naturally occurring phenomenon into a patent–eligible application." *Id*. at 1376-78. Instead, the Federal Circuit considered only the patent–eligible claim elements, in isolation from cffDNA, and concluded that because these elements "were well-understood, routine, and conventional activity" that the claims were not directed to an inventive concept as required under *Mayo*'s second step. *Id*. at 1377-78.

The Federal Circuit's erroneous application of *Mayo* and *Alice* in this case echoes the court's prior decision in *University of Utah Research Foundation v. Ambry Genetics Corp*., 774 F.3d 755 (Fed. Cir. 2014), another case involving genetic testing technology. In *Ambry*, after determining that the claims encompassed an abstract idea, the court stated: "*Alice* dictates that we ask whether the remaining elements, either in isolation or combination with the other *non–patent–ineligible elements*, are sufficient to 'transform the nature of the claim into a patent–eligible application.'" *Id*. at 764 (quoting *Alice*, 134 S. Ct. at 2355 (quoting *Mayo*, 132 S. Ct. at 1297)) (emphasis added) (internal quotation marks omitted).

The erroneous nature of the Federal Circuit's parsing of the claims is particularly striking in the present case where the district court expressly found

that the claimed application of a natural phenomenon constituted an "inventive component" of the claims, yet incongruously concluded that the claims were not subject–matter eligible. *See Ariosa*, 19 F. Supp. 3d at 953. The district court mistakenly believed that, under this Court's precedent, the interplay of a natural phenomenon with other claim elements does not count in the subject–matter eligibility analysis, unless those other elements are themselves non–conventional. *Id*. at 951. Rather than recognizing and correcting this legal error, the appeals court affirmed. *See Ariosa*, 788 F.3d at 1377-78.

Confining subject–matter eligibility determinations to only the *patent–eligible elements of a claim* contravenes this Court's precedent directing that "[i]n determining the eligibility of [a] claimed process for patent protection under § 101, the[ ] claims must be considered as a whole." *See Diamond v. Diehr*, 450 U.S. 175, 188 (1981). In effect, the appeals court has contorted *Mayo*'s inventive concept step into a tool to dissect claims into their individual components and disregard critical combinations of elements that define the actual invention. Moreover, this application of *Mayo* creates conflict with § 103 by making the claim in question different for purposes of subject–matter eligibility than for obviousness.

A. *Mayo*'s Inventive Concept Analysis Must Permit Consideration of a Natural Phenomenon as Part of the Claim as a Whole

The determination of subject–matter eligibility under § 101 requires consideration of the claim "as a whole." *Diehr*, 450 U.S. at 188; *see also Flook*, 437 U.S. at 594 (holding claim not patent eligible "because the application, considered as a whole, contained no

patentable invention"). In turn, the analysis of a claim as a whole under § 101 includes the recited natural phenomenon and its relation to any other claim elements. *Diehr*, 450 U.S. at 187 (implementation of a mathematical formula considered in the analysis of a process for curing rubber). Indeed, *Mayo* referred to *Diehr* as finding "the overall process patent eligible because of the way the additional steps of the process *integrated* the equation into the process as a whole" to "transform[] the process into an inventive application of the formula." *Mayo*, 132 S. Ct. at 1298 (emphasis added). More recently, *Alice* reaffirmed that the analysis of a claim as a whole includes "all claim elements, both individually and in combination." *Alice*, 134 S. Ct. at 2355 n.3.

Conversely, this Court's precedent does *not* support excising a natural phenomenon from the claims prior to the analysis of subject–matter eligibility. *See Diehr*, 450 U.S. at 189 n.12 ("[W]e did not hold in *Flook* that the mathematical algorithm could not be considered at all when making the § 101 determination."). Although *Flook* indicated that "[t]he process itself, not merely the mathematical algorithm, must be new and useful," *Flook* treated the natural phenomenon as if in the prior art and the application of the natural phenomenon, as a whole, analyzed for patent eligibility. *Flook*, 437 U.S. at 591-95.

The "inventive concept" test articulated in *Mayo* did not discard the longstanding requirement that claims be analyzed "as a whole." *See Diehr*, 450 U.S. at 188. On the contrary, this Court addressed the claims in *Mayo* by stating that "the *three steps as an ordered combination* adds nothing to the laws of nature that is not already present when the steps are considered separately." *Mayo*, 132 S. Ct. at 1298 (emphasis

added). The Court further added that the three method steps, "*when viewed as a whole*, add nothing significant beyond the sum of their parts taken separately" and that "the steps are not sufficient to transform un–patentable natural correlations into patentable applications . . . ." *Id*. (emphasis added). The three steps referred to by *Mayo* were: (1) an administering step; (2) a determining step; and (3) a wherein step that "simply tell[s] a doctor about the relevant natural laws . . . ." *Id*. at 1297-98. Thus, rather than divorcing the natural phenomenon from the claims, *Mayo* expressly included the natural phenomenon in the wherein step as part of its analysis of the claim as a whole.

The requirement to consider a claim as a whole is not limited to subject–matter eligibility determinations, but also applies to obviousness analyses under § 103. 35 U.S.C. § 103. Unlike § 103, however, the basis for analyzing the claim as a whole under § 101 stems from this Court's precedent, rather than from the Patent Statute. In *Flook*, the Court noted the statutory requirements of § 103, adding that "[a]lthough this does not necessarily require that analysis of what is patentable *subject matter* under § 101 proceed on the same basis, we agree that it should." *Flook*, 437 U.S. at 594 n.16 (emphasis in original). Thus, under *Flook*, consideration of "the claim as a whole" is the same, whether for § 101 or § 103.

Analysis of a claim as a whole must consider the interplay of claim elements. It would be improper "to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis." *Diehr*, 450 U.S. at 188. Also, as explained in *KSR*, "inventions in most, if not all, instances rely

upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418-19 (2007). Thus, for obviousness, "it can be important to identify a reason that would have prompted a person of ordinary skill . . . *to combine the elements in the way the claimed invention does*." *Id*. (emphasis added). Particularly for process claims, "a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made." *Diehr*, 450 U.S. at 188. Simply stated, considering the claim as a whole takes into account the interaction and relation of claim elements. The same principles are relevant to a § 101 or § 103 analysis despite the different considerations that come into play under each section of the Patent Statute.

In a process claim, a combination of claim elements often entails "an act . . . performed upon the subject–matter to be transformed and reduced to a different state or thing." *Cochrane v. Deener*, 94 U.S. 780, 787-788 (1877). The interplay between the act and the subject matter to be transformed defines the process actually claimed. For a one–step process, this would constitute the invention as a whole. For example, in a chemical process that reacts A and B using technique X to produce C, the interplay of A, B, and X and the resultant product C defines the claimed process step. Analysis of such a claim *as a whole*, whether for purposes of § 101 or § 103, would consider the interplay of all the claim elements, rather than the elements in isolation.

In re Ochiai, 71 F.3d 1565 (Fed. Cir. 1995), illustrates how the interplay between an act and subject matter to be transformed can define a patentable process claim. The claim in *Ochiai* recited a process for producing a novel antibiotic by the reaction of a known amine with a novel acid using a known reaction technique. *Id*. at 1567-68. The Patent Office ignored the novel acid and rejected the claim for obviousness on the grounds that the reaction technique itself was "standard" and "conventional." *Id*. Considering the claim as a whole, however, the Federal Circuit reversed because of the novelty and non–obviousness of the acid and the absence of any teaching in the art "to support the conclusion that the *particular process recited* . . . is obvious." *Id*. at 1569-70 (emphasis added). In other words, the operation of a standard or conventional technique on a novel and nonobvious composition defined a patentable process claim.

Process claims at issue in the present case also depend on the interplay between an act and subject matter to be transformed. For instance, claim 1 of U.S. Patent No. 6,258,540 ("the '540 patent") recites "amplifying a paternally inherited nucleic acid from the serum or plasma and detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample." The interplay between a natural phenomenon (cell–free fetal DNA ("cffDNA") in a maternal serum or plasma sample) and an act performed on the natural phenomenon (amplification) produces a sample containing amplified cffDNA. In effect, the original natural sample of cffDNA is transformed into a different state or thing, i.e., a sample containing an unnaturally enriched amount of cffDNA. In another step, a separate detecting act is performed on the sample containing the enriched cffDNA.

In *inter partes* review proceedings involving the claims of the '540 patent, the Patent Trial and Appeal Board ("PTAB") analyzed the interplay of claim elements in reaching a decision that claim 1 would not have been obvious. *See Ariosa Diagnostics v. ISIS Innovation Ltd*., Final Written Decision, No. IPR2012-00022, slip op., at 37-47 (Sept. 2, 2014). The prior art allegedly taught amplification and detection of DNA from maternal serum ("Kazakov") and that the *cellular* component of maternal blood contained fetal DNA ("Simpson"). *Id*. at 30, 39, 41. In its § 103 analysis, the PTAB considered whether the art taught the *specific combination* of amplification and detection with fetal DNA from maternal serum, concluding that it did not. The PTAB found that the skilled artisan would not have subjected the serum samples of Kazakov to the analysis of fetal DNA taught by Simpson because the "ordinary artisan would not have had a reasonable expectation that the fetal DNA would have been present in maternal *serum* in sufficient quantities for detection using amplification methods, such as [polymerase chain reaction], given the understanding in the art that fetal cells were a rare occurrence in maternal blood." *Id*. at 43 (emphasis added).

Importantly, the PTAB's § 103 analysis of the claims did not disregard the interplay between cffDNA and amplification and detection. Rather, that interplay of claim elements was central to its consideration of the claims as a whole. Despite the different purposes of § 101 and § 103, a proper analysis of these claims for subject–matter eligibility should proceed "on the same basis." *Flook*, 437 U.S. at 594 n.16.

B. The Federal Circuit Erred by Excluding cffDNA from its Inventive Concept Analysis

The Federal Circuit in this case ignored the relationship between a natural phenomenon and other claim elements in its subject–matter eligibility analysis. This analysis failed to consider the claim as a whole by disregarding that the interplay of claim elements defines the invention. As a result, the appeals court distilled the patentee's claims down to a mere aggregation of cffDNA and certain biochemical techniques, and required the latter alone to supply an inventive concept under *Mayo*, completely apart from the cffDNA.

The Federal Circuit began its inventive concept analysis by citing *Mayo* for the proposition that claims reciting a natural phenomenon "must include 'additional features' to ensure 'that the [claim] is more than a drafting effort designed to monopolize [the natural phenomenon].'" *Ariosa*, 788 F.3d at 1377 (quoting *Mayo*, 132 S. Ct. at 1297) (first alteration in original). Citing *Flook*, the court stated that "[f]or process claims that encompass natural phenomenon, the process steps are the additional features that must be new and useful." *Id*. However, instead of considering the patentee's process as a whole, as *Mayo* and *Flook* require, the court limited its analysis to whether the *techniques* recited in the claims supplied an inventive concept, without considering how those techniques interact with the natural phenomenon element of the claim:

> 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.

Id. (emphasis added). Much like the examiner in the *Ochiai* case discussed above, the court could only arrive at this conclusion by segregating the cffDNA (subject matter to be transformed) and the amplification and detection (acts) into separate elements and finding that the acts, in isolation from the cffDNA, were conventional or routine. This analysis failed to consider the claim as a whole.

Judge Lourie's opinion concurring in the Federal Circuit's denial of rehearing en banc acknowledges that "applying *Mayo*, we are unfortunately *obliged to divorce the additional steps from the asserted natural phenomenon* to arrive at a conclusion that they add nothing innovative to the process." *Ariosa*, 809 F.3d at 1286 (Lourie, J., concurring) (emphasis added). Likewise, Judge Dyk interpreted *Mayo* as instructing that the asserted natural phenomenon should be put to the side in analyzing a claim for inventive concept. *See id.* at 1287 (Dyk, J., concurring). Thus, Judge Dyk understood *Mayo* to require that an inventive concept must be based on applying unconventional techniques to a natural phenomenon, even though the natural phenomenon may be newly discovered. *See id*. at 1289.

Not only did the Federal Circuit in this case misapply *Mayo* and *Flook*, but it also ignored other relevant precedent, such as *Diehr*. None of this Court's jurisprudence provides authority for ignoring claim elements, whether determining subject–matter eligibility or, more specifically, searching for an inventive concept. As discussed above, *Mayo* explicitly included in its analysis the step embracing the natural

phenomenon. *Mayo*, 132 S. Ct. at 1297-98. Moreover, *Diehr* explained that *Flook* did *not* hold that a natural phenomenon "could not be considered at all when making the § 101 determination." *Diehr*, 450 U.S. at 189 n.12. Indeed, the Federal Circuit's reliance on *Flook* as authority for disregarding the asserted natural phenomenon is particularly off the mark, since *Flook* stated that a determination under § 101 or § 103 "should proceed on the same basis," insofar as the claim being considered as a whole. *Flook*, 437 U.S. at 594 n.16. Claim elements would never be ignored under a § 103 analysis, and should not be ignored under a § 101 analysis.

The Federal Circuit may have understood *Mayo* to provide a general rule of the law that mechanically labels the natural phenomenon in a claim as the solution, and anything else as mere extra–solution activity. *Mayo*, however, articulated no such rule. The active process steps in *Mayo* (i.e., administering and determining) were known procedures, as actually claimed, that operated wholly apart from the natural phenomenon recited in the "wherein" clauses. *See Mayo*, 132 S. Ct. at 1297-1300. *Mayo* did *not* divorce the administering and determining steps from the natural phenomenon, as the Federal Circuit did in this case. Instead, the *patentee* in *Mayo* had divorced these elements by the form in which the claim was written. At most, the claims in *Mayo* linked the natural phenomenon only to the abstract idea of needing to adjust the dose of the drug. *See id*. Because the administering and determining steps were untethered to the natural phenomenon, they could be described as insignificant extra–solution activity. *See id.* at 1298. Even the ordered combination of steps as a whole in *Mayo* was no more than the sum of the parts individually. *Id*.

Here, rather than analyzing the claims as written, the Federal Circuit tried to fit the patentee's claims into the mold of the supposed rule distilled from *Mayo*'s facts. For example, the court characterized the claims as merely "appending routine, conventional steps to a natural phenomenon, specified at a high level of generality . . . ." *Ariosa*, 788 F.3d at 1378. As written, however, Sequenom's claims do not simply append routine and conventional steps to a natural phenomenon. Rather, cffDNA is intertwined with amplification and detection to create non–routine and non–conventional process steps, as the PTAB found in its § 103 analysis. *See Ariosa*, Final Written Decision, No. IPR2012-00022, slip op., at 37-47. Judge Lourie found it "undisputed that before this invention, the amplification and detection of *cffDNA from maternal blood*, and use of these methods for prenatal diagnoses, were *not* routine and conventional." *Ariosa*, 809 F.3d at 1286 (Lourie, J., concurring) (emphasis in original).

This critical combination of elements defines the invention in this case. Even the district court found that the interplay of a natural phenomenon and process techniques constituted an "inventive component" of the claims. *See Ariosa*, 19 F. Supp. 3d at 953. By all accounts, the claimed processes are both new and highly useful. *See, e.g.*, *Ariosa*, 788 F.3d at 1379-80.

Characterizing amplification and detection as mere insignificant post–solution activities also ignores how the interplay of cffDNA with amplification and detection contributes to the solution. The natural phenomenon in this case would remain undiscovered (i.e., unsolved) in the absence of amplification and detection. Only through hindsight may the existence

of cffDNA in maternal serum be posited as the solution itself. The appeals court's application of *Mayo*, however, does not distinguish claims encompassing an inventive component, as here, from ones that merely cobble together a natural phenomenon with insignificant extra–solution activity.

A proper analysis for subject–matter eligibility should have looked at the claimed process as a whole, not just at the component techniques. Amplification (e.g., with polymerase chain reaction), for example, is not a "process step," but rather, is a technique applied to cffDNA. The actual process step is the act of amplification, performed on a maternal sample of cffDNA, to transform the sample, by enriching it with unnatural levels of cffDNA. The interplay of elements defines the step, not the act itself. Likewise, detecting cffDNA in the sample containing unnaturally enriched levels of cffDNA constitutes an act performed on a heretofore unknown sample containing enriched amounts of cffDNA.

The differences between the claims in this case and in *Mayo* are manifest. Here, a sample is *transformed* by amplification to contain enriched amounts of cffDNA not found in nature. While not necessarily dispositive in all cases, this transformation suggests strongly the presence of patent–eligible subject matter. *See Bilski v. Kappos*, 561 U.S. 593, 604-05 (2010) (noting the "machine–or–transformation test is a useful and important clue" that "may provide a sufficient basis for evaluating processes . . . grounded in a physical or tangible form"). Also, unlike *Mayo*, this transformative aspect of the claims was not routine or conventional. *See Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 628 F.3d 1347, 1355-57 (Fed. Cir. 2010), and *Mayo*, 132 S. Ct. at 1298

(administering step considered "transformative" by the appeals court and, at the same time, routine or conventional by the Supreme Court).

Had the facts of this case been the same or similar to those before the Court in *Mayo*, the Federal Circuit's approach might have made sense. However, as explained above, unlike here, the active process steps in *Mayo* were not enmeshed with the natural phenomenon. The claims in *Mayo* did not link the administering and determining steps with the natural phenomenon, and so divorcing the steps from the phenomenon would not reduce the steps to mere techniques. The Federal Circuit's improper approach resulted in it missing these critical factual differences between the claims in these cases. The court should have been guided by those differences in analyzing the § 101 issue. The Federal Circuit's disregard for the interaction of claim elements in this case contravenes this Court's requirement that claims be considered as a whole under § 101. *Diehr*, 450 U.S. at 188.

CONCLUSION

Amicus curiae urges that this Court grant the petition for writ of certiorari, set aside the Federal Circuit's mistaken interpretation of *Mayo* and *Alice*, and consider the patent eligibility of Sequenom's claims in light of the inventive component found by the district court.

Respectfully submitted,

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