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**Comments on USPTO's Guidance on the Proposed Procedure For Subject Matter Eligibility Analysis Of Claims Reciting Or Involving Laws Of Nature/Natural Principles, Natural Phenomena, And/Or Natural Products**

July 30, 2014

The Center for Food Safety (CFS) is a national, nonprofit public interest and environmental advocacy organization working to protect human health and the environment by curbing the use of harmful food production technologies. In furtherance of this mission, CFS uses legal actions, groundbreaking scientific and policy reports, books and other educational materials, and grassroots campaigns, on behalf of its more than 500,000 members. CFS is a recognized national leader on the issue of genetically engineered (GE) organisms and pesticides, and has worked on improving their regulation and addressing their impacts continuously since the organization's inception in 1997.

CFS hereby submits the following comments on the "Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products" (New Guidance). The New Guidance addresses the patentability of claims reciting or involving naturally occurring things, i.e., laws of nature, natural products, and natural phenomena. Pursuant to the New Guidance, claims are, as a whole, given the broadest reasonable interpretation in accordance with Manual of Patent Examining Procedure (MPEP) § 2103 and are examined following the procedures outlined in the flowchart questions 1–3. CFS agrees with the proposed examination of claims and supports the New Guidance's approach to evaluate whether claims involving naturally occurring things are patent-eligible subject matter under this guidance. The New Guidance proposes to implement and properly apply the Supreme Court decisions in *Assn. for Molecular Pathology v. Myriad Genetics, Inc. (Myriad)*<sup>1</sup> and *Mayo Collaborative Servs. v. Prometheus Labs., Inc. (Mayo)*<sup>2</sup> to patent eligibility examinations.

CFS favors the New Guidance in its current form and commends USPTO for combining

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<sup>1</sup> 133 S.Ct. 2107 (2013).

<sup>2</sup> 132 S.Ct. 1289 (2012).

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existing patent law and case precedent into a logic and user-friendly line of inquiry into the patent eligibility of natural products pursuant to 35 U.S.C. §§ 101–103 and 112. In the New Guidance, USPTO has admitted and recognized, in part, what CFS along with our fellow Amicus Curiae petitioners and many others have explained and warned: products of nature are not patentable and any efforts to patent products of nature will likely cause significant environmental, agronomic, and socioeconomic harm. CFS will incorporate by reference and restate remarks that it has already submitted to the Supreme Court as Amicus Curiae in *Myriad*.<sup>3</sup> In sum, USPTO’s proposal follows all applicable statutes, is proper in light of Supreme Court precedent, is supported by sound science, and otherwise is in accordance with the law.

## COMMENTS

### I. Natural Products Are Not Patentable Subject Matter.

For more than a century and a half, the Supreme Court has held that the laws and phenomena of nature are not patentable, as required by Article I, Section 8, Clause 8 of the U.S. Constitution (the patent clause of the U.S. Constitution), as well as 35 U.S.C. § 101 (the patent statute subject matter requirements). Building on precedent since the early nineteenth century, the Supreme Court has consistently and emphatically upheld the § 101 exception that nature is not patentable.<sup>4</sup> Most recently, in *Myriad*, the Supreme Court once again reaffirmed the exception to § 101, that laws of nature, natural phenomena, and abstract ideas are not patentable and that “‘they are the basic tools of scientific and technological work’ that lie beyond the domain of patent protection.”<sup>5</sup> Following a long tradition of precedent, CFS commends USPTO

<sup>3</sup> Br. Amici Curiae Int’l Ctr. Tech. Assessment, Council for Responsible Genetics, Greenpeace, Indigenous Peoples Council on Biocolonialism, Friends of the Earth, and Ctr. For Env’tl. Health in Support of Pet’rs, *Ass’n for Molecular Biology v. Myriad Genetics, Inc.*, No. 12-398, 2013 WL 417732 (2013) (hereinafter “Amicus Brief”).

<sup>4</sup> See, e.g., *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (“The laws of nature, physical phenomena, and abstract ideas have been held not patentable.”); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948) (“[P]atents cannot issue for the discovery of the phenomena of nature.”); see also *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int’l, Inc.*, 534 U.S. 124, 130, 134 (2001) (referring to *Chakrabarty*’s assertion that for purposes of § 101, “the relevant distinction [is] not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions.”)(quoting *Chakrabarty*, 447 U.S. at 313); *Diamond v. Diehr*, 450 U.S. 175, 185 (1981) (“This Court has undoubtedly recognized limits to § 101 and every discovery is not embraced within the statutory terms. Excluded from such patent protection are laws of nature, natural phenomena, and abstract ideas.”); *Parker v. Flook*, 437 U.S. 584, 593 (1978) (“The rule that the discovery of a law of nature cannot be patented rests, not on the notion that natural phenomena are not processes, but rather on the more fundamental understanding that they are not the kind of ‘discoveries’ that the statute was enacted to protect.”); *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972) (“Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work.”); *O’Reilly v. Morse*, 56 U.S. (15 How.) 62, 116 (1854) (“[T]he discovery of a principle in natural philosophy or physical science[] is not patentable.”); *Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 175 (1853) (“A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right.”).

<sup>5</sup> *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S.Ct. 2107, 2116 (2013) (citing *Mayo*, 132 S. Ct. 1289, 1292 (internal quotation marks and brackets omitted)); see accord, *Mayo v. Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S.Ct. 1289, 1293–94 (2012); *Bilski v. Kappos*, 130 S.Ct. 3218, 3225 (2010).

on the Guidance that follows the interpretation of *Myriad*, disallowing the patenting of products of nature.

For over 150 years, the Supreme Court has held that nature is not patentable, and no reason exists to change history or U.S. patent law now. In its forum presentation on May 9, 2014, USPTO emphasized that “[o]ver the last 65 years, the Supreme Court has repeatedly explained that a mere discovery of nature’s handiwork is not [patent] eligible.”<sup>6</sup> Thus, by its own affirmation, USPTO is “bound by the Supreme Court’s interpretation of [35 U.S.C. § 101],” which excludes laws of nature, natural phenomena, and abstract ideas from patent-eligibility.<sup>7</sup> Patenting natural products would, therefore, be in contravention of over 150 years of Supreme Court precedent and USPTO’s interpretation of *Myriad*, and would be a violation of fundamental common law principles, the public domain, and the public trust doctrine. Therefore, CFS strongly encourages USPTO to leave the New Guidance unaltered as it correctly and aptly combines over a century of American case law as well as an established interpretation of § 101 into a helpful and beneficial line of inquiry into the patentability of natural products.

The New Guidance de-emphasizes the term “discovery” in 35 U.S.C. § 101 and gives Supreme Court precedent more weight, thereby binding USPTO to the Supreme Court’s interpretation that mere discovery of natural phenomena is not eligible subject matter.<sup>8</sup> In *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, the Court found that “[h]e who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes.”<sup>9</sup> The Court continued to explain that “[i]f there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end.”<sup>10</sup> Through the decisions in *Chakrabaty* and *Funk*, USPTO is legally bound to the Supreme Court’s broad construction of § 101, where Congress previously defined patentable subject matter in § 101 to exclude phenomena of nature and natural products,<sup>11</sup> as correctly set forth in the New Guidance. In *Flook*, the Court further explained that “[t]he rule that the discovery of a law of nature cannot be patented rests, not on the notion that natural phenomena are not processes, but rather on the more fundamental understanding that they are not the kind of ‘discoveries’ that the statute was enacted to protect.”<sup>12</sup> More recently, under the New Guidance’s application of *Myriad*, the court construes the limitations of the term “discovery” even further, holding that “[g]roundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry.”<sup>13</sup> Consequently, natural products are excluded from patent-eligible discoveries unless they “come from the application of the law of nature to a new and useful end” and are practically applied.<sup>14</sup>

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<sup>6</sup> USPTO, Presentation, Subject Matter Eligibility Forum at 11 (May 9, 2014), *available at* [http://www.uspto.gov/patents/announce/may9forum\\_uspto.pdf](http://www.uspto.gov/patents/announce/may9forum_uspto.pdf) (last accessed July 28, 2014).

<sup>7</sup> *Id.*; *see also* cases cited *supra* note 1.

<sup>8</sup> *See Chakrabaty*, 447 U.S. at 309 (holding that “[t]he laws of nature, physical phenomena, and abstract ideas have been held not patentable”); *accord Parker v. Flook*, 437 U.S. 584, 593 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972).

<sup>9</sup> 333 U.S. 127, 130 (1948).

<sup>10</sup> *Id.*

<sup>11</sup> *Chakrabaty*, 447 U.S. at 315.

<sup>12</sup> *Flook*, 437 U.S. at 593.

<sup>13</sup> *Myriad*, 133 S.Ct. at 2117.

<sup>14</sup> *Funk*, 333 U.S. at 130.

In sum, the term “discovery” in 35 U.S.C. § 101 excludes natural phenomena and products of nature from patentable subject matter. The New Guidance’s proposed steps to determine which subject matter is excluded are properly outlined and in accordance with clear case law and statutory definitions.

## **II. The New Guidance Properly Invokes a Line of Inquiry into Patent-Eligibility of Claims Involving Natural Products Pursuant to 35 U.S.C. §§ 101–103 and 112, and Aptly Gives Claims, as a Whole, the Broadest Reasonable Interpretation to Determine Patent-Eligibility.**

The patent clauses of the U.S. Constitution and 35 U.S.C. §§ 101–103 and 112 set forth the basic and indisputable requirements for patentability, requiring that the invention be patentable subject matter, novel, nonobvious, and fully and particularly described. Thus, the line of inquiry applying patent eligibility requirements pursuant to § 101 is the proper path for USPTO to examine claims pursuant to the tried and tested MPEP § 2103. In its first step, the Guidance correctly begins the line of inquiry with a determination of the claim under the four statutory categories, namely processes, machines, manufactures, and compositions of matter. This start of analysis follows the protocol under MPEP § 2103 and compact prosecution principles. Under the New Guidance—and in line with statutory requirements, precedent, and other established legal principles—laws of nature, natural phenomena, and natural products are properly excluded from patentability. Further following the line of inquiry according to the Guidance, therefore, the patent examiner will, in the first line of inquiry, readily determine whether the claim in question is drawn to ineligible subject matter under § 101. This is the established threshold step in patent-eligibility examination and USPTO merely corroborates this in the New Guidance.

In the following steps of patent examination according to the New Guidance, USPTO correctly gives claims, as a whole, the broadest reasonable interpretation. As long as the claim is a process, a machine, a manufacture, or a composition of matter, the examiner proceeds to review whether the claim invokes any judicial exceptions, such as laws of nature, natural phenomena, and natural products, all of which are ineligible for patent protection. In fact, the line of inquiry requires that each claim be analyzed individually through the consistent application of the factors set forth by the New Guidance.<sup>15</sup> This is a simple and easy-to-follow process that patent applicants can readily anticipate and predict. The New Guidance, therefore, provides a streamlined and anchored approach to examine patentability of natural products that is user-friendly and a correct application of existing patent law.

Following the New Guidance’s logical line of inquiry,<sup>16</sup> it becomes clear when a claim has to be rejected under § 101. Only if the claim, as a whole, recites something significantly different than the judicial exceptions, i.e., something that, pursuant to the third and final step of inquiry under the Guidance, does not fall under the laws of nature, natural phenomena, and

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<sup>15</sup> New Guidance at 4–5.

<sup>16</sup> *Id.* at 2.

natural products, does the claim qualify as patent-eligible subject matter; otherwise, the claim has to be rejected for lack of eligible subject matter. Nonetheless, examiners are obligated to consider 35 U.S.C. §§ 101–103 and 112 to evaluate each claim. This examination of claims as a whole, rather than in isolation, follows a fair path of inquiry and is soundly based on the applicable legal frameworks to determine eligibility. Drawing upon the New Guidance, which appropriately proposes the series of steps for examination of any given claim following established case law and statutory requirements,<sup>17</sup> the line of inquiry leads to the exclusion of laws of nature, natural phenomena, and natural products only if the claim as a whole is not significantly different from natural products.<sup>18</sup>

Although the New Guidance provides no bright-line rule to patent-eligibility of natural products, it reconciles *Myriad* and *Mayo* through clarification of what satisfies the “markedly” or “significantly different” standard for eligibility. Under this standard, the claim must be something markedly different, as defined through the factors set forth in the Guidance or, in the alternative, add significantly more to the judicial exception to render the claimed natural product markedly different in structure from naturally occurring products.<sup>19</sup> Using the example in *Myriad*, the New Guidance properly combines factors “a) and g) [which] concern the question of whether something that initially appears to be a natural product is in fact non-naturally occurring *and* markedly different from what exists in nature, i.e., from naturally occurring products.”<sup>20</sup> This added requirement of a marked difference provides both clarity and predictability to the patent examination process because it sets the bar higher to define a “marked difference” as “a significant difference, i.e., more than an incidental or trivial difference.”<sup>21</sup> As a result, the New Guidance clarifies the impact of *Myriad* on the patentability of natural products and it no longer restricts the required marked difference to structural or functional changes, as may have been the case in the previous, less-streamlined examination protocol from *Chakrabarty*, where the Court set forth the criteria for a structural difference between nature’s and man’s handiwork as possessing “markedly different characteristics from any found in nature and one having the potential for significant utility.”<sup>22</sup> Through the evaluation of factors (a) and (g) of the New Guidance, it is this marked difference giving rise to structural and functional differences that gives examiners a logical and coherent means to determine whether the natural products exception of § 101 applies to the claims at hand. Finally, in evaluating factors (b)–(f) and (h)–(l), examiners will merely follow *Mayo*’s “significantly more” pathway to eligibility as it was intended to be applied by the Supreme Court’s construction of patent law.<sup>23</sup> CFS is in favor of this combination of *Myriad* and *Mayo* in the New Guidance, which provides helpful steps to

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<sup>17</sup> *Id.* at 2–3.

<sup>18</sup> *Id.*; see also *In re Hiniker Co.*, 150 F.3d 1362, 1369 (Fed. Cir. 1998) (stating that “the name of the game is the claim”); accord MPEP § 2103(C) (affirming that “[t]he claims define the property rights provided by a patent, and thus require careful scrutiny”).

<sup>19</sup> New Guidance at 3–4.

<sup>20</sup> *Id.* at 5 (emphasis in original).

<sup>21</sup> *Id.*

<sup>22</sup> *Chakrabarty*, 447 U.S. at 310.

<sup>23</sup> See *Mayo*, 132 S.Ct. at 1294 (“[A] process that focuses upon the use of a natural law [must] also contain other elements . . . sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself.”).

examine patentability of natural products.

Another reason to support the New Guidance's approach to examining claims involving laws of nature, natural phenomena, and natural products "is that many claims presented by applicants concern two or more different types of judicial exceptions, for example both natural products and laws of nature, and so [USPTO] examiners needed guidance on how to examine these types of claims."<sup>24</sup> The step-by-step analysis outlined in the Guidance provides examiners with a clear line of inquiry that will ultimately both benefit the USPTO's efficiency and streamline the processes of patent eligibility examination for the increasing numbers of application invoking natural products from the biotechnology, agricultural sciences, and pharmaceutical sectors. In fact, the 6.4% increase of filings from 2012 to 2013 calls for improved patent examination guidelines in order to preserve the USPTO's "three strategic goals and one management goal" in support of the Office's mission to "foster[] innovation, competitiveness, and economic growth. . . by delivering high-quality and timely examination of patent and trademark applications,"<sup>25</sup> as set forth in USPTO's 2013 Performance and Accountability Report. Providing clarification on the natural products exception to § 101 through the New Guidance is an appropriate response to streamline examination guides and further USPTO's goals to improve efficiency in light of the increased numbers of applications.

### **III. Natural Products Should Be Broadly Excluded from Patentable Subject Matter Because Patenting Nature Would Create Rights of Unknown Scope and Significance, and Retard the Progress of Science in Contravention of the Patent Act's Purpose.**

Case law dictates that "naturally occurring things" is a broad term<sup>26</sup> and "patents cannot issue for the discovery of phenomena of nature."<sup>27</sup> Laws of nature essentially "exist in principle apart from any human action."<sup>28</sup> According to this universal principle, the Supreme Court has held that

a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that  $E=mc^2$ ; nor could Newton have patented the law of gravity. Such discoveries are manifestations of . . . nature, free to all men and reserved exclusively to none.<sup>29</sup>

In *Myriad*, the Supreme Court recognized that "patent protection strikes a delicate balance between creating 'incentives that lead to creation, invention, and discovery' and 'imped[ing] the

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<sup>24</sup> June Cohan, Ali Salimi, and Daniel Sullivan, USPTO, *Evaluating Subject Matter Eligibility Under 35 U.S.C. § 101*, Biotechnology/Chemical/Pharmaceutical Customer Partnership at 19 (April 16, 2014), available at [http://www.uspto.gov/patents/announce/myriad-mayo\\_bcp\\_20140416.pdf](http://www.uspto.gov/patents/announce/myriad-mayo_bcp_20140416.pdf) (last accessed July 28, 2014).

<sup>25</sup> USPTO, *Performance and Accountability Report, Fiscal Year 2013*, available at <http://www.uspto.gov/about/stratplan/ar/USPTOFY2013PAR.pdf> (last accessed July 25, 2014).

<sup>26</sup> *Chakrabarty*, 447 U.S. at 316 ("Congress employed broad general language in drafting § 101 precisely because such inventions are often unforeseeable.")

<sup>27</sup> *Funk*, 333 U.S. at 130–31 (internal citations omitted).

<sup>28</sup> *Mayo*, 132 S.Ct. at 1296–97.

<sup>29</sup> *Id.* at 1293 (citing *Chakrabarty*, 447 U.S. at 309 (internal quotations omitted)).

flow of information that might permit, indeed spur, invention.”<sup>30</sup> For the reason that “extensive effort alone is insufficient to satisfy § 101’s demands,”<sup>31</sup> it is essential not to have patents on products of nature or laws of nature. As the Supreme Court held in *Gottschalk*, “[p]henomena of nature . . . are the basic tools of scientific and technological work,”<sup>32</sup> and monopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it. Justice Breyer has explained that “the reason for the exclusion is that sometimes *too much* patent protection can impede rather than ‘promote the Progress of Science and useful Arts,’ the constitutional objective of patent and copyright protection.”<sup>33</sup> CFS supports USPTO’s construction of the exemption of natural products from eligibility in the New Guidance, which not only satisfies § 101 demands but also acts in accordance with the Constitution’s underlying intention to spur innovation.

#### **IV. Patenting Natural products would have significant negative scientific, social, cultural and environmental consequences.**

##### **A. *The Privatization of Natural Products Violates the Fundamental Common Law Precepts of Common Heritage, the Public Domain, and the Public Trust.***

Natural products are part of the common heritage of humanity and should be held as part of the public trust, as *res communis*, the common heritage and inheritance of mankind, owned by all people, not granted to a single firm to the exclusion of all others. Pursuant to the common heritage theory, public resources such as genes are available for use by all without restriction, for the benefit of humanity. The common heritage doctrine has been applied in many other areas, to a variety of resources, including the sea floor, activities in outer space, the use of seeds, preservation of historical artifacts, and the conservation of environmental resources.<sup>34</sup> Similarly, the importance of the public domain is recognized in patent law by the exclusion of the laws of nature, natural phenomena, and abstract ideas from patent eligibility.<sup>35</sup>

The Supreme Court has long held that existing knowledge and materials that exist in the public domain are not to be patented: “Congress may not authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to

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<sup>30</sup> *Myriad*, 133 S.Ct. at 2116 (citing *Mayo*, 132 S.Ct. at 1292).

<sup>31</sup> *Id.* at 2110.

<sup>32</sup> *Gottschalk*, 409 U.S. at 67.

<sup>33</sup> *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 126–27 (2006) (Breyer, J., dissenting) (quoting U.S. Const. art. I, § 8, cl. 8).

<sup>34</sup> Kemal Baslar, *The Concept of the Common Heritage of Mankind in International Law* 31–37, 108–09 (Kluwer Law International 1998); Andrew Chin, *Research in the Shadow of DNA Patents*, 87 J. Pat. & Trademark Official Soc’y 846, 864 (Nov. 2005); see also Emmanuel Agius, *Our Responsibilities Towards Future Generations*, 133–43 (Salvino Busuttill, Peter Serracino Inglott and Tony Macelli eds., 1990) (“If there is an obvious component of the common heritage of mankind, indeed, more obvious than the resources of the sea-bed itself, it is the human genetic system.”).

<sup>35</sup> *Mayo*, 132 S.Ct. at 1293.

materials already available.”<sup>36</sup> Additionally, the Court has interpreted patent law in favor of the present argument because “[a] patent by its very nature is affected with a public interest.”<sup>37</sup> Granting patents on products of nature would contravene Supreme Court precedent and permit the monopolization products of nature, take information out of the public domain, and impede the progress of science, contrary to the express intent of the Constitution.<sup>38</sup> Thus, the array of precedent cited herein evidences that the importance of the public domain is recognized in patent law by the exclusion of the laws of nature, natural phenomena, and abstract ideas. The patenting of natural products would stall research into these processes, a result that is antithetical to the purpose of U.S. patent law. Privatizing products of nature would turn nature and all of its components into treasure troves to be exploited for economic gain, in violation of cultural and religious values.

**B. *Natural Products Patents Facilitate the Exploitation of Indigenous Peoples and Violate International Law.***

The United Nations Declaration on the Rights of Indigenous Peoples, adopted in 2007 by the U.N. General Assembly, recognizes that “[i]ndigenous peoples have the right to maintain, control, protect and develop their cultural heritage, . . . including human and genetic resources . . . .”<sup>39</sup> This right stems from the central right of self-determination, which includes a “right to autonomy or self-government in matters relating to their internal and local affairs.”<sup>40</sup> In the United States, this right is embodied through the recognition and exercise of tribal sovereignty for federally-recognized tribes. The U.N. Declaration also recognizes the obligation upon States to obtain the free, prior, and informed consent (FPIC) of indigenous peoples when legislative or administrative actions may affect them, as well as prior to the extraction of their resources.<sup>41</sup> Given the demonstrated history of exploitation of indigenous peoples’ genetic material and natural products without their informed consent, any extension of patent protection to natural products or genes obtained from indigenous peoples without their FPIC is an infringement of their internationally-recognized rights. Hence, properly excluding products of nature, such as gene sequences according to *Myriad*, as impermissible subject matter pursuant to the product of nature doctrine would serve to protect the historically violated rights of indigenous peoples under international and federal law.

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<sup>36</sup> *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 6 (1966); see also *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 151 (1989) (explaining that “free exploitation of ideas will be the rule, to which the protection of a federal patent is the exception”); *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945) (“[A] patent is an exception to the general rule against monopolies . . .”).

<sup>37</sup> *Precision Instrument*, 324 U.S. at 816.

<sup>38</sup> U.S. Const. art. I, § 8, cl. 8; *Mayo*, 132 S.Ct. at 1293 (warning against the “monopolization” of “basic tools of scientific and technological work” through patents); *In re Marden*, 47 F.2d 958, 959 (C.C.P.A. 1931) (holding that “pure vanadium is not new in the inventive sense, and, it being a product of nature, no one is entitled to a monopoly of the same”).

<sup>39</sup> Declaration on the Rights of Indigenous Peoples, G.A. Res. 61/295, U.N. GAOR, 61st Sess., U.N. Doc. A/RES/61/295, at art. 31 (Sept. 13, 2007).

<sup>40</sup> *Id.* at art. 4.

<sup>41</sup> *Id.* at arts. 19 & 32.2.

## V. The Guidance Appropriately Requires That Inventions Be Markedly Different in Function and in Structure from Naturally-Occurring Products.

The Supreme Court's holding in *Myriad* squarely supports the broad reading of "markedly different" that the Guidance applies in its examples. In Example B (amazonic acid), the New Guidance distinguishes between the ineligible first claim and the patent-eligible second claim with great detail and clarity.<sup>42</sup> Claim 1 is ineligible for lack of marked differences as mentioned in the background section to the claim and Factor (g) is satisfied.<sup>43</sup> However, Claim 2 satisfies Factor (a) and illustrates the structural difference required for patentability.<sup>44</sup> Ultimately, the claims are considered as a whole and the factors weigh toward patentability, so that the Patent Act's purpose to protect and encourage innovation is honored while the criteria for eligibility are clarified. Through the Guidance, as illustrated in Example B, USPTO proactively and appropriately combined the *Myriad* and *Mayo* standard into a clear rule that patent examiners may apply to both functional and structural differences when determining eligibility as a whole.

The New Guidance, on the first page, discusses *Myriad*'s reaffirmation of the USPTO's "reliance on *Chakrabarty*'s criterion for eligibility of natural products (i.e., whether the claimed product is a non-naturally occurring product of human ingenuity that is markedly different from naturally occurring products)" and incorporates previous case law to clarify that *Myriad* relied on *Chakrabarty* as "central" to the eligibility inquiry.<sup>45</sup> Despite the Supreme Court's clarification "that not every change to a product will result in a marked difference, and that the mere recitation of particular words (e.g., 'isolated') in the claims does not *automatically* confer eligibility,"<sup>46</sup> the Court also acknowledged that "eligibility does not 'depend simply on the draftsman's art.'"<sup>47</sup> Thus, while the holding in *Myriad* was limited to nucleic acids, *Myriad* is a reminder that claims reciting or involving natural products should be examined for a marked difference under *Chakrabarty* and confirms the intent to disallow the patenting of natural products in the more recent *Mayo* decision.

## VI. The New Guidance Extends to All Patent Claims Invoking Laws of Nature and Properly Restricts Patentable Subject Matter with Respect to Natural Products-Related Inventions.

The application of the *Myriad* holding to the New Guidance is *not* too broad, and any argument otherwise is without merit in light of the Guidance's clear and helpful language. *Myriad* illustrates one of the paths of inquiry within the context of other Supreme Court cases<sup>48</sup> concluding with the previously-established broad principle that the claims drawn to something

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<sup>42</sup> New Guidance at 7.

<sup>43</sup> *Id.*

<sup>44</sup> *Id.* at 8.

<sup>45</sup> *Id.* at 1..

<sup>46</sup> New Guidance at 1 (citing *Myriad*, 133 S.Ct. at 2119) (emphasis in original)

<sup>47</sup> Guidance at 1 (citing *Mayo*, 132 S.Ct. at 1294).

<sup>48</sup> See cases cited *supra* note 1.

natural were held ineligible.<sup>49</sup> USPTO made no indication that *Myriad* shall be the sole signpost to determine patentability of natural products. On the contrary, the New Guidance references the Patent Act, MPEP, and several other cases upon which the line of inquiry is based to determine patentability “regardless of whether particular words (e.g., ‘isolated’, ‘recombinant’, or ‘synthetic’) are recited in the claim.”<sup>50</sup> Thus, *Myriad* updated previously-established, legally binding principles to incorporate the novel issues of genetic engineering and modern medical diagnostics.

Although the question at issue in *Myriad* concerned nucleic acids, it is *Myriad’s* impact on the examination of claims in light of other long-standing precedent and statutory authority—not just *Myriad’s* holding as a new rule—which the Guidance seeks to establish. *Myriad* properly “relies on *Chakrabarty* and serves as a reminder that *Chakrabarty’s* markedly different criterion is the eligibility test across all technologies for product claims reciting natural products; and *Myriad* cites *Mayo* in support of its statement that there is a ‘rule against patents on naturally occurring things.’”<sup>51</sup> Combining statutes and case law into rules binding executive agencies is within USPTO’s purview and essential to furthering progressive legislation. The Guidance is an excellent example for an agency’s successful implementation of the law, provided that no alterations are made to the current draft. CFS commends USPTO for correctly applying the Supreme Court’s long-standing rule against patents on naturally occurring things, as expressed in its earlier precedent, including *Chakrabarty* and *Mayo*.<sup>52</sup>

The application of § 101 in *Myriad* further clarifies that the limited scope of the case does not limit the applicability of the holding to other instances where claims are ineligible for patenting. In support, the New Guidance properly draws upon Examples E, F, and H to illustrate how the impact of *Myriad* affects the line of inquiry into patentability of products of nature.<sup>53</sup> Other examples, however, illustrate the protocol under the New Guidance pursuant to previous case law, such as *Chakrabaty* in Example A(2) and *Funk* in Example D.<sup>54</sup> Thus, the Guidance addresses the impact of *Myriad*, while the intent of the Guidance is to supersede prior protocols and “assist examiners in determining whether a claim reflects a significant difference from what exists in nature and thus is eligible.”<sup>55</sup> *Myriad*, therefore, serves as a conduit to update patent examination policy of natural products clearly and correctly.

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<sup>49</sup> *Myriad*, 133 S.Ct. at 2111 (holding that “a naturally occurring DNA segment 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”).

<sup>50</sup> New Guidance at 3.

<sup>51</sup> Cohan et al., *Evaluating Subject Matter Eligibility Under 35 USC § 101* at 16.

<sup>52</sup> *Id.*

<sup>53</sup> New Guidance at 11–14, 18.

<sup>54</sup> *Id.* at 6–7, 10.

<sup>55</sup> Memorandum, Andrew H. Hirshfeld, Deputy Commissioner For Patent Examination Policy (Mar. 4, 2014).

## VII. Under the Correct Application of the New Guidance, Genes, as One of Many Examples from Nature, are Not Patentable Subject Matter and Should Remain Ineligible.

The New Guidance, as the examples illustrate, combine *Myriad* and *Mayo* into a rule that supports the exclusion of the genes in *Myriad* from patentability and CFS supports this line of reasoning. Gene sequences are not akin to a conventional chemical substance or a drug; they are instead fundamentally information, an informational molecule embodying the genetic code. The patent for a particular gene sequence patents the information contained in the sequence—for example, the As, Ts, Cs, and Gs of the genetic code.<sup>56</sup> The tens of thousands of genes in our bodies are involved in the production of over 100,000 biological proteins.<sup>57</sup> The patent holder that purports to describe one commercial use should not then have a monopoly on all possible functions, particularly given that each commercial use covers only a small amount of what the patented gene does.<sup>58</sup> Recent scientific advances have undermined prior assumptions of the gene's role, and instead revealed a much more complicated and nuanced relationship between the DNA and the human body. Privatizing these building blocks of a larger systemic and not-yet-understood field further impedes the progress of science.

As previously stated in the Amicus Brief, natural laws and phenomena are “nature’s handiwork,”<sup>59</sup> “the basic tools of scientific and technological work.”<sup>60</sup> As such, the doctrine establishes a “bright-line prohibition against patenting laws of nature” which also serves as a “proxy for the underlying ‘building-block’ concern.”<sup>61</sup> Hence “patents cannot issue for the discovery of the phenomena of nature, [which are] part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none.”<sup>62</sup> Permitting the patenting of these indispensable building blocks is contrary to the fundamental purposes of patent law, because it would “monopoliz[e]” those “basic tools of scientific and technological work,” “impede innovation more than . . . promote it,” and “risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries.”<sup>63</sup> The privatization of genetic heritage also violates fundamental common law precepts of common heritage, the public domain, and the public trust. Finally, the granting of gene patents creates a system where people are reduced to “treasure troves” to be mined for private economic gain, violating the fundamental rights of indigenous peoples as well as patients.

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<sup>56</sup> See, e.g., Sunny Bains, *Double Helix Doubles as Engineer*, 279 *Sci.* 2043, 2044 (1998) (detailing the four bases making up DNA: cytosine, guanine, adenine, and thymine).

<sup>57</sup> See, e.g., Alan E. Guttmacher & Francis S. Collins, *Genomic Medicine—A Primer*, 347 *New Eng. J. Med.* 1512, 1514 (2002).

<sup>58</sup> *Funk*, 333 U.S. at 132 (“[W]e cannot so hold without allowing a patent to issue on one of the ancient secrets of nature now disclosed.”).

<sup>59</sup> *Chakrabarty*, 447 U.S. at 310.

<sup>60</sup> *Gottschalk*, 409 U.S. at 67.

<sup>61</sup> *Mayo*, 132 S.Ct. at 1303.

<sup>62</sup> *Funk Bros.*, 333 U.S. at 130 (citing *Le Roy*, 55 U.S. (14 How.) at 175); accord *Bilski*, 130 S.Ct. at 3225; *Chakrabarty*, 447 U.S. at 309.

<sup>63</sup> *Mayo*, 132 S.Ct. at 1293–94.

CFS opposes the patenting of genes because genes are a part of nature. USPTO correctly maintains that the “Supreme Court made it clear in *Myriad* that isolating a gene, even though it ‘creates a nonnaturally occurring molecule’, is not enough for eligibility. Instead, eligibility requires the creation of something not naturally occurring, which is markedly different from what exists in nature.”<sup>64</sup> A substance whose characteristics and function are indistinguishable from those of its naturally-occurring counterpart, such as a gene, cannot constitute patentable subject matter.<sup>65</sup> Therefore, genes, as indisputable products of nature are not patentable subject matter. Similarly, laws of nature and natural products, for which genes are merely an example, should be excluded from patentability for all the aforementioned reasons because “[p]urely ‘conventional or obvious’ ‘[pre]-solution activity’ is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law.”<sup>66</sup> For all these reasons, the New Guidance correctly excludes natural products from patent eligibility.

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<sup>64</sup> USPTO, Presentation, Subject Matter Eligibility Forum at 22.

<sup>65</sup> Amicus Brief at 6 (citing *Funk*, 333 U.S. at 130–31).

<sup>66</sup> *Mayo*, 132 S.Ct. at 1298 (citing *Flook*, 437 U.S. at 590; *Bilski*, 3225 (holding that ‘the prohibition against patenting abstract ideas ‘cannot be circumvented by’ . . . adding ‘insignificant post-solution activity’” (internal citation omitted)).



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## CONCLUSION

For all the foregoing reasons, CFS supports the unaltered and unchanged Guidance as it currently stands and encourages USPTO to abide by the line of inquiry set forth in determining the patent-eligibility of claims reciting or involving laws of nature, natural principles, natural phenomena and natural products.

Thank you for the opportunity to provide comments.

Respectfully submitted,

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