P. Michael Walker
Vice President, Assistant General Counsel
Chief Intellectual Property Counsel
Legal Department
974 Centre Road
Chestnut Run Plaza 721-2264
Wilmington, DE 19805

July 31, 2014

The Honorable Michelle K. Lee
Deputy Under Secretary of Commerce for Intellectual Property
and Deputy Director of the United States Patent and Trademark Office
600 Dulany Street
P.O. Box 1450
Alexandria, VA 22313

VIA EMAIL: myriad-mayo_2014@uspto.gov

Re: Comments in Response to the USPTO's Guidance for Determining Subject Matter Eligibility of Claims Reciting or Involving Laws of Nature, Natural Phenomena & Natural Products

Dear Deputy Director Lee:

This letter is submitted on behalf of E. I. du Pont de Nemours and Company ("DuPont") in response to the United States Patent and Trademark Office's ("USPTO's") Guidance for Determining Subject Matter Eligibility of Claims Reciting or Involving Law of Nature, Natural Phenomena, & Natural Products and the related published examiner training materials ("Guidance"). We would like to thank the USPTO for this opportunity as well as for the forum hosted on May 9, 2014 held to receive public feedback on the Guidance.

DuPont is a market-driven science company developing technologies and products for the food, energy and protection needs of a growing population. DuPont seeks to protect these innovations though patents and other intellectual property, having been granted about 1,050 new U.S. patents in 2013 with an additional 1800 new U.S. filings covering technologies aimed at addressing the needs of people around the world.[1]

[1] http://www.dupont.com/corporate-functions/our-approach/science.html

DuPont recognizes the authority of the USPTO to provide training to the examining corps as part of an effort to continually improve the quality of the U.S. patent system and to allow the USPTO to more effectively carry out its mission. However, in providing such training, it is critical that any guidelines provided for this purpose should be in accord with the governing statutory authority as interpreted by the U.S. Courts. In particular, we contend that the present Guidance is not in accord with the decisions of the Supreme Court cases setting forth the judicial exceptions to patent-eligible subject matter specified in section 101 of Title 35 and that the Guidance improperly extends the exceptions to patent-eligible subject matter beyond the scope interpreted by the Supreme Court.

A. Guidance Provides Unjustified Expansion of the Holding in *Myriad*

In formulating the current Guidance, the USPTO appears to have interpreted the Supreme Court decision in *Myriad* in a way that results in the unjustified expansion of the intentionally narrow holding in that case. In *Myriad*, the Supreme Court stated "[w]e merely hold that genes and the information they encode are not patent eligible under §101 simply because they have been isolated from the surrounding genetic material."[2] In making this determination, the Court held that "naturally occurring DNA is a product of nature and not patent eligible merely because it has been isolated, but that cDNA is patent eligible because it is not naturally occurring."[3] Thus, proper interpretation of *Myriad*, and reliance thereon by the USPTO, must appreciate the intent of the Court to narrowly limit its holding to claims directed to genetic information (*e.g.*, isolated, naturally occurring DNA).

As currently drafted, the Guidance expands the holding in *Myriad* far beyond subject matter directed to genetic information in a manner which now applies to the patentability of any claim reciting or involving laws of nature/natural principals, natural phenomena, and/or natural products including proteins, antibodies, and antibiotics. In doing so, the Guidance from the USPTO has *de facto* expanded the narrow holding in *Myriad* to now affect industries which may operate in areas wholly unrelated to DNA-based technologies.

In its training materials ("Overview of Eligibility Guidance, presented May 9th at the partnership forum held at the USPTO hereinafter "Overview"), the USPTO suggests that its departure from the limited holding in *Myriad* is justified by the Supreme Court holdings in ten different cases. (*see* slide 7). However the USPTO has extended the interpretation of these cases beyond their specific holdings to suggest that the Supreme Court is of the view that the term "naturally occurring" should be construed broadly. This interpretation is in direct conflict with the limited holding in *Myriad*.

---

[2] *Association for Molecular Pathology v. Myriad Genetics, Inc*., 569 U.S. ___, ___, 133 S. Ct. 2107, 186 L. Ed. 2d 124 (2013).

[3] *Association for Molecular Pathology v. Myriad Genetics, Inc*., 569 U.S. ___, ___, 133 S. Ct. 2107, 2111, 186 L. Ed. 2d 124 (2013).

DuPont's position is that the decision in *Myriad* should not be improperly applied to extend its narrowly tailored holding to support the Guidance's rationale that all compositions and molecules that originate from a natural product, as well as methods related to their use, should be examined under the patent eligibility framework set forth therein. Rather, the Guidance's interpretation of *Myriad* should be aligned with the Court's intent to narrowly limit its holding to isolated, naturally occurring DNA.

B. No Clear Basis for the "Significantly Different" Standard Set Forth in the Guidance.

The Guidance sets forth a new hybrid standard for patent eligibility, purportedly drawn from the holdings of both the *Mayo* and *Myriad* decisions[4]. The new "significantly different" standard set forth in the Guidance may be satisfied in multiple ways, including the addition of elements or steps to a claim that add *significantly more* to the judicial exception, and/or including features or steps demonstrating that the claimed subject matter is *markedly different* from what exists in nature.

i. The *Myriad* decision is narrow in holding; Eligible subject matter is broad

The "significantly different" standard does not appear in the case law relied on by the USPTO Examiner Guidance, and therefore raises the possibility of misinterpretation or misapplication of Supreme Court decisions on patent eligibility. One potential way in which the Supreme Court decisions on patent eligibility may be misinterpreted or misapplied is in the scope of patent eligible subject matter. The Supreme Court has repeatedly cautioned that Congress intended the scope of § 101 to be broad and that the holdings of certain Supreme Court decisions should be narrowly applied.[5]

For example, in the *Myriad* case the Supreme Court stated that

> [i]t is important to note what is not implicated by this decision. First, there are no method claims before this Court… Similarly, this case does not involve patents on new *applications* of knowledge about the BRCA1 and BRCA2 genes… We merely hold that genes and the information they encode

[4] Office of Patent Legal Admin., U.S. Patent & Trademark Office, Presentation to the Biotechnology/Chemical/Pharmaceutical Customer Partnership (Apr. 16, 2014), available at http://www.uspto.gov/patents/announce/myriad-mayo_bcp_20140416.pdf (the "USPTO Guidance Presentation").

[5] *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc*, 534 U.S. 124, 131 (2001)([W]e are mindful that this Court has already spoken clearly concerning the broad scope and applicability of § 101."); *Diamond v. Charkrabarty*, 447 U.S. 303, 308 (1980)("Congress plainly contemplated that the patent laws would be given wide scope.").

> are not patent eligible under §101 simply because they have been isolated from the surrounding genetic material. [6]

In so stating, the Supreme Court cautioned that the rule against patents on naturally occurring things is not without limits, because "… all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas …" and "… too broad an interpretation of this exclusionary principle could eviscerate patent law…"[7] The Guidance ignores this cautionary note raised by the Supreme Court.

ii. The Guidance focuses on structure and ignores other distinguishing "characteristics"

The Guidance presents certain factors weighing toward or against eligibility that Examiners should consider when evaluating the patent eligibility of claimed subject matter. Whether favorable or not, the first factor Examiners are instructed to consider is whether a product claim recites something that appears to be a natural product, and whether that claimed product is or is not markedly different in structure from naturally occurring products.

The Guidance emphasizes marked differences in "structure" as the lead factor weighing both for and against patent eligibility. However, the Court has never actually indicated that a composition of matter must be markedly different in **structure** to be patent eligible. Although a marked difference in structure may be sufficient to indicate that a material is patent eligible, a marked difference in structure is not an absolute requirement for patent eligibility. For example, the Court in *Myriad* found that "cDNA is patent eligible because it is not naturally occurring"; however, the Court did not create a requirement that any material must have a marked difference in structure to be considered patent eligible.[8]

The Supreme Court noted in the *Myriad* decision: "Myriad recognizes that our decision in *Chakrabarty* is central to this inquiry … The *Chakrabarty* bacterium was new 'with markedly different **characteristics** from any found in nature …'"[9] Different characteristics may include for example functional differences or structural differences, among other differences. The Guidance itself quotes the Supreme Court on this point, stating:

---

[6] *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. ___, ___, 133 S. Ct. 2107, 2119, 2120, 186 L. Ed. 2d 124 (2013).)(emphasis added).
[7] *Mayo Collaborative Services v. Prometheus Laboratories, Inc*., 566 US __, __(slip op., at 2), 132 S. Ct. 1289 at 1293, 182 L.Ed.2d 321 (2012).
[8] *Association for Molecular Pathology v. Myriad Genetics, Inc*., 569 U.S. ___, ___, 133 S. Ct. 2107, 2111, 186 L. Ed. 2d 124 (2013).
[9] *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. ___, ___, 133 S. Ct. 2107, 2116-2117, 186 L. Ed. 2d 124 (2013). (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 310, 100 S. Ct. 2204, 65 L.Ed.2d 144 (1980)(emphasis added).

> The combination of species produces no new bacteria, no change in the six species of bacteria, and no enlargement of the range of their utility. Each species has the same effect it always had. The bacteria perform in their natural way. Their use in combination does not **improve** in any way their natural **functioning**.[10]

Notwithstanding this quotation, the Guidance does not effectively instruct Examiners that other distinguishing characteristics may weigh in favor of patent eligibility. For example, with respect to composition claims, none of the exemplified factors in the Guidance expressly instruct Examiners to consider functional attributes that by themselves may impart patent eligibility to a claimed composition, such as a combination of natural products.[11] To this point, the USPTO provided training materials which utilize the framework set forth in the Guidance to assert that gunpowder, in and of itself, is not patent eligible because it is a simple mixture of three naturally occurring materials: potassium nitrate, sulfur and charcoal.[12] The Guidance supports this assertion by stating that none of the components in gunpowder have been changed **structurally** due to their combination. However, this analysis fails to consider that gunpowder possesses distinct functional characteristics that are not found in any of its underlying naturally occurring components. DuPont contends that such characteristics should not be overlooked in determining patent eligibility.

Thus, the Guidance exceeds the rulings of *Chakrabarty* and *Myriad* by, in effect, requiring a determination whether a claim is patent eligible by being "… markedly different in **structure** from naturally occurring products."[13] The Federal Circuit recently recognized this distinction in a decision in which a live-born clone (purportedly the cloned sheep "Dolly") was determined not to be patent-eligible material.[14] In particular, the Federal Circuit noted the following (page 11):

> The clones are defined in terms of the identity of their nuclear DNA to that of the donor mammals. **To be clear, having the same nuclear DNA as the donor mammal may not necessarily result in patent ineligibility in every**

---

[10] *See* March 4, 2014 USPTO Memorandum to the Patent Examining Corps, Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products, Example D (Composition Claim Reciting Multiple Natural Products)(quoting Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 131 (1948)(emphasis added)).

[11] Examples 1 and 2 of the Guidelines rely on <u>both</u> structural and functional differences in reaching a determination of patent eligibility.

[12] Office of Patent Legal Admin., U.S. Patent & Trademark Office, Presentation to the Biotechnology/Chemical/Pharmaceutical Customer Partnership (Apr. 16, 2014), available at http://www.uspto.gov/patents/announce/myriad-mayo_bcp_20140416.pdf (the "USPTO Guidance Presentation").

[13] *See* March 4, 2014 USPTO Memorandum to the Patent Examining Corps, Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products, at page 4, section II. How To Analyze "Significantly Different" (emphasis added).

[14] *In re Roslin Institute* (USCAFC 2013-1407, May 8, 2014), 2014 WL 1814014 (Fed. Cir. 2014).

> **case.** Here, however, the claims do not describe clones that have markedly different characteristics from the donor animals of which they are copies.[15]

The general tendency of decisions regarding patent eligibility is one of caution. Moreover, the Supreme Court has recognized the intent of Congress to give the patent laws wide scope. Accordingly, the Guidance should be narrowly tailored to reflect the holding of the Supreme Court in *Myriad*. Alternatively, the Guidance should be modified so that the factors Examiners are instructed to take into consideration when making eligibility determinations take into account other eligibility-conferring characteristics, such as function.

DuPont contends that the Guidance, in its present form, creates a new hybrid legal standard that unnecessarily restricts the patent eligibility of certain categories of technologies. In so doing, the Guidance risks damage to the biotechnology sector, which the United States has historically been a leader. Moreover, because biotechnology relies heavily upon capital investment to fund continued growth and innovation, the uncertainty cast on current and future intellectual property by the Guidance will have the real-world effect of limiting investment, growth, and job creation in biotechnology at a time when this technology sector is poised to address the global challenges of feeding an ever-growing population as well as reducing our dependence upon fossil fuels.

DuPont appreciates the USPTO's efforts in formulating the Guidance and values the opportunity to provide comment thereon. Additionally, we welcome any opportunity to continue the dialogue with the USPTO regarding revising the present Guidance in a manner in which the determination of patent eligible subject is in better accord with existing Supreme Court jurisprudence.

Respectfully submitted,

P. Michael Walker

[15] *Id*. at 11. (emphasis added).