THE *SEQUENOM* PREDICATE ISSUE: THE "QUESTION PRESENTED"[*]

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I. **OVERVIEW**

On or shortly before the April 1, 2016, deadline, a petition for *certiorari* will be filed in *Sequenom, Inc. v. Ariosa Diagnostics, Inc*., Supreme Court No. 15A871. A great deal of controversy exists whether the *Sequenom* case represents merely an important case for the patentee, or whether the patent community at large has a stake in the positive evolution of case law that may be possible if *Sequenom* proceeds to the merits stage.

This paper addresses the question whether potential *amici* should "wait and see" at the *certiorari* stage without *amici* participation, and then participate at the merits stage *if* the Court grants *certiorari* – or plunge in as *amici* at the earlier stage.

The *Sequenom* patent, itself, presents an overwhelming case of an invention that is clearly patent-eligible. Whether prospective *amici* should join the Supreme Court case to a great extent depends upon how the *Questions Presented* are styled in the petition for *certiorari.* Will the *Questions Presented* be styled to highlight manifest patent-eligibility even under the most extreme interpretation of recent case law? If yes, then by all means *certiorari* support should be of positive value.

For example, consider the following *Questions Presented* that would make out a best case scenario:

***The Questions Presented*:** The Sequenom invention is an undeniably pioneer invention that permits genetic testing to identify fetal DNA by a simple blood test where a blood sample is drawn from the arm of a pregnant mother, a remarkable and unquestioned advance over the traditional fetal blood test where a fluid sample is drawn from *within a womb-invasive sampling of a mother's amniotic fluid*.

When the claimed invention is viewed *as a whole* and giving weight to "all elements" of the invention, there can be no doubt that the claimed subject matter is "inventive" under the classic tests of Supreme Court case law, complemented by the *Diehr* case that cabins limiting dicta of the *Flook* case.

A mother's blood contains *de minimis* fetal DNA, a fact recognized by the inventors and which requires for the genetic test a *multiplication* of that DNA through use of Polymerase Chain Reaction (PCR) technology.

It is unquestioned that the invention *as a whole* involving the combination of drawing maternal blood and *amplifiying* the DNA, e.g., with PCR technology, represents a breakthrough and *a fortiori* "inventive" method.

It is also unquestioned that the Sequenom invention involves DNA only as the object of *identification* of known DNA, i.e., the invention makes no claim to any DNA of any kind nor to any method of use of DNA.

The *Questions Presented* are thus:

(1) Does classic Supreme Court case law requiring consideration of "all elements" of an invention remain viable to determine the patent-eligibility of a method which, *as a whole*, is clearly "inventive." In other words, does the "all elements" rule as applied in *Diehr* trump the dissection of claims as in *Flook*?

(2) Does case law denying patent-eligibility to claims to DNA, *per se* (or claims to its method of use) preclude patent-eligibility of a claim which merely *identifies* the presence or absence of DNA, but in no way, shape nor form claims that DNA nor its use? In other words, there is no DNA "preemption" issue of any kind.

Whether the case *as presented at the trial court and Federal Circuit* provides basis for presentation of the *Questions Presented* as posed above is unclear. Assuming, *arguendo*, that there is no problem with the record as established below, then if the proposed *Questions Presented* could go forward, *amici* participation at the *certiorari* stage should be applauded.

But, to the extent that the hypothetical *Questions Presented* are *not* the basis for going forward, then the question is raised whether *amici* are well served by joining this case at the *certiorari* stage. It must also be remembered that patentees and patent applicants who *do* reach the merits stage are more frequently than not the losers of the resultant decision, particularly in patent-eligibility cases (as seen from the chart at page 5). No final decision needs to be made by a prospective *amicus* party at present, because *amici* joining at the *certiorari* stage do so after the petition is filed.

To the extent the Supreme Court grants *certiorari*, *amici* participation at the merits stage would then be welcomed. Then, the Court could venture into uncharted patent waters which have been the exclusive province of the courts of appeal. *See* § II, *Opening Uncharted Patent Waters to the Court.*

At first blush, one may wonder *how* it was possible for the Federal Circuit to reach the conclusion that it did, given the underlying facts of the case. *See* § III, *The Facts Establish a Patent-Eligible Invention.*

Given the publicity and importance of the case, the issue is whether prospective *amici* <u>*should*</u> participate at the Supreme Court? If so, when is the appropriate time to do so? *See* § V, *Whither Amici Participation.* Certainly, there are serious dangers raised for the patent community if this case is taken for review

by the Supreme Court, including a potential for a binding, precedential Supreme Court affirmance of the Federal Circuit decision.

At least as important as the impact on the instant patent-eligibility issue is the fact that several long standing doctrines at the Federal Circuit have never been tested at the Supreme Court could in the wake of a merits review, here, wind up at the highest court. *See* § V-A, *Dangers of Amici Participation at the Petition Stage.* While caution and restraint in terms of *amici* participation at the *certiorari* petition stage is an appropriate course to take, *if* and when *certiorari* is granted in this case, at that time there is nothing to lose: To the contrary, at the merits briefing stage the participation of *amici* can be most important. *See* § V-B, *Positive Impact of Participation at the Merits Stage.*

If *certiorari* is denied, the door remains open for a challenge in a case with similar facts at the Patent Trial and Appeal Board in a Post Grant Review. While the negative ruling in *Sequenom* may force the case to go to the Federal Circuit, a panel may well be able to *distinguish* the current case or, if necessary, a party may seek *en banc* review to successfully overturn *Sequenom.* Either option is far better than if the Supreme Court ends up taking and affirming the *Sequenom* case which would then complicate matters.

Some have the thought that the Federal Circuit seems to be a "dead end" for the issues in this case, so, why not take a shot at the Supreme Court? This is a very dangerous attitude, given the fact that the Supreme Court rarely hears a patent case and when it does it is generally against the patentee, particularly in the area of patent-eligibility challenges under 35 USC § 101 (*as seen from the chart which follows on the next page*).

§ 101 Patent-Eligibility *Certiorari* Grants

	Year[1]	Case	Eligible	Ineligible
1	1966	*Brenner v. Manson*, 383 U.S. 519		X
2	1972	*Gottschalk* v. *Benson*, 409 U.S. 63		X
3	1976	*Dann v. Johnston*, 425 U.S. 219[2]		X
4	1978	*Parker* v. *Flook*, 437 U.S. 584		X
5	1980	*Diamond v. Bergy* (*cert. dismissed*)[3]	--	--
6	1980	*Diamond v. Chakrabarty*, 447 U.S. 303	⇧⇧	
7	1981	*Diamond v. Diehr*, 450 U.S. 175	⇧⇧	
8	2001	*J.E.M. Ag Supply v Pioneer*, 534 U.S. 124	⇧⇧	
		2002 – 2009 No Cases Decided		
9	2010	*Bilski v. Kappos*, 561 U.S. 593		X
10	2012	*Mayo v. Prometheus*, 132 S. Ct. 1289		X
11	2013	*Ass'n Mol. Path. v. Myriad*, 133 S. Ct. 2107		X
12	2014	*Alice v. CLS Bank*, 134 S. Ct. 2347		X
	2016	***Sequenom v. Ariosa* (petition due April 1)**		??

[1] Year given is for the merits decision, not the year when the petition was granted.

[2] *Certiorari* was granted for each of two *Questions Presented*, the first concerning patent eligibility and the second concerning Section 103 obviousness. The Court chose to decide the case solely on the second issue.

[3] The decision below, *In re Bergy*, 596 F.2d 952 (CCPA 1979), involved a problematic invention where, upon grant of *certiorari*, the assignee cancelled took appropriate action leading to dismissal to pave the way for the successful outcome in the companion *Chakrabarty* appeal.

II. OPENING UNCHARTED PATENT WATERS TO THE COURT

It will be recalled that beginning with following *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), and *Diamond v. Diehr*, 450 U.S. 175 (1981), and with the exception of *J.E.M. Ag Supply, Inc. v Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124 (2001), there had been nearly three full decades of peace in the patent-eligibility arena, but following *Bilski v. Kappos*, 561 U.S. 593 (2010), there has been a stream of negative rulings denying patent-eligibility in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012)(a method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder); the *Myriad* case, *Ass'n for Molecular Pathology v. Myriad Genetics., Inc.*, 133 S. Ct. 2107 (2013)("[a]n isolated DNA coding for a BRCA1 polypeptide"); and *Alice Corp. v. CLS Bank International*, 134 S. Ct. 2347 (2014)(a computerized scheme for mitigating "settlement risk").

The danger posed by grant of review in *Sequenom* poses potentially great risks for the pharmaceutical industry. Perhaps the gravest danger to unsettle the pharma field would be a review of the law of nonobviousness of pharmaceutical compounds established more than fifty years ago in *In re Papesch*, 315 F.2d 381 (CCPA 1963), but never tested at the Supreme Court. *See In re Dillon*, 919 F.2d 688, 696 (Fed. Cir. 1990)(en banc)(Lourie, J.)(discussing *Papesch*). To be sure, the *Myriad* case at first blush appears to present similar issues, but the question of obviousness of a particular low molecular weight molecule was not at all in issue.

III. THE *FACTS* ESTABLISH A PATENT-ELIGIBLE INVENTION

To be sure, the invention in the *Sequenom* case is surely a meritorious and patentable invention. In particular, it is impossible to say anything other than that the *claimed invention* is unobvious: Imagine, creation of a blood test to determine fetal DNA when the state of the art had required a womb-invasive sampling of fluid within the amniotic sac of the mother. First of all, it is clear that when the invention *as a whole* is considered including the limitations of "all elements", there is no realistic way to conclude any way other than that the invention is patent-eligibile. *See* § III-A, *The Invention "As a Whole" is Patent-Eligible.* Even disregarding this important point, whereas DNA is mentioned in the claims, the DNA is the object of identification and neither claimed nor part of a method of use. *See* § III-B, *Identifying the Presence of Certain DNA.* But, these two points represent the reality of the factual setting of the case, and not the reality of how the case was decided.

A The Invention "As a Whole" *is* Patent-Eligible

First of all, the invention *as a whole* – considering "all elements" of the claimed invention – is clearly novel and nonobvious and, *a fortiori* "inventive." It is against more than a century of Supreme Court case law to dissect a claim to a combination to consider each element as a separate entity.

As explained in *Adams Battery* case, "[w]hile the claims of a patent limit the invention, and specifications cannot be utilized to expand the patent monopoly, *Burns v. Meyer*, 100 U.S. 671, 672 (1880); *McCarty v. Lehigh Valley R. Co*., 160 U.S. 110, 116 (1895), it is fundamental that claims are to be construed in the light of the specifications and both are to be read with a view to ascertaining the invention[.]" Adams Battery case, *United States v. Adams*, 383 U.S. 39, 48-49 (1966)(citing *Seymour v. Osborne*, 78 U.S. (11 Wall.) 516, 547 (1871); *Schriber-Schroth Co. v. Cleveland Trust Co*., 311 U.S. 211, 312 U.S. 654 (1940); *Schering Corp. v. Gilbert*, 153 F.2d 428 (2nd Cir. 1946)).

It has been hornbook patent law since the nineteenth century that a combination invention must be viewed *as claimed* and that by including a specific element in the claim, that specific element is a material part of the combination that cannot be ignored. Whether that element, *in vacuo*, is "conventional", the overriding issue is whether *the invention* – the claimed combination – is or is not obvious. In the context of patent infringement it has been well settled that a combination claim must be viewed as that – an invention to the *combination* – and not from the standpoint of any of the component elements, alone. *Prouty v. Draper*, 41 U.S. (16 Pet.) 335 (1842); *Vance v. Campbell*, 66 U.S. (1 Black) 427, 429 (1861); *Water-Meter Co. v. Desper*, 101 U.S. (11 Otto) 332, 337 (1879); *White v. Dunbar*, 119 U.S. 47 (1886). As explained in these cases in the context of infringement:

Where "[t]he patent is for a combination … [that] is the thing patented. The use of any two of these parts only, or of two combined with a third, which is substantially different, in form, or in the manner of its arrangement and connection with the others, is, therefore, not the thing patented." *Prouty v. Draper*, 41 U.S. (16 Pet.) at 341.

"The combination is an entirety; if one of the elements is given up, the thing claimed disappears." *Vance v. Campbell*, 66 U.S. (1 Black) at 429 (1861).

"[T]he courts of this country cannot always indulge the same latitude which is exercised by English judges in determining what parts of a machine are or are not material. Our law requires the patentee to specify particularly what he claims to be new, and if he claims a combination of certain elements or parts, we cannot declare that any one of these elements is immaterial. The patentee makes them all material by the restricted form of his claim." *Water-Meter v. Desper*, 101 U.S. (11 Otto) at 337.

"The claim is a statutory requirement, prescribed for the very purpose of making the patentee define precisely what his invention is; and it is unjust to the public, as well as an evasion of the law, to construe it in a manner different from the plain import of its terms." *White v. Dunbar*, 119 U.S. at 52.

As explained by the Court in *KSR Int'l Co. v. Teleflex Inc*., 550 U.S. 398 (2007), in the case of a claim to a combination patent, the issue is "to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit. See *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)('[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead,

there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness').""

B. Identifying the Presence of Certain DNA

Secondly, and perhaps more importantly from the standpoint of patent-eligibility, the process claimed to *identify* certain known DNA does not in any way involve a claim to the DNA, *per se*, nor to a method of use of DNA. Rather, the DNA involved in the claimed invention is the *object* of *identification* to determine the presence of certain DNA. The Number One concern of the Supreme Court in considering whether an invention is patent-eligible is whether it does or does not "preempt" research or future use of the DNA. Quite clearly, *known* DNA is the object of the identification test claimed by Sequenom: There is no possible preemption of any use of the DNA based upon the claimed invention.

Just as a "microscope" can be used to identify the makeup of biological samples, the Sequenom invention in the *Ariosa* case provides a method to *identify* certain DNA. The *Ariosa* case has nothing to do with making, using or modifying DNA or creating brand new DNA, but, instead, the *Ariosa* case provides a pioneer genetic test to *identify* the presence or absence of specific, known DNA to see whether a fetus has such DNA, Remarkably, the test involves a blood test can be made based upon a simple blood sample drawn from the pregnant mother's arm – as opposed to the classic, invasive amniocentesis involving invasion of the womb to collect a serum sample.

Sequenom is thus an invention to *identify* DNA contained in amniotic fluid but where the identification can be made without amniocentesis. As a method of identification of material in a sample, the invention in the *Ariosa* case may be analogized to a biotechnology "microscope" to identify the presence or absence of DNA.

The Sequenom invention thus provides a novel pre-natal test to *identify* paternal DNA from a blood test that is based upon blood drawn from a pregnant mother's arm, a breakthrough from the prior art womb-invasive collection of fluid through amniocentesis.

As defined by claim 1, the Sequenom invention involves a test "performed on a maternal serum or plasma sample from a pregnant female" that, for example, is directly drawn from the mother's arm as with any regular blood test, where the \method then involves "amplifyi[cation of] a paternally inherited nucleic acid from the serum or plasma sample" which takes an otherwise too sparse amount of the DNA to be sampled, when is then followed by "detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample."[*]

[*]Claim 1: "A method for detecting a paternally inherited nucleic acid of fetal origin performed on a maternal serum or plasma sample from a pregnant female, which method comprises
amplifying a paternally inherited nucleic acid from the serum or plasma sample and
detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample."

While the factual setting surely should lead to a conclusion of patent-eligibility, the reality is that the case turned on different issues: It is these different issues that form the legal predicate for any argument at the Supreme Court, and why this is a poor choice for a test case to reach the Supreme Court. *See* § IV, *A Unique Decision Departing from Key Facts*

IV. A UNIQUE DECISION DEPARTING FROM KEY FACTS

The Federal Circuit decision focused upon the fact that DNA is named in the claimed invention, without considering the fact that there is no claim to DNA, per se, nor to the use of DNA, nor the fact that the DNA in the process is merely the *object of identification*, and – as *known* DNA is clearly lacking patentability under 35 USC § 102 above and beyond the issue of patent-eligibility.

As to patent-eligibility, the prime concern of the Supreme Court patent-eligibility case law has been that a patent should not "preempt" future research or use of the DNA, but, here, such preemption is not possible. Thus, there was no "use" of DNA claimed, contrary to what is said by members of the court. *Ariosa Diagnostics , Inc. v. Sequenom, Inc.*, __ F.3d __, __ slip op. at 11 (Dec. 2, 2015) (Lourie, J., joined by Moore, J., concurring in den. reh'g en banc)("[T]he claims here are directed to an *actual use* of the natural material of [cell-free fetal DNA]. They recite innovative and practical *uses* for it[.]")(original emphasis), *id.*, slip op. at 11 ("[I]f the concern is preemption of a natural phenomenon, this is, apparently, a novel process and that is what patents are intended to incentivize and be awarded for."); *id.*, slip op. at 14 (Dyk, J., concurring in den. reh'g en banc)(quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1294 (2012), quoting *Parker v. Flook*, 437 U.S. 584, 594 (1978))("The *Mayo* Court found that prior Supreme Court decisions 'insist that a process that focuses upon the *use of a*

natural law also contain other elements or a combination of elements, sometimes referred to as an 'inventive concept,' sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself.'")(emphasis added)

V. WHITHER *AMICI* PARTICIPATION

A. Dangers of Amici Participation at the Petition Stage

To be sure, a *petitioner* at the Supreme Court often clearly needs *amici* support to gain *certiorari*. Conversely, a potential *amicus* who does not want grant of review best plays his cards at the petition stage by standing pat: He should refrain from amicus participation as the more participation there is at this level, the more attention the Court will pay to the particular case, and therefore the greater the chance that four of the members of the Court will vote for review – the magic number for grant of *certiorari.*

To be sure, the *facts* of the Sequenom patent are compelling and cry out for a ruling of patent-eligibility. But, the *legal* ground for denial of patent-eligibility do not reflect an argument keyed to the "all elements" rule and, indeed, the above-quoted remarks of Circuit Judge Dyk show that that the case was viewed as one involving "use of a natural law" whereas, in fact, the claimed invention is merely to *identify* certain DNA.

The dual factors of a failure of the appellate tribunal to understand the *Adams Battery* case and the "all elements" rule, coupled with the misunderstanding that the invention involves the use of the DNA all suggest that there is clear basis for a properly argued case to distinguish *Ariosa v. Sequenom* at the *en banc* level

of the court. Quite clearly, even though *en banc* review is difficult, it is far, far easier to shape the law in this manner than butting heads at the Supreme Court where a patentee has a remarkably low chance of success.

More important from the standpoint of the pharmaceutical industry and potential *amici*, the question must be raised: Which is more important, seeking to play the long odds against a patentee prevailing at the Supreme Court *versus* opening a pandora's box to fresh consideration at the Supreme Court of the *Papesch* line of case law and other pharmaceutical patent issues?

B. Positive Impact of Participation at the Merits Stage

Conversely, at the *merits* stage once *certiorari* has been granted, at *that* point in time, *amicus* participation can be extremely important either from the standpoint of specific legal arguments that may be missed by the petitioner or by explaining the practical significance to a particular industry that will result from the Court's decision.

VI. A FUTURE TEST CASE COMING FROM A POST GRANT REVIEW

Assuming that *certiorari* is denied in *Sequenom*, this would leave the Federal Circuit decision outstanding. It would then be inevitable that a Post Grant Review proceeding will at some point in the near future be taken against a patent with facts similar to the *Ariosa* decision. Here, this represents perhaps the best chance to undo the damage of the *Ariosa* decision. In the first instance, a patent-knowledgeable decision is likely to be rendered by the Patent Trial and Appeal Board and, thereafter, there can be review at the Federal Circuit.

It may well be that the *Ariosa* decision can be distinguished, thereby avoiding the need for *en banc* review.

VII. CONCLUSION

Anyone who expects the Supreme Court to necessarily provide a nuanced approach to patent-eligibility should consider the sobering facts concerning the patent experience available to the Court.

Unlike the Federal Circuit which has several patent attorneys on the bench and where all but the newest members of the court have had a daily diet of patent cases and thus gained expertise on the bench, the Supreme Court has no patent attorney amongst its members nor does any of the members of the court have a long track record of hearing patent cases: Generally, there are only two or three patent cases at the Supreme Court per year. Unlike the Federal Circuit which has a staff of about fifty law clerks, most having a technical degree and patent expertise, none of the roughly forty law clerks at the Supreme Court has *any* patent experience.

While the current posture of the *Sequenom* case is negative, it remains to be seen how the petitioner fashions the *Question Presented* at the Supreme Court. Given that *amici* briefs are filed after the petition is filed, potential *amici* can have an open mind, today, and first await reading the *certiorari* petition to reach a final decision whether to file *amici* briefs in support of the petition.