

THE SEQUENOM *CERTIORARI* PETITION: WHITHER PATENT-ELIGIBILITY?*

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I. OVERVIEW

Sequenom, Inc. v. Ariosa Diagnostics, Inc., is the styling of the expected certiorari petition due March 1, 2016, from *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, ___ F.3d ___ (Fed. Cir. Dec. 2, 2015)(Order denying en banc review), *panel proceedings*, 788 F.3d 1371 (Fed. Cir. 2015). Perhaps the most relevant question to ask the Court is as follows:

The Ariosa invention is a pioneer breakthrough diagnostic method that is an undeniably nonobvious method for genetic testing for the presence or absence of certain fetal DNA which permits sampling blood drawn from the mother's arm *versus* the classic method practiced for years of a womb-invasive serum sampling through invasive amniocentesis. The Question Presented is thus:

Where a combination of steps to test for the presence of a particular substance is clearly nonobvious, does the fact that the invention *identifies* the presence or absence of certain DNA disqualify this invention as patent-ineligible under Section 101, any more than a testing method to identify DNA with a "microscope" should be disqualified?

The unique and pioneer invention of *Ariosa* is considered in § II, *Ariosa, a Pioneer Method to Identify DNA*. The *Ariosa* invention is much like the "Adams Battery" invention which must be evaluated for patent-eligibility by looking to "all elements" of the claimed combination. *See* § III, *An "Adams Battery" Invention*.

To be sure, if elements of a claimed invention are dissected from the claim as a whole, patent-eligibility determined on an element by element basis may lead to different results. But, to do so is to violate the long-standing Supreme Court "all elements" rule. *See* § IV, *Mayo versus the "All Elements" Rule*.

II. *ARIOSIA*, A PIONEER METHOD TO IDENTIFY DNA

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 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.

Ariosa 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 *Ariosa* 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 *Ariosa* 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.”*

Ariosa thus has nothing to do with “DNA” in terms of a discovery as to making, using or modifying any DNA nor any “abstract” software idea from the recent body of case law dealing with Section 101 issues. The cases are *Bilski v. Kappos*, 561 U. S. 593 (2010)(software driven hedge risk method); *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").

*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.”

III. AN “ADAMS BATTERY” INVENTION

The *Ariosa* invention is a *combination* invention, including all of its elements in the combination of the claim that is to be evaluated for patent-eligibility and nonobviousness: The claim is not to be dissected element by element.

As explained in the *Adams Battery* case, “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[.]” *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)).

As explained in the *Adams Battery* case:

“While 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, *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).”

Adams Battery case, *United States v. Adams*, 383 U.S. 39, 48-49 (1966).

Looking to the claimed invention *as a whole* including all its features is axiomatic from the case law in the field of chemistry and biotechnology. *See In re Dillon*, 919 F.2d 688, 701 (Fed. Cir. 1990)(en banc)(Newman, J., joined by Cowen, Mayer, JJ., dissenting) (“[P]ertinent considerations in determination of whether a prima facie case [of obviousness] is made include the closeness of the prior art subject matter to the field of the invention, the motivation or suggestion in the prior art to combine the reference teachings, the problem that the inventor was trying to solve, the nature of the inventor's improvement as compared with the prior art, and a variety of other criteria as may arise in a particular case; *all with respect to the invention as a whole*, and decided from the viewpoint of a person of ordinary skill in the field of the invention.”)(emphasis added).

Thus, determination of obviousness [is made] by comparing the structures and properties taught in the prior art with those disclosed by the applicant, and bringing judgment to bear on ‘the subject matter as a whole.’” *Id.*, 919 F.2d at 705(quoting *In re de Montmollin*, 344 F.2d 976, 979 (CCPA 1965))

It is axiomatic that the patentability of a *claim* to a *combination* of elements must be judged in terms of the *claimed combination* including all of its elements and – particularly – the determination whether there is *motivation* to combine the several elements in the manner *stated in the claim*. 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 this line of case law 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.

Wegner, *The Sequenom Certiorari Petition*

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').” As explained in *Kahn*:

Most inventions arise from a combination of old elements and each element may often be found in the prior art. [*In re Rouffet*, 149 F.3d 1350, 1357 (Fed.Cir. 1998)]. However, mere identification in the prior art of each element is insufficient to defeat the patentability of the combined subject matter as a whole. *Id.* at 1355, 1357. Rather, to establish a prima facie case of obviousness based on a combination of elements disclosed in the prior art, the Board must articulate the basis on which it concludes that it would have been obvious to make the claimed invention. *Id.* In practice, this requires that the Board ‘explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious.’ *Id.* at 1357-59.

In re Kahn, 441 F.3d 977, 984 (Fed. Cir. 2006)(Linn, J.).

The importance of looking to the *claim* as the definition of the invention was stressed in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005)(en banc). As explained by Circuit Judge Bryson:

“Because the patentee is required to ‘define precisely what his invention is,’ the Court explained, 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. 47, 52(1886); *see also Cont’l Paper Bag Co. v. E. Paper Bag Co.*, 210 U.S. 405, 419 (1908) (‘the claims measure the invention’); *McCarty v. Lehigh Valley R.R. Co.*, 160 U.S. 110, 116 (1895) (‘if we once begin to include elements not mentioned in the claim, in order to limit such claim ..., we should never know where to stop’); *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 339 (1961) (‘the claims made in the patent are the sole measure of the grant’).”

Phillips v. AWH, 415 F.3d at 1312.

IV. MAYO VERSUS THE “ALL ELEMENTS” RULE

Taking *dicta* from *Mayo*, *in vacuo*, leads to an unnecessary conflict within the case law of the Supreme Court that has uniformly required consideration of the invention as a whole, “all elements” of the claimed invention in their combination defined by the patentee. In the context of patent infringement, the cases repeatedly spoke of the judicial requirement to construe the subject matter under the “all elements” rule. There is a rich history of precedent more from more than one hundred years ago that established the rule that was established by Justice Story. *See Barrett v. Hall*, 2 F.Cas. 914, 924 (No. 1047)(D. Mass. 1818)(Story, J., riding circuit)(“the patent [is] for the combination only[;] it is no infringement of the patent to use any of the machines separately, if the whole combination be not used; for in such a case the thing patented is not the separate machines, but the combination; and the statute gives no remedy, except for a violation of the thing patented.”); *see also Prouty v. Draper*, 20 F.Cas. 11, 12 (No. 11,446) (D. Mass. 1841)(Story, J.; riding circuit), *aff’d*, 41 U.S. (16 Pet.) 336 (1842)(Taney, C.J.)(“

“The plaintiffs' patent is for an entire combination of all the three things, and not for a combination of any two of them. A patent for a combination of A, B and C, cannot be technically or legally deemed at once a combination of A, B and C, and of A and B alone.”); *Eames v. Godfrey*, 68 U.S. (1 Wall.) 78, 79 (1864)(“[T]here is no infringement of a patent which claims mechanical powers in combination unless all the parts have been substantially used. The use of a part less than the whole is no infringement.”); *Water-Meter Co. v. Desper*, 101 U.S. (11 Otto) 332, 335-37 (1879)(“It is a well-known doctrine of patent law, that the claim of a combination is not infringed if any of the material parts of the combination are omitted. ***”).

The quoted cases are merely illustrative of the many “all elements” cases from the nineteenth century that include, *inter alia*, *Vance v. Campbell*, 66 U.S. (1 Black) 427, 429 (1861); *Eames v. Godfrey*, 68 U.S. (1 Wall.) 78, 79 (1864); *Gould v. Rees*, 82 U.S. (15 Wall.) 187 (1872); *Dunbar v. Myers*, 94 U.S. (4 Otto) 187, 202 (1876); *Water-Meter Co. v. Desper*, 101 U.S. (11 Otto) 332, 335-37 (1879); *Case v. Brown*, 69 U.S. (2 Wall.) 320, 327-28 (1864); *Gill v. Wells*, 89 U.S. (22 Wall.) 1, 26-30 (1874); *Fuller v. Yentzer*, 94 U.S. (4 Otto) 288, 297 (1876); *Gage v. Herring*, 107 U.S. (17 Otto) 640, 648 (1882); *Fay v. Cordesman*, 109 U.S. 408, 420-21 (1883); *Rowell v. Lindsay*, 113 U.S. 97, 102 (1885); *Sargent v. Hall Safe & Lock Co.*, 114 U.S. 63, 86 (1885); *Brown v. Davis*, 116 U.S. 237, 252 (1886); *Yale Lock Mfg. Co. v. Sargent*, 117 U.S. 373, 378 (1886); *McClain v. Ortmyer*, 141 U.S. 419, 425 (1891); *Wright v. Yuengling*, 155 U.S. 47, 52(1894); *Black Diamond Coal Mining Co. v. Excelsior Coal Co.*, 156 U.S. 611, 617-18 (1895); *Cimiotti Unhairing Co. v. American Fur Ref. Co.*, 198 U.S. 399, 410 (1905)).

The long line of case law concerning the “all elements” rule that is denied in *Parker v. Flook*, 437 U.S. 584 (1978), an aberrational decision that was soon distinguished by the Court in *Diamond v. Diehr*, 450 U.S. 175 (1981). To the extent that *Flook* stands for the proposition that one may dissect a claim into its constituent elements to determine patent-eligibility based upon the patent-eligibility of one of the components, *Flook* was cabined by *Diamond v. Diehr*, 450 U.S. 175 (1981).

In *Diehr* the Court expressly stated that “[i]n determining the eligibility of [the patent applicants’] claimed process for patent protection under § 101, their *claims must be considered as a whole*. It is inappropriate 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.

V. CONCLUSION

Whether the Supreme Court grants *certiorari* remains to be seen. If it does, the Court will have the chance to restore a measure of balance to the law of patent-eligibility under Section 101.