MYRIAD TURNS THE 1952 PATENT ACT ON ITS HEAD[*]

Harold C. Wegner[**]

I. OVERVIEW

In the *Myriad* case, *Association for Molecular Pathology v. U.S. Patent and Trademark Office*, __ F.3d __ , 2011 WL 3211513 (Fed. Cir. 2011)(Lourie, J.), the panel upheld the patent-eligibility under 35 USC § 101 of composition of matter claims to DNA under reasoning that conflates § 101 patent-*eligibility* with *patentability* under 35 USC § 103. The great achievement of the 1952 Patent Act was the *creation* of a split statutory scheme that separated patent-eligibility from the new patentability standard of Section 103: The panel conflated the statutory requirements, reintroducing an uncertainty to the patent law that had seemingly been obviated by the 1952 Patent Act.

The panel treated its subject matter seemingly without regard to a rich thicket of binding case law from the Supreme Court, the Federal Circuit and the earlier Court of Customs and Patent Appeals. In particular, the panel repudiated the binding precedent authored by the late Giles Sutherland Rich in *In re Bergy*, 596 F.2d 952 (CCPA 1979). Apart from his efforts in creating the statutory test for nonobviousness under 35 USC § 103 as part of the 1952 Patent Act, *Bergy* is

---

[*] This paper represents the personal views of the writer and does not necessarily reflect the views of any colleague, organization or client thereof. The writer acknowledges participation for an *amicus* party involved in this case as listed in the opinion of the Court. VERSION 6 August 1, 2011.

[**]Former Director of the Intellectual Property Law Program and Professor of Law, George Washington University Law School; partner, Foley & Lardner LLP

hwegner@foley.com

perhaps Judge Rich's single most important contribution, overturning the tide of anti-patent rulings on patent-eligibility under 35 USC § 101 in *Brenner v. Manson*, 383 U.S. 519 (1966), *Gottschalk v. Benson*, 409 U.S. 63 (1972), and *Parker v. Flook*, 437 U.S. 584 (1978). *Bergy* paved the way for an affirmance and broad interpretation of § 101 in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), and opened the door to software-patent eligibility in *Diamond v. Diehr*, 450 U.S. 175 (1981).

Significantly, *Myriad* was an appeal of the district court's grant of patent invalidity under 35 USC § 101. As pointed out in a concurring opinion, however, "DNA is a chemical polymer. In principle, a polymeric DNA sequence is no different than any other well known polymer, for example, nylon." *Myriad*, __ F.3d at __ (Moore, J., concurring). That being the case, and had the court followed the *Bergy* analysis, the summary judgment of invalidity under 35 USC § 101 should have been simply *reversed* and the case remanded to determine whether the patent-eligible chemical compounds – the DNA claimed by *Myriad* – represent *patentable* subject matter as to novelty under 35 USC § 102 and nonobviousness under 35 USC § 103.

Since the initial District Court filing in this case, it has been the apparent intention of the plaintiffs to take their crusade against patenting DNA to the Supreme Court. Whatever merits interest the Court may have in granted *certiorari* is now blunted by the fact that as of the date of the *Myriad* opinion, there is serious doubt that any of the plaintiffs have continued standing to challenge validity. This could very well result in the dismissal of this case under the mootness doctrine. *See* § II, *Supreme Court Review Thwarted by Mootness?*

As to the merits of the case, what is most striking is a flagrant disrespect for binding precedent. Apart from a footnote, nowhere in the entire 108 pages of the combined slip opinions in *Myriad* does the court even *mention* the *Bergy* opinion. Instead, buried in footnote 7 of the majority opinion is the statement "that *Bergy* is no longer binding law" . This statement is made on the basis of a clear misunderstanding of the facts. *See* § III, *Failure to Follow Binding Precedent.*

The court on the merits *sustained* the patent-eligibility of all of the composition claims, some only by a majority vote. *See* § IV, *Compositions: Patent-Eligibility versus Patentability.* As part of the attraction for the Supreme Court in its possible review of this case, the majority parted company with the late Giles Sutherland Rich and his analysis of patent-eligibility in *Bergy.* Indeed, the analytical methods used by the majority in *Myriad* and by Judge Rich in *Bergy* are incompatible. The majority attempts to dismiss this problem by saying that the opinion in *Bergy* is not binding. *See* § IV-A, *The Manifest Conflict between Bergy and Myriad.*

One of the major points where the opinion should draw scholarly interest is the view that *Funk Bros. Seed Co. v. Kalo Innoculant Co.*, 333 U.S. 127 (1948), deals with patent-eligibility under 35 USC § 101, whereas in reality this pre-1952 Patent Act dealt with what is today obviousness under 35 USC § 103 but at the time was viewed as a question of "patentable invention". *See* § IV-B, *Misinterpreting Funk v. Kalo.*

That the proper statutory home for a case by case determination of patentability is better housed under 35 USC § 103 nonobviousness as opposed to a blanket rule of patent-eligibility under 35 USC § 101 is perhaps best illustrated in *Myriad* by the three way split amongst the panel members as to how and why various new DNA fragments are or are not patent-eligible. Some were unanimously held to be patent-eligible while a split existed on others, even though each represented a new chemical molecule, much like "nylon". *See* § IV-D, *DNA Patentability: "No Different than ... Nylon"*.

The problems with conflating patent-eligibility and patentability sections of the law are graphically seen from the attempt in *Myriad* to distinguish "isolated" from "purified" products on the basis of patent-eligibility. Focusing on *how* a product is made as opposed to whether that product is a "composition of matter" is reminiscent of the Supreme Court aberration in *Cuno Engineering t*hat denied patents to inventions made by routine experimentation in favor of those manifesting a "flash of creative genius". *Cuno Engineering Corp. v. Automatic Devices Corp*., 314 U.S. 84, 91 (1941). *See* § IV-D, *Turning the Clock Back 70 Years to Cuno Engineering*.

Several steps remain open for both parties along the road to the Supreme Court. *See* § V, *On the Road to the Supreme Court.*

The *Myriad* opinion also deals with claims to *methods* which are outside the scope of this paper.

II. SUPREME COURT REVIEW THWARTED BY MOOTNESS?

While it has been the apparent intention of the ACLU plaintiffs to take their anti-patenting crusade to the Supreme Court, the road to *certiorari* may be tripped over a *MedImmune* stumbling block:

The *Myriad* case should never have reached the merits because of a lack of standing under *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007). In the *Myriad* opinion, the court holds that one of the many plaintiff's does have standing because in his declaration he alleged that he would "*immediately begin* … testing" if the Myriad patents were held invalid.

The Court concluded that there was standing for Dr. Harry Ostrer of New York University because of his "*actual*[ ] *and immediate*[ ]" intention to practice the invention if the patents were held invalid. Thus, Dr. Harry Ostrer "clearly alleges a sufficiently real and imminent injury because he alleges *an intention to actually and immediately* engage in allegedly infringing BRCA-related activities." (emphasis added) Thus, "Dr. Ostrer has … alleged a controversy of sufficient reality and immediacy, *MedImmune*, 549 U.S. at 127…. Ostrer not only has the resources and expertise to immediately undertake clinical BRCA testing, but also *states unequivocally that he will immediately begin such testing.*" *Myriad*, __ F.3d at __ (emphasis added)

But, unknown to the court when it issued its opinion was the fact that this plaintiff is in the process of changing employment: In a letter filed with the court the very day of the opinion, the plaintiff retreated from his position that he would "immediately begin… testing" and instead his counsel has characterized his client's current view that he "*wishes* to do so". This is an at best speculative position that hardly meets the standard of immediacy under *MedImmune.*

B. "Mootness Doctrine" Dismissal of any Appeal

To the extent that there is only a speculative "wish[ ]" to practice the invention, under this changed circumstance the case could be dismissed under the mootness doctrine. As explained by Leandra Lederman:

> Mootness doctrine requires a continuing interest in resolution of the lawsuit in order for the court to decide the case. … The Supreme Court has stated that a case is moot when either there is no longer a 'live' controversy or the 'parties lack a legally cognizable interest in the outcome.' [*United States Parole Comm'n. v. Geraghty*, 445 U.S. 388, 396 (1980)] (quoting *Powell v. McCormack*, 395 U.S. 486, 496 (1969)).... If a judgment has become moot [while awaiting review], this Court may not consider its merits, but may make such disposition of the whole case as justice may require.') (quoting *Walling v. James V. Reuter, Inc.*, 321 U.S. 671, 677 (1944)); *Lake Coal Co. v. Roberts & Schaefer Co.*, 474 U.S. 120 (1985)….

Leandra Lederman, *Precedent Lost: Why Encourage Settlement, and Why Permit Non-Party Involvement in Settlements?*, 75 Notre Dame L. Rev. 221, 237 n.93 (1999).

III. FAILURE TO FOLLOW BINDING PRECEDENT

The shocking failure to follow *Bergy* represents a fundamental flaw of *Myriad*. How does the panel distinguish *Bergy?*

It doesn't.

Rather, it begins footnote 7 with the incorrect statement that "[w]e note that *Bergy* is no longer binding law."

A. The Supreme Court has Adopted the Bergy Methodology

Even if it were true that *Bergy* "is no longer binding law" (which is not the case), the critical analytical test of *Bergy* has been adopted by the Supreme Court, so it would not matter if a Federal Circuit case saying the same thing is or is not precedential.

Thus, the Supreme Court in *Diamond v. Diehr* followed the analytical framework of *Bergy* which it *quoted*. *See Diamond v. Diehr,* 450 U.S. 175, 189–90 (1981)(quoting *Bergy*, 596 F.2d at 961):

> Section 101, however, is a general statement of the type of subject matter that is eligible for patent protection 'subject to the conditions and requirements of this title.' Specific conditions for patentability follow and § 102 covers in detail the conditions relating to novelty. The question therefore of whether a particular invention is novel is 'wholly apart from whether the invention falls in a category of statutory subject matter.

Even assuming, *arguendo,* that the *Bergy* case itself were not binding precedent (which is not the situation), the Federal Circuit has repeatedly cited and adopted *Bergy* as precedent. It has adopted the *Bergy* analytical framework *in toto* for distinguishing patent *eligibility* and patent*ability* through a detailed quotation of

Bergy in *State Street Bank & Trust Co. v. Signature Financial Group,* 149 F.3d 1368 (1998).

There, the court quoted the *Bergy* analytical framework:

"The first door which must be opened on the difficult path to patentability is § 101 .... The person approaching that door is an inventor, whether his invention is patentable or not .... Being an inventor or having an invention, however, is no guarantee of opening even the first door. What kind of an invention or discovery is it? In dealing with the question of kind, as distinguished from the qualitative conditions which make the invention patentable, § 101 is broad and general; its language is: 'any * * * process, machine, manufacture, or composition of matter, or any * * * improvement thereof.' Section 100(b) further expands 'process' to include 'art or method, and * * * a new use of a known process, machine, manufacture, composition of matter, or material.' If the invention, as the inventor defines it in his claims (pursuant to § 112, second paragraph), falls into any one of the named categories, he is allowed to pass through to the second door, which is § 102; 'novelty and loss of right to patent' is the sign on it. Notwithstanding the words 'new and useful' in § 101, the invention is not examined under that statute for novelty because that is not the statutory scheme of things or the long-established administrative practice."
State Street Bank, 149 F.3d at 1372 n.2 (quoting *Bergy,* 596 F.2d at 960).

B. The Federal Circuit Cites *Bergy* as Precedent

Beyond *State Street Bank, Bergy* continues to be cited as binding precedent by this court. *See e.g., Constant v. Advanced Micro-Devices, Inc.,* 848 F.2d 1560, 1564 n.4 (Fed. Cir. 1988)(citing "*In re Bergy*, 596 F.2d 952, 958 (CCPA 1979), *aff'd sub nom. Diamond v. Chakrabarty,* 447 U.S. 303 (1980)."); *In re Nielson,* 816 F.2d 1567, 1571 (Fed. Cir. 1987)("*In re Bergy,* 596 F.2d 952, 972 (CCPA 1979), *aff'd on other grounds, sub nom. Diamond v. Chakrabarty*, 447 U.S. 303 (1980)"); In re Comiskey, 554 F.3d 967, 973 (Fed. Cir. 2009)("*State St. Bank & Trust Co. v. Signature Fin. Group, Inc.,* 149 F.3d 1368, 1372 n. 2 (Fed.Cir.1998)(quoting *In re Bergy,* 596 F.2d 952, 960 (CCPA 1979))" *SmithKline Beecham Corp. v. Apotex*

Corp., 403 F.3d 1331, 1362 (Fed. Cir. 2005)(Gajarsa, J., concurring)("*In re Bergy*, 596 F.2d 952 (CCPA 1979), *rev'd [sic] sub nom Diamond v. Chakrabarty*, 447 U.S. 303 (1980)").

C. The *Bergy* Opinion is Binding Precedent

The majority opinion justifies its position that *"Bergy* is no longer binding law" by stating in footnote 7 that "*Bergy* was the companion case to *Charkarbarty*, and was vacated by the Supreme Court and remanded for dismissal as moot. *Diamond v. Chakrabarty*, 444 U.S. 1028 (1980)."

But, the *opinion* in *In re Bergy* was *also* the opinion in *In re Chakrabraty* for *both* the *Bergy* invention *and* the *Chakrabarty* invention which were part of the consolidated opinion, *In re Bergy*. The *opinion* remains as viable precedent as far from being dismissed by the Supreme Court, the appellate court decision in *Chakrabarty* was affirmed.

This was fully explained by the Supreme Court itself in its *Chakrabarty* opinion. After noting the procedural history of the Chakrabarty case where the original *In re Chakrabarty* opinion was vacated and the case returned to the appellate court, then "[t]he Court of Customs and Patent Appeals then vacated its judgment in Chakrabarty and *consolidated the case with Bergy for reconsideration*. …[T]hat court… reaffirmed its earlier judgments. 596 F.2d 952 (1979). The Commissioner of Patents and Trademarks again sought certiorari, and we granted the writ as to both Bergy and Chakrabarty. 444 U.S. 924 (1979). Since then, Bergy has been dismissed as moot, 444 U.S. 1028 (1980), leaving only Chakrabarty for decision." *Diamond v. Chakrabarty*, 447 U.S. at 306-07 (emphasis added).

Thus, the opinion "In re Bergy" was a consolidated opinion for the appeals of *both* Malcolm Bergy *and* Dr. Chakrabarty, so the dismissal of one of the appeals (Bergy's) did not change the status of *In re Bergy* as binding precedent.

IV. COMPOSITIONS: PATENT-ELIGIBILITY V. PATENTABILITY

A. The Binding *Bergy* Analysis

As seen from Judge Moore's previously quoted analysis, *any* chemical compound is by definition a "composition of matter", whether a "small molecule" or a larger polymer. The majority opinion fails to appreciate the basic approach of *Bergy*, which distinguishes between whether a product is *patent-eligible* under 35 USC § 101 and whether a patent-*eligible* product is also *patentable* because it is novel, 35 USC § 102, and nonobvious, 35 USC §103.

Following the reasoning of *Bergy* it must be concluded that all the composition claims in the *Myriad* case are patent-eligible under 35 USC § 101; it is a different question whether the claims relate to patentable subject matter under 35 USC §§ 102, 103.

B. Misinterpreting *Funk v. Kalo*

1. *Funk v. Kalo* was an "Obviousness" Case

The fundamental misunderstanding of *Bergy* is compounded by a lack of understanding of *Funk Bros. Seed Co. v. Kalo Innoculant Co.,* 333 U.S. 127 (1948). *Funk v. Kalo* is an *obviousness* case under what is today 35 USC § 103 and not a patent-eligibility case under what is today 35 USC § 101. This fundamental misunderstanding is underscored by the opening discussion of the case law:

"The Supreme Court's decisions in *Chakrabarty* and *Funk* [*v. Kalo*] set out the framework for deciding the patent eligibility of isolated DNA molecules." (footnote omitted).

In the omitted footnote, the majority suggests that *Funk v. Kalo* was decided on the basis of patent-eligibility under what is today 35 USC § 101. __ F.3d at __ n.6 ("Other Supreme Court decisions cited by the parties and amici were decided based on lack of novelty, *not patentable subject matter*.")(emphasis added).

Yet, it is clear that *Funk v. Kalo* was decided on the basis of lack of *patentable invention* prior to the statutory codification of patentable invention case law as the law of nonobviousness under 35 USC § 103. Thus, the *Funk v. Kalo* invention was clearly directed to a "composition of matter" under the *Bergy* analysis, but failed the nonobviousness test, in the rubric of the times, one of "patentable invention".

2. Why *Dictum* on *Funk v. Kalo* was included in *Chakrabarty*

A cardinal mistake of the majority opinion was its failure to distinguish between the *holding* of the *Chakrabarty* opinion which *affirmed* the *Bergy* opinion conclusion that the Chakrabarty invention is patent-eligible from the *dictum* in *Chakrabarty* that distinguished *Funk v. Kalo*. In particular, the majority, citing *Chakrabarty,* 447 U.S. at 310, states that "[t]he *Chakrabarty* Court … concluded that what distinguished Chakrabarty's bacteria from those claimed in *Funk* [*v. Kalo*], and made the former patent eligible, was that Chakrabarty's bacteria had 'markedly different characteristics from any [bacterium] found in nature' based on the efforts of the patentee."

A contemporaneous view of *Chakrabarty* explains why this *Funk v. Kalo dictum* was included in the opinion: It was obvious that without such statements the fifth vote for a one vote majority in favor of reversal required concessionary language borrowed from the majority opinion in *Parker v. Flook* that transformed what would have been a 5-4 reversal in *Chakrabarty* into the 5-4 affirmance of the *Bergy* opinion.

D. DNA Patentability: "No Different than … Nylon"

"DNA is a chemical polymer. In principle, a polymeric DNA sequence is no different than any other well known polymer, for example, nylon. Like any polymer, DNA is made up of repeating monomer units, connected by chemical bonds to form one larger molecule."

Myriad, __ F.3d at __ (Moore, J., concurring)

The Court split three ways as to whether various forms of DNA are patentable or not, each authoring separate opinions on this point. The Court unanimously held that c-DNA represents patent-eligible subject matter while one member of the Court dissented on the patent-eligibility of novel isolated DNA fragments.

1. New Molecules: Fragments of Native DNA

The isolated DNA fragments are distinct molecular species which, however, one member of the Court says is insufficient to establish patentability.

Indeed, patenting DNA *is* like patenting a new form of "nylon". A three way split developed in *Myriad* with each member of the panel writing separately as to patent-*eligibility* of various DNA forms. The panel unanimously held c-DNA forms to be patent-eligible, while isolated and purified forms led to a split with one member finding the scope of the structural changes insufficient to avoid a finding that they were, in effect, obvious. Assuming, *arguendo*, that the changes *are* generally insufficient to avoid a conclusion of unpatentability, a hard and fast rule of unpatentability is reminiscent of the Patent Office view of "structural obviousness" that barred patentability of a new chemical compound where it had a close structural relationship to the prior art. A black and white rule of "structural obviousness" developed that barred patenting "structurally obvious" compounds even when they had an entirely different or far superior practical utility.

An isolated DNA molecule has different chemical bonds as compared to the 'unisolated' sequence in the chromosome (the ends are different). … Creating the claimed isolated DNA sequences therefore results in a distinctly unnatural molecule. Even the dissent agrees that the isolated DNA molecules at issue require cleaving chemical bonds, though it disputes the importance of the resulting distinct "'molecular species.'"
Myriad, __ F.3d at __ (Moore, J., concurring)(footnote omitted).

Yet, the dissent argues for what amounts to a per se rule of unpatentability for such fragments on the basis of their close structural relationship to native DNA:

The majority characterizes the question in this case as turning on the breaking of covalent bonds linking the BRCA genes to the rest of the DNA in chromosomes 13 and 17, but its analysis appears to place patentable weight on the breaking of other chemical bonds, such as the hydrogen bonds that are broken when separating DNA from histones or …the ionic bonds that are broken when lithium is derived from a salt. *It is difficult to see why differences between types of chemical bonds should matter for patentability purposes, and I see little support for such a distinction in the governing precedents.*
Myriad, __ F.3d at __ n.3 (Bryson, J., dissenting in part)(emphasis added).

Indeed, for the great majority of cases, differences between types of chemical bonds should not matter for patentability purposes. The black and white proposed exclusion of a class of what may be considered "structurally obvious" compounds under the label of patent-eligibility under 35 USC § 101 is reminiscent of the black and white structural obviousness rules in organic chemistry more than forty years ago that barred claims to new chemical compounds which had a "structurally obvious" variation vis a vis the prior art compound.

Yet, for DNA fragments, here, as with chemical compounds more than forty years ago, there will be unexpected differences that come up from time to time that should break the general rule and which should be basis for patentability. In 1963

in the historic *Papesch* case, the "structural obviousness" ban on patenting closely related compounds based upon structural similarity was overturned:

> From the standpoint of patent law, a compound and all of its properties are inseparable; they are one and the same thing. The graphic formulae, the chemical nomenclature, the systems of classification and study such as the concepts of homology, isomerism, etc., are mere symbols by which compounds can be identified, classified, and compared. *But a formula is not a compound and while it may serve in a claim to identify what is being patented, as the metes and bounds of a deed identify a plot of land, the thing that is patented is not the formula but the compound identified by it. And the patentability of the thing does not depend on the similarity of its formula to that of another compound but of the similarity of the former compound to the latter. There is no basis in law for ignoring any property in making such a comparison.* An assumed similarity based on a comparison of formulae must give way to evidence that the assumption is erroneous.

In re Papesch, 315 F.2d 381, 391 (CCPA 1963)(Rich, J.)(emphasis added). Unexpected results continue to play an outcome-determinative role in the patentability of new compounds. *See Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350 (Fed. Cir. 2011).

2. *Per Se* Rule against Patenting Elements

Generalizations in *Myriad* are not limited to structural obviousness issues relating to new compounds. The dissent explores the patenting of an element, per se, and uses the example of the element, lithium:

"Once isolated, lithium has many industrial applications, and in order to isolate lithium, it is necessary to break ionic bonds in the lithium compounds that are found in nature. But the majority acknowledges that elemental lithium (like other elements) would not be patentable subject matter because it 'is the same element whether it is in the earth or isolated.'"

Myriad, __ F.3d at __ (Bryson, J., dissenting in part).

To be sure, lithium is not *patentable* because it lacks *novelty* but it surely *is* a "composition of matter" under the *Bergy* analysis and hence patent-*eligible* under 35 USC § 101. It is furthermore an unsafe generalization to say that an element, per se, is unpatentable. Thus, in the *Seaborg* case claim 1 reads "1. Element 95." Yet, even though Dr. Seaborg's invention was an element, it was patentable. *In re Seaborg*, 328 F.2d 996 (CCPA 1964).

3. Case by Case Patentability, not Patent-Eligibility

In the end, all compounds are like "nylon", they are all "compositions of matter" under 35 USC § 101. Whether they are sufficiently different from the prior art or have unexpected properties to render them patentable is really a question to be decided on a case by case basis under standards of nonobviousness under 35 USC § 103, and not a conflated analysis to create a hard and fast pigeonhole of what is patentable and what is not under patent-eligibilty rules under 35 USC § 101.

E.. Turning the Clock Back 70 Years to *Cuno Engineering*

A claim to a variety of "nylon" (or any chemical or biochemical molecule) has one common feature under 35 USC § 101: It is a patent-*eligible* "composition of matter", which is the case whether new or old, whether "isolated" or "purified" or whether prima facie obvious but patentable under *Papesch.* It is a different question whether any patent-*eligible* "composition of matter" is *also patentable* as novel under 35 USC § 102 and nonobvious under 35 USC § 103.

The attempted distinction in *Myriad* between "isolated" and "purified" products under 35 USC § 101 perhaps best illustrates the confusion created by conflating patentability considerations with patent-eligibility. Professor Chris Holman has pointed out this unfortunate aspect of *Myriad.* Professor Chris Holman, *AMP v. PTO Casts doubt on Patent Eligibility of "Purified" (as Opposed to "Isolated") Biomolecules,* Holman's Biotech Blog, (August 1, 2011), http://holmansbiotechipblog.blogspot.com/2011/08/amp-v-pto-casts-doubt-on-patent.html. Thus, *Myriad* states that "isolated DNA is not purified DNA. Purification makes pure what was the same material, but was previously impure. [Isolated DNA] has … been manipulated chemically so as to produce a molecule that is markedly different from that which exists in the body. It has not been purified by being isolated." *Myriad,* __ F.3d at __.

But, patent-eligibility shouldn't turn on whether a product is "purified" or "isolated": What happens, for example, if the identical product is produced by two different inventors, one who "isolated" the product and another who "purified" a substance to create the identical product?

How a product is obtained should not be of primary concern to patent-eligibility of a new product. Seventy years ago, the Court thought otherwise when it dismissed inventions other than if made through a "flash of creative genius." *Cuno Engineering,* 314 U.S. at 91. . Order to the patent world was restored a decade later through the 1952 Patent Act that overruled *Cuno Engineering,* while *Myriad* includes a movement back to consideration of *how* the invention was made, reminiscent of *Cuno Engineering.*

1. Patentability is not "Negatived" by the Way the Invention is Made

For a claim to a new product which is a pharmaceutical or other chemical or biochemical entity, both patent-eligibility under 35 USC §101 and the nonobviousness test for patentability under 35 USC § 103 should focus upon the *product, per se,* and not as to how or why it was made, whether through toil and experimentation or a flash of genius, blind luck or otherwise

The patentability focus for product claims should be on the product, per se, and not on *how* the invention was made. *Cuno Engineering* was overruled as part of the 1952 Patent Act through the second sentence of 35 USC § 103.

As pointed out by the late Learned Hand, under this new statutory provision, "patentability … is not to be negatived by the manner in which the invention was made, that is, it is immaterial whether it resulted from long toil and experimentation or from a flash of genius." *Lyon v. Bausch & Lomb Optical Co.,* 224 F.2d 530, 536 n. 9 (2nd Cir. 1955)(L. Hand, J.).

As explained in *Graham v. Deere,* this means that "it is immaterial whether [the invention] resulted from long toil and experimentation or from a flash of genius." *Graham v. John Deere & Co.,* 383 U.S. 1, 16 n.8 (1966)(quoting

Reviser's Note to 35 USC § 103). Thus, "the path that leads an inventor to the invention is expressly made irrelevant to patentability by statute." *Life Techs., Inc. v. Clontech Labs., Inc.*, 224 F.3d 1320, 1325 (Fed.Cir.2000). "The discovery may be by design, by accident, by a vision in a dream, by a sudden flash of genius, or by any other conceivable means. 'Patentability shall not be negatived by the manner in which the invention was made.' 35 USC § 103." .*Oscar Mayer Foods Corp. v. ConAgra, Inc.*,45 F.3d 443, 1994 WL 712488 (Fed. Cir. 1994)(nonprecedential).

2. New Pharmaceuticals are often "Purifications" of Old Products

It may be correct that in many instances a purified form of a known product is *prima facie* obvious over the known product, but under *Papesch*, even if prima facie obvious, a showing of unexpected properties for the purified product may nevertheless establish patentability.

Remarkable pharmaceuticals have been achieved which are in essence purified forms of known molecules. As stated by Judge Rich, "[s]everal courts, including [the CCPA], have considered the patentability of purified naturally occurring products and found them generally to be within the purview of § 101 or its predecessors. See *In re Bergstrom*, 427 F.2d 1394 (CCPA 1970) (prostaglandin compounds); *Merck v. Olin Mathieson Chemical*, 253 F.2d 156 (4th Cir. 1958) and *Merck v. Chase Chemical*, 273 F.Supp. 68 (D.N.J.1967) (Vitamin B-12); *Sterling Drug v. Watson, Comr. Pats.*, 135 F.Supp. 173 (D.C.D.C.1955) (1-arterenol); *Parke-Davis v. Mulford*, 196 F. 496 (2d Cir. 1912) (adrenalin)." *Bergy*, 596 F.2d at 996 n.4.

The *Vitamin B_{12} Case, Merck v. Olin Mathieson*, 253 F.2d at162-64), in turn

summarizes and quotes from holdings of patentability of several notable pharmaceuticals that were, in essence, mere purifications of known products, including the Aspirin case, *Kuehmsted v. Farbenfabriken of Elberfeld Co.*, 179 Fed. 701 (7th Cir. 1910); and the Adrenalin case, *Parke-Davis v. Mulford*, 196 F. 496 (2d Cir. 1912)(L. Hand, J.)

In the Aspirin case:

"Hoffmann has produced a medicine indisputably beneficial to mankind-something new in a useful art, such as our patent policy was intended to promote. Kraut and his contemporaries, on the other hand, had produced only, at best, a chemical compound in an impure state. And it makes no difference, so far as patentability is concerned, that the medicine thus produced is lifted out of a mass that contained, chemically, the compound; for, though the difference between Hoffmann and Kraut be one of purification only – strictly marking the line, however, where the one is therapeutically available and the others were therapeutically unavailable – patentability would follow. In the one case the mass is made to yield something to the useful arts; in the other case what is yielded is chiefly interesting as a fact in chemical learning."

Merck v. Olin Mathieson, 253 F.2d at 163 (quoting *Kuehmsted*, 179 F. at 705).

In the *Adrenaline* case, Judge Learned Hand explained:

"Nor is the patent only for a degree of purity, and therefore not for a new 'composition of matter.' As I have already shown, it does not include a salt, and no one had ever isolated a substance which was not in salt form, and which was anything like [the inventor,] Takamine's. Indeed, Sadtler supposes it to exist as a natural salt, and that the base was an original production of Takamine's. That was a distinction not in degree, but in kind. But, even if it were merely an extracted product without change, there is no rule that such products are not patentable. Takamine was the first to make it available for any use by removing it from the other gland-tissue in which it was found, and, while it is of course possible logically to call this a purification of the principle, it became for every practical purpose a new thing commercially and therapeutically. That was a good ground for a patent."

Merck v. Olin Mathieson, 253 F.2d at 163 (quoting *Parke-Davis v. Mulford*, 196 F. at 103).

3. *Myriad* Rationalization for "Purified" Drugs

It should be beyond question that breakthrough drugs such as aspirin and adrenalin, although "purified" from known substances, nevertheless in their pure form represent novel and patent-eligible products under 35 USC § 101. Two members of the Court recognized that such purified products *are* patent-eligible and came up with a distinction that is difficult to rationalized with the general statement in the majority opinion that a purified product lacks patent-eligibility:

Thus, the majority opinion sought to contrast an "isolated" versus a "purified" compound and while recognizing that the patent to adrenalin is to a purified product seek to show that adrenalin is, for practical purposes, something new: Thus, the majority opinion states:

"[I]solated DNA is not purified DNA. Purification makes pure what was the same material, but was previously impure. Although isolated DNA must be removed from its native cellular and chromosomal environment, it has also been manipulated chemically so as to produce a molecule that is markedly different from that which exists in the body. It has not been purified by being isolated. Accordingly, this is not a situation, as in *Parke–Davis & Co. v. H.K. Mulford Co.*, in which purification of adrenaline resulted in the *identical* molecule being 'for every practical purpose a new thing commercially and therapeutically. 189 F. 95, 103 (C.C.N.Y.1911)."

Myriad, __ F.3d at ___ (Lourie, J.).

A second member of the court reaches the same result through a different pathway:

"Judge Learned Hand held that purified adrenaline, a natural product, was patentable subject matter. Judge Hand explained that even if the claimed purified adrenaline were 'merely an extracted product without change, there is no rule that such products are not patentable.' *Parke–Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 103 (S.D.N.Y.1911). This is because 'while it is of course possible logically to call this a purification of the principle' the resulting purified adrenaline was 'for every practical purpose a new thing commercially and therapeutically.' *Id."*

Myriad, __ F.3d at __ (Moore, J., concurring).

V. ON THE ROAD TO THE SUPREME COURT

In the end, it has always been the goal of the plaintiffs to reach the Supreme Court. To the extent that the plaintiff's were to clarify Dr. Harry Ostrer's continued "wish[ ]" to practice the Myriad patented inventions as one cast in greater terms of immediacy, it may well be that the plaintiffs could survive a mootness challenge.

Because the panel took a total of 108 pages of opinions by all three members of the panel alone may gain the interest of the Supreme Court. By conflating patent-eligibility with patentability the panel has further created a better climate for grant of review.

If the plaintiffs move directly to the Supreme Court and there is no extension of time granted, a petition for Supreme Court review would be due October 27, 2011, which would lead to a decision whether to grant *certiorari* this coming winter, If granted, there would be an argument either in Spring 2012 or the October 2012 Term of the Court.

It is also possible that a suggestion for rehearing en banc could be filed with the Federal Circuit, which would toll the 90 day period for seeking Supreme Court review until a decision denying en banc review is issued (or, if issued, until a new merits decision would be reached).