Sequenom v. Ariosa* (*con'd*): Danger! Beware the *Amici

Responsive to the publication of the original SEQUENOM WHITE PAPER, several colleagues have pointed to uncertainties in the patent law with the idea that *certiorari* should be granted in such cases of uncertainty. Obviously, if that is a person's view of the present case, then *amici* briefing *should* be encouraged to raise the profile of the case and thus enhance the chance for grant of *certiorari.*

The chance of Winning is 27 %: The other side of the coin is the sobering reality that patent applicants and patentees who have had their Section 101 issues heard by the Court on the merits have not always fared too well.

The attached chart shows the outcomes of the twelve Section 101 challenges where, if one excludes the one case where petitioner successfully sought dismissal of his appeal, patent applicants and patentees have won roughly once in every four cases, a 27% win rate.

But, What Happens if the Patentee Loses? To the extent that the patentee *loses* a Supreme Court merits appeal, what happens next? Does a merits loss slam the door shut on yet another area of inventions that are no longer patent-eligible? How does the biotechnology industry break down the slammed shut door?

Also attached is a slightly edited version of the original paper,
A SEQUENOM WHITE PAPER.

Regards,

Hal

§ 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 March 1)**		??

[1] Year given is that of the decision and not the (often) year earlier 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 the claim in controversy leading to dismissal to pave the way for the successful outcome in the companion *Chakrabarty* appeal.

A *SEQUENOM* WHITE PAPER[*]

Harold C. Wegner[**]

---

[*]This paper is authored pro bono and without support from any other person or organization. This version: February 24, 2016. [original version Feb. 23, 2016]

[**]President, The Naples Roundtable, Inc., https://www.thenaplesroundtable.org/. This paper represents the personal views of the author and is neither written for nor endorsed by The Naples Roundtable, Inc.
Correspondence address: hwegner@gmail.com

I. OVERVIEW

March 1st is the deadline for the expected petition for *certiorari* in *Sequenom, Inc. v. Ariosa Diagnostics, Inc*., Supreme Court No. 15A871. To the extent the Supreme Court grants the petition, the Court will 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.*

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*

Give the publicity and importance of the case, should *amici* 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 is the fact that long standing doctrines at the Federal Circuit that have never been tested at the Supreme Court could 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 certiorari* is granted, 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, then the door will become 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 *Ariosa* decision or, if necessary, a patentee may still seek *en banc* review to successfully distinguish or overturn *Sequenom.* Either option is far better than if the Supreme Court ends up granting *certiorari* and affirming the *Sequenom* decision which would then block a Federal Circuit ruling to the contrary.

II. OPENING UNCHARTED PATENT WATERS TO THE COURT

Beginning with *Diamond v. Chakrabarty,* 447 U.S. 303 (1980), and *Diamond v. Diehr*, 450 U.S. 175 (1981), there had been nearly three full decades of peace in the patent-eligibility arena without a single Supreme Court denial of patent-eligibility. (In that period the Court granted *certiorari* but *sustained* patent-eligibility in *J.E.M. Ag Supply, Inc. v Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124 (2001))

But, *Bilski v. Kappos,* 561 U.S. 593 (2010), reopened the interest in patent-eligibility of a new generation of Supreme Court members. This has led to a steady stream of negative rulings: Patent-eligibility has been denied 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 a special risk for the pharmaceutical industry as this would open the door to review of important doctrines 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: The modern law has a genesis more than fifty years ago in *In re Papesch*, 315 F.2d 381 (CCPA 1963). *See In re Dillon*, 919 F.2d 688, 696 (Fed. Cir. 1990)(en banc)(Lourie, J.)(discussing *Papesch*). *Papesch* has never been tested at the Supreme Court. (The closest the Court has come to *Papesch* is the *Myriad*, but the *Papesch* test for nonobviousness was not implicated in *Myriad*.)

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

The invention in the *Sequenom* case permits fetal DNA testing by drawing blood from a pregnant mother's arm, just the same as a regular blood test: The invention is a manifestly meritorious and and patentable contribution versus the prior art method that had required a womb-invasive sampling of fluid within the amniotic sac.

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-eligible. *See* § III-A, *The Invention "As a Whole"*

is Patent-Eligible. Furthermore, whereas DNA is mentioned in the claims, the DNA is the object of identification and neither claimed, *per se*, nor claimed as part of a method of use. *See* § III-B, *Identifying the Presence of Certain DNA.* The two points represent the reality of the factual setting of the case, but not the reality of how the case was considered and decided.

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

The invention *as a whole* – considering "all elements" of the claimed invention – is clearly novel and nonobvious and, *a fortiori* "inventive." To otherwise interpret the claim butts heads with more than a century of Supreme Court case law which proscribes dissection of a claim to a combination to instead 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). These cases explain this point:

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, as an independent point, 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, DNA is the *object* of *identification*, to determine its presence in the sample.

The Number One concern of the Supreme Court in considering whether an invention is patent-eligible is whether the claims do or do not "preempt" research or future use of the DNA. On its face, there is no preemption of the use of DNA in the claim. (And, quite clearly, the DNA is *known* and unpatentable in any event.).

Just as a "microscope" can be used to identify the makeup of biological samples, the invention in *Ariosa* provides a method to *identify* certain DNA. *Ariosa* has nothing to do with making, using or modifying DNA or creating brand new DNA, but, instead, *Ariosa* 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 draws 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 *Ariosa* 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, which is then followed by "detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample."[*]

IV. A UNIQUE DECISION DEPARTING FROM KEY FACTS

The Federal Circuit decision focused upon the presence of DNA within the claims, without sufficiently 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, independently, the DNA is *known* DNA, clearly lacking novelty above and beyond the issue of 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. There was no "use" of DNA claimed, contrary to what is said by members of the court.

---

[*]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."

Two members of the court boldly (and incorrectly) state that "the 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[.]" *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)(original emphasis),

The same members of the court compound their misunderstanding of the case with their reference to preemption: ("[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 11.

Yet another jurist stated that would only be relevant if the DNA (or its use) was claimed: "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.'" *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))(emphasis added)..

V. WHITHER AMICI PARTICIPATION

A. Dangers of Amici Participation at the Petition Stage

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 does not reflect an argument keyed to the "all elements" rule. Circuit Judge Lourie bluntly speaks to the contrary and the remarks of Circuit Judge Dyk show that that the case was viewed as one involving "use of a natural law"

.

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 DNA all suggest that, if this case is permitted to stand, *as is,* without Supreme Court intervention, 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 on a patent-eligibility issue: Indeed, patentees are batting zero in the current *Bilski* era.

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 if and when *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 POST GRANT REVIEW

Assuming that *certiorari* is denied in *Sequenom*, this would leave outstanding the current Federal Circuit decision. It would then be inevitable that a Post Grant Review proceeding will at some point be taken involving a patent with facts similar to *Ariosa*. This may represent 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

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 at the petition stage are filed *after* the petition is filed and can be carefully considered by potential *amici*, such potential *amici* can keep an open mind on a filing decision, today, and first await a study of the *certiorari* petition, and *then* reach a final decision whether to file *amici* briefs in support of the petitioner.

A *SEQUENOM* WHITE PAPER[*]

Harold C. Wegner[**]

---

[*]This paper is authored pro bono and without support from any other person or organization. This version: February 24, 2016. [original version Feb. 23, 2016]

[**]President, The Naples Roundtable, Inc., https://www.thenaplesroundtable.org/. This paper represents the personal views of the author and is neither written for nor endorsed by The Naples Roundtable, Inc.
Correspondence address: hwegner@gmail.com

I. OVERVIEW

March 1st is the deadline for the expected petition for *certiorari* in *Sequenom, Inc. v. Ariosa Diagnostics, Inc*., Supreme Court No. 15A871. To the extent the Supreme Court grants the petition, the Court will 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.*

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*

Give the publicity and importance of the case, should *amici* 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 is the fact that long standing doctrines at the Federal Circuit that have never been tested at the Supreme Court could 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 certiorari* is granted, 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, then the door will become 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 *Ariosa* decision or, if necessary, a patentee may still seek *en banc* review to successfully distinguish or overturn *Sequenom.* Either option is far better than if the Supreme Court ends up granting *certiorari* and affirming the *Sequenom* decision which would then block a Federal Circuit ruling to the contrary.

II. OPENING UNCHARTED PATENT WATERS TO THE COURT

Beginning with *Diamond v. Chakrabarty,* 447 U.S. 303 (1980), and *Diamond v. Diehr*, 450 U.S. 175 (1981), there had been nearly three full decades of peace in the patent-eligibility arena without a single Supreme Court denial of patent-eligibility. (In that period the Court granted *certiorari* but *sustained* patent-eligibility in *J.E.M. Ag Supply, Inc. v Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124 (2001))

But, *Bilski v. Kappos,* 561 U.S. 593 (2010), reopened the interest in patent-eligibility of a new generation of Supreme Court members. This has led to a steady stream of negative rulings: Patent-eligibility has been denied 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 a special risk for the pharmaceutical industry as this would open the door to review of important doctrines 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: The modern law has a genesis more than fifty years ago in *In re Papesch*, 315 F.2d 381 (CCPA 1963). *See In re Dillon*, 919 F.2d 688, 696 (Fed. Cir. 1990)(en banc)(Lourie, J.)(discussing *Papesch*). *Papesch* has never been tested at the Supreme Court. (The closest the Court has come to *Papesch* is the *Myriad*, but the *Papesch* test for nonobviousness was not implicated in *Myriad*.)

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

The invention in the *Sequenom* case permits fetal DNA testing by drawing blood from a pregnant mother's arm, just the same as a regular blood test: The invention is a manifestly meritorious and and patentable contribution versus the prior art method that had required a womb-invasive sampling of fluid within the amniotic sac.

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-eligible. *See* § III-A, *The Invention "As a Whole"*

is Patent-Eligible. Furthermore, whereas DNA is mentioned in the claims, the DNA is the object of identification and neither claimed, *per se*, nor claimed as part of a method of use. *See* § III-B, *Identifying the Presence of Certain DNA.* The two points represent the reality of the factual setting of the case, but not the reality of how the case was considered and decided.

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

The invention *as a whole* – considering "all elements" of the claimed invention – is clearly novel and nonobvious and, *a fortiori* "inventive." To otherwise interpret the claim butts heads with more than a century of Supreme Court case law which proscribes dissection of a claim to a combination to instead 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). These cases explain this point:

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, as an independent point, 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, DNA is the *object* of *identification*, to determine its presence in the sample.

The Number One concern of the Supreme Court in considering whether an invention is patent-eligible is whether the claims do or do not "preempt" research or future use of the DNA. On its face, there is no preemption of the use of DNA in the claim. (And, quite clearly, the DNA is *known* and unpatentable in any event.).

Just as a "microscope" can be used to identify the makeup of biological samples, the invention in *Ariosa* provides a method to *identify* certain DNA. *Ariosa* has nothing to do with making, using or modifying DNA or creating brand new DNA, but, instead, *Ariosa* 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 draws 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 *Ariosa* 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, which is then followed by "detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample."[*]

IV. A UNIQUE DECISION DEPARTING FROM KEY FACTS

The Federal Circuit decision focused upon the presence of DNA within the claims, without sufficiently 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, independently, the DNA is *known* DNA, clearly lacking novelty above and beyond the issue of 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. There was no "use" of DNA claimed, contrary to what is said by members of the court.

---

[*]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."

Two members of the court boldly (and incorrectly) state that "the 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[.]" *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)(original emphasis),

The same members of the court compound their misunderstanding of the case with their reference to preemption: ("[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 11.

Yet another jurist stated that would only be relevant if the DNA (or its use) was claimed: "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.'" *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))(emphasis added)..

V. WHITHER AMICI PARTICIPATION

A. Dangers of Amici Participation at the Petition Stage

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 does not reflect an argument keyed to the "all elements" rule. Circuit Judge Lourie bluntly speaks to the contrary and the remarks of Circuit Judge Dyk show that that the case was viewed as one involving "use of a natural law"

.

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 DNA all suggest that, if this case is permitted to stand, *as is,* without Supreme Court intervention, 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 on a patent-eligibility issue: Indeed, patentees are batting zero in the current *Bilski* era.

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 if and when *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 POST GRANT REVIEW

Assuming that *certiorari* is denied in *Sequenom*, this would leave outstanding the current Federal Circuit decision. It would then be inevitable that a Post Grant Review proceeding will at some point be taken involving a patent with facts similar to *Ariosa*. This may represent 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

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 at the petition stage are filed *after* the petition is filed and can be carefully considered by potential *amici*, such potential *amici* can keep an open mind on a filing decision, today, and first await a study of the *certiorari* petition, and *then* reach a final decision whether to file *amici* briefs in support of the petitioner.