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950 F STREET, NW, SUITE 300 • WASHINGTON, DC 20004 • 202-835-3400 • PhRMA.org

David E. Korn
Vice President, Intellectual Property & Law

July 31, 2014

VIA EMAIL: myriad-mayo_2014@uspto.gov

Raul Tamayo
Senior Legal Advisor
Office of Patent Legal Administration

Re: Guidance for Determining Subject Matter Eligibility of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products:

I am writing on behalf of the Pharmaceutical Research and Manufacturers of America ("PhRMA") to convey the views of PhRMA's members on the Guidance for Determining Subject Matter Eligibility of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products.

PhRMA's members are leading pharmaceutical research and biotechnology companies devoted to researching and developing new medicines to allow patients to live longer, healthier and more productive lives. PhRMA's members lead the way in finding cures and new treatments as well as in developing critically important improvements to existing therapies. Patent protection is an important incentive to promote the innovative research necessary for such advances and to make available to society the benefits of that research.

The enclosed comments include views of PhRMA's members on the Guidance. PhRMA's members appreciate the PTO seeking comments on the Guidance, and would welcome further dialogue with the PTO with respect to the Guidance.

Please feel free to contact me if you have any questions.

Sincerely,

David E. Korn

Enclosure

Comments of the Pharmaceutical Research and Manufacturers of America
Submitted to: myriad-mayo_2014@uspto.gov
July 31, 2014

Comments of the Pharmaceutical Research and Manufacturers of America in Response to the United States Patent and Trademark Office's Request for Comments on its *Guidance for Determining Subject Matter Eligibility of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products*

The Pharmaceutical Research and Manufacturers of America (PhRMA) submits these comments in response to the United States Patent and Trademark Office's (PTO's) Request for Comments on its *Guidance for Determining Subject Matter Eligibility of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products* (Mar. 4, 2014) (Guidance).

PhRMA represents the country's leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for new cures. PhRMA members alone invested an estimated $51 billion in 2013 in discovering and developing new medicines. We offer the comments below from the perspective of research-based biopharmaceutical companies who depend on the patent system for the development of new drugs and biologics.

Comments

To foster continued economic growth and deliver the new breakthroughs that are needed to address the most complex and costly diseases and lower health care costs, PhRMA members rely on pro-innovation public policies, including an intellectual property regime that encourages and protects innovation. PhRMA members depend upon an efficient and fair system for examining and granting patents. The Guidance will add unnecessary uncertainty, cost and burden to PhRMA members in their efforts to secure patent protection for new and improved therapies. In fact, the Guidance is already creating tremendous uncertainty in the process of securing patent protection for pharmaceutical inventions. The Guidance is also adding unnecessary cost and burden to the PTO as Examiners are now directed to make subject matter eligibility rejections under 35 U.S.C. § 101 in a vast number of life sciences patent applications that would previously have been considered to recite patent eligible claims not requiring such scrutiny.

Given the importance of strong intellectual property rights to continued innovation in medicine, PhRMA provides the following comments regarding the Guidance.

Comments of the Pharmaceutical Research and Manufacturers of America
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1. ***The Guidance improperly goes beyond Myriad and Mayo holdings***

The PTO has gone beyond the holdings of *Association for Molecular Pathology Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013), and *Mayo Collaborative Services. v. Prometheus Laboratories, Inc.* 132 S. Ct. 1289 (2012). These cases must be understood within the bounds of the subject matter in those cases.

Myriad addressed the question whether a naturally occurring segment of deoxyribonucleic acid (DNA) or a synthetically created DNA known as complementary DNA (cDNA) is patent eligible under 35 U.S.C. § 101. *See Myriad*, 133 S. Ct. at 2111. The Supreme Court "[held] 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." *Id.*

Mayo addressed the question whether a process claim directed to a method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder was patent eligible. The Supreme Court reasoned that the process claims in question "purport[ed] to apply natural laws" and that "the claimed processes have [not] transformed these unpatentable natural laws into patent-eligible applications of those laws." *See Mayo*, 132 S. Ct. at 1294. The Court found that "the steps in the claimed processes (apart from the natural laws themselves) involve well-understood, routine, conventional activity previously engaged in by researchers in the field." *Id.*

Given these holdings, the PTO should have limited the scope of the Guidance. Instead, the PTO has cast an extraordinarily large net around all "natural products" which the PTO claims:

> includes, *but is not limited to*: chemicals derived from natural sources (e.g., antibiotics, fats, oils, petroleum derivatives, resins, toxins, etc.); foods (e.g., fruits, grains, meats and vegetables); metals and metallic compounds that exist in nature; minerals; natural materials (e.g., rocks, sands, soils); nucleic acids; organisms (e.g., bacteria, plants and multicellular animals); proteins and peptides; and other substances found in or derived from nature).

(Guidance at 3, emphasis in original).

This expansion of subject matter caught up by the PTO's heightened scrutiny of patent eligible subject matter is inappropriate and threatens further development on many inventions for which PhRMA members are currently seeking or had been planning to seek patent protection.

Gordon Cragg and David Newman, researchers in the Natural Products Branch of the National Cancer Institute at the National Institutes of Health, have analyzed and documented the importance of natural based therapies over the past 30 years of drug

development, from 1981 to 2010. *See* David J. Newman & Gordon M. Cragg, Natural Products As Sources of New Drugs over the 30 Years from 1981 to 2010 *J. Natural Prods.* 75: 311-335 (2012). They "demonstrat[e] that natural products play a dominant role in the discovery of leads for the development of drugs for the treatment of human diseases." *Id.* at 330. Cragg and Newman "strongly advocate *expanding*, not decreasing, the exploration of Nature as a source of novel active agents that may serve as the leads and scaffolds for elaboration into desperately needed efficacious drugs for a multitude of disease indications." *Id.* at 332 (emphasis in original). Yet the PTO's overbroad reading of the Supreme Court precedent could instead discourage such innovation.

The Guidance ignores the limitations of the Supreme Court ruling in *Myriad* and *Mayo*. The Guidance also fails to heed the Supreme Court's own warnings about the limits of the *Myriad* and *Mayo* holdings and instead improperly elevates and expands the Court's *dicta* statements, and takes them out of context.

In *Myriad*, the Supreme Court importantly noted "what is *not* implicated by this decision." *Myriad*, 133 S. Ct. at 2119 (emphasis in original). First, the Court pointed out that there were no method claims before it. Second, the Court noted that "this case does not involve patents on new *applications* of knowledge about the BRCA1 and BRCA2 genes." *Id.* at 2120 (emphasis in original). Third, the Court stated as follows:

> Nor do we consider the patentability of DNA in which the order of the naturally occurring nucleotides has been altered. Scientific alteration of the genetic code presents a different inquiry, and we express no opinion about the application of §101 to such endeavors. *Id*.

The Court in *Mayo* also made a point of noting that it was *not* deciding "whether were the steps at issue here less conventional, these features of the claims would prove sufficient to invalidate them." 132 S. Ct. at 1302. In addition, the Court distinguished the claims at issue from what it viewed as a typical drug use patent: "Unlike, say, a typical patent on a new drug or a new way of using an existing drug, the patent claims do not confine their reach to particular applications of [the natural laws at issue]." *Id.*

2. *The Guidance improperly synthesizes case law*

While PhRMA appreciates that the PTO desires to provide guidance to the examining corps regarding Supreme Court decisions, it is not appropriate to synthesize such decisions as has been done in the Guidance. By synthesizing the case law, the Guidance improperly expands the scope of an exception to patentability, making it a rule rather than an exception. As a matter of legal analysis, this is incorrect since a basic tenet of statutory interpretation is that exceptions should be interpreted narrowly. *See, e.g., Commissioner v. Clark*, 489 U.S. 726, 739 (1989) ("In construing provisions . . . in which a general statement of policy is qualified by an exception, we usually read the exception

narrowly in order to preserve the primary operation of the provision,") also citing *Phillips, Inc. v. Walling,* 324 U.S. 490, 493 (1945) ("To extend an exemption to other than those plainly and unmistakably within its terms and spirit is to abuse the interpretative process and to frustrate the announced will of the people.").

Indeed, the Supreme Court has cautioned against an overbroad reading of the laws of nature exception to patent eligibility under 35 U.S.C. § 101. In *Mayo*, the Court "recognized . . . that too broad an interpretation of this exclusionary principle could eviscerate patent law. For all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." *Mayo,* 132 S. Ct. at 1293. This concern was reiterated in *Myriad*, 133 S. Ct. at 2116, and most recently in *Alice Corp. v. CLS Bank*, 134 S. Ct. 2347, 2354 (2014) ("At the same time, we tread carefully in construing this exclusionary principle lest it swallow all of patent law.") . In his concurring opinion in *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 135 (1948), Justice Frankfurter had similarly cautioned that an overbroad reading of the exception "would lay the basis for denying patentability to a large area within existing patent legislation."

The Guidance should have presented and analyzed the relevant cases individually, since each case represents an exception to the statutory provision dictating subject matter eligibility. That is, each Supreme Court case describing an exception to patentability should have been construed narrowly and its rulings should not have been broadened by the Guidance.

Instead, the PTO has generated a "factor-based analysis" that lists six factors weighing toward eligibility and six factors weighing against eligibility based on a synthesized reading of all of the cases. *See* PTO's Guidance, and PTO's Eligibility Guidance Quick Reference Sheet (Reference Sheet). The PTO directs examiners that "[t]he determination of eligibility is not a single, simple determination, but is a conclusion reached by weighing the relevant factors, keeping in mind that the weight accorded each factor will vary based upon the facts of the application." Reference Sheet at 1. The problem with this approach is that the factors have been generated based on a broad reading of the case law, and without regard to the actual holding of each case as informed by the facts and limitations of each case. The all-encompassing definition of natural products presented by the PTO has further exacerbated the problem, such that a vast number of patent applications are now under a threat of patentable subject matter scrutiny pursuant to the Guidance. The factor-based analysis in the Guidance, therefore, is improper.

It is also inappropriate to justify this analysis on the basis that the same approach is used in an enablement analysis using the factors set forth in *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (*Wands* factors). An enablement analysis goes not to an exception to patentability (which by its nature should therefore be interpreted narrowly) but rather to the disclosure requirements for patent protection. In addition, since all of the *Wands* factors stem from one decision, it is appropriate to combine them in a multifactorial analysis since the factors are meant to be considered together and to carry equal weight.

The same cannot be said of the collection of Supreme Court cases that the PTO has synthesized in the Guidance.

In addition, the PTO has improperly combined passages from the *Myriad* and *Mayo* decisions to create the PTO's "significantly different" test. To the extent these passages can even be elevated to tests, they should have been kept separate and aligned with the holdings in the Supreme Court decisions. The Supreme Court in *Mayo* presented a "significantly more" inquiry as it relates to process or method claims. ("[The Court's precedents] insist that a process that focuses upon the use of a natural law also contain other elements or a combination of elements, sometimes referred to as an "inventive concept," sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself.)" *Mayo*, 132 S. Ct. at 1294. Referring to *Diamond v. Chakrabarty,* 447 U.S. 303(1980) the Supreme Court in *Myriad* observed that "[t]he *Chakrabarty* bacterium was new 'with markedly different characteristics from any found in nature' . . . due to the additional plasmids and resultant 'capacity for degrading oil.)'" *Myriad*, 133 S. Ct. at 2117 (quoting *Chakrabarty,* 447 U.S. at 310, 305 n.1). The Court, however, did not announce that this reasoning applied to its consideration of the DNA-based inventions in *Myriad*. The Guidance should stay true to Supreme Court precedent.

3. ***The Guidance must direct examiners to consider the claim as a whole***

The Guidance improperly focuses the Examiner's attention on the recitation of judicial exceptions as an element of the claim rather than on the recited claim as a whole. Question 2 in the Guidance asks: "Does the claim recite or involve one or more judicial exceptions?" Moreover, in applying the "significantly different" test, the PTO directs examiners to focus on individual claim elements.

In Mayo, the Court stated that a claim should be read as a whole and not dissected into parts when considering whether it embodies patentable subject matter. 132 S. Ct. at 1298: Steps in a claim must be "viewed as a whole." *Id.*

More recently, the Supreme Court issued its decision in *Alice Corp. v. CLS Bank*,134 S. Ct. 2347 (2014) in which it indicated that consideration of patent eligibility requires that "we consider the elements of each claim both individually and 'as an ordered combination' to determine whether the additional elements 'transform the nature of the claim' into a patent-eligible application." *Id.* at 2355 (quoting *Mayo*, 132 S. Ct. at 1298, 1297). Importantly, the Court emphasized in a footnote that the above approach "is consistent with the general rule that patent claims 'must be considered as a whole.'" *Id.* at 2355 n.3 (quoting *Diamond v. Diehr*, 450 U.S. 175, 188 (1981));

The Guidance should be amended to direct examiners to analyze claims in their entirety (i.e., "as a whole") to determine whether there is patent eligible subject matter, and then to not pursue the additional analysis contemplated by the Guidance or to formulate a

rejection if the answer is "yes." This could be accomplished by adding a question prior to Question 2 in the Guidance that asks: "Does the claim as a whole recite patent eligible subject matter?" If the answer is "yes," an Examiner would not need to pursue additional subject matter eligibility analysis under the Guidance. It would be appropriate to implement this change in both the questions and the flowchart. The proposed revision is in line with Supreme Court case law and would promote cost-efficient and less burdensome prosecution for both the PTO and for stakeholders.

4. *The Guidance improperly disqualifies functional features in claims*

According to the Guidance, a natural product can only be patent eligible if it has a "***marked*** difference in structure." *See* Guidance at 5. The discussion in the Guidance then provides several examples which impose requirements of increasingly detailed structural claim limitations to satisfy subject matter eligibility. This is improper. Rather than focusing only on the "marked difference," the Guidance should focus on patentability of the claim read as a whole as noted above. In addition, the Guidance's focus on marked differences in structure means that functional differences are overlooked.

Chakrabarty presents the following analysis for determining whether a claim is entitled to patentable subject matter:

> Here, by contrast, the patentee has produced a new bacterium with ***markedly different characteristics*** from any found in nature ***and one having the potential for significant utility***. His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under § 101.

Chakrabarty, 447 U.S. at 310 (emphasis added).

This analysis was referenced in *Myriad*. *See Myriad*, 133 S. Ct. at 2116-17. In *Funk Brothers*, the Court had also considered whether each of the species of root-nodule bacteria had acquired a different use and decided that "[e]ach of the species of root-nodule bacteria contained in the package infects the same group of leguminous plants which it always infected." *See Funk Brothers*, 333 U.S. at 131. Therefore, the Supreme Court case law permits functional limitations to define the scope of a claim and to render it patentable; so too should the Guidance.

5. *The Guidance may lead to improper prior art consideration*

The Guidance initially reminds examiners "that § 101 is not the sole tool for determining patentability" and notes that "sections 102, 103 and 112 will provide additional tools for ensuring that the claim meets the conditions for patentability." However, by focusing on the element or step that provides a "significant difference, " the

Examples in the Guidance may encourage examiners to improperly dissect claims and undertake improper prior art considerations during a § 101 analysis.

The Court in *Mayo* held as follows:

> To put the matter more succinctly, the claims inform a relevant audience about certain laws of nature; ***any additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community***; and those steps, ***when viewed as a whole***, add nothing significant beyond the sum of their parts taken separately. For these reasons we believe that the steps are not sufficient to transform unpatentable natural correlations into patentable applications of those regularities.

Mayo, 132 S. Ct.at 1298 (emphasis added)

Mayo at most suggests that it is appropriate to consider whether a step provides something more than just engaging in "well-understood, routine, conventional activity." This is only a general inquiry that should not invite examiners to review prior art. It is also an inquiry that pertains to the analysis of a method claim, not a product claim.

In making its assessment in *Mayo*, the Court reasoned that "scientists routinely measured metabolites as part of their investigations into the relationships between metabolite levels and efficacy and toxicity of thiopurine compounds." *Mayo*, 132 S. Ct. at 1298. Citing *Parker v. Flook*, 437 U.S. 584, 590 (1978), the Court found that this aspect of the claim added a "[p]urely 'conventional or obvious' '[pre]-solution activity' [that] is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law." *Id.* Citing *Diamond v. Diehr*, 450 U.S. 175, 191-192 (1981), the Court found that "the prohibition against patenting abstract ideas 'cannot be circumvented by . . . adding 'insignificant post-solution activity'." *Id.* The Guidance should not expand the PTO's analysis beyond the scope of the *Mayo* decision.

The Court in *Alice* also recently presented the following "framework for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts" 134 S. Ct. at 2355:

> First, we determine whether the claims at issue are directed to one of those patent-ineligible concepts. *Id.* at 2355. If so, we then ask, "[w]hat else is there in the claims before us?" *Id.* (quoting *Mayo*, 132 S. Ct. at 1297). To answer that question, we consider the elements of each claim both individually and "as an ordered combination" to determine whether the additional elements "transform the nature of the claim" into a patent-eligible application. *Id.* (quoting *Mayo*, 132 S. Ct. at 1298, 1297). We have described step two of this analysis as a search for an "'inventive concept'"—i.e., an element or combination of elements that is "sufficient to ensure that the patent in

> practice amounts to significantly more than a patent upon the [ineligible concept] itself." *Id.* (quoting *Mayo* 132 S. Ct. at 1294).

The Supreme Court reiterated the meaning of "inventive concept," provided in *Mayo,* 132 S. Ct. at 1294, and showed that a prior art analysis is not appropriate in an analysis under 35 U.S.C. § 101. Appropriate cautionary statements accordingly must be included in the Guidance to discourage examiners from engaging in a prior art review in the context of an analysis under 35 U.S.C. §101.

6. ***PTO steps beyond its powers***

The PTO's creation of the "significantly different" test goes beyond its powers. As noted above, the Guidance presents a new "significantly different" test for assessing patentable subject matter. The test combines the "*markedly different characteristics* from any found in nature" observation mentioned in *Myriad* and the "addition of *significantly more* to the judicial exception" inquiry presented in *Mayo*. Even assuming that the PTO is correct that these are the standards for assessing subject matter eligibility for natural products, the PTO's creation of a new test is fundamentally improper. The PTO is an agency that falls within the executive branch, not a court within the judiciary. As such, it does not have the power to create such a new legal standard.

The PTO's powers are set forth in 35 U.S.C. § 2. Generally, the PTO is responsible for granting and issuing patents and for disseminating to the public information with respect to patents. *See* 35 U.S.C. §2(a). More specifically, the PTO "may establish regulations, not inconsistent with the law which—(A) shall govern the conduct of proceedings in the Office; [and which] (B) shall be made in accordance with section 553 of title 5." *See* 35 U.S.C. §2(b.) The PTO does not have substantive rulemaking powers. *See, e.g., Animal Legal Defense Fund v. Quigg*, 932 F.2d 920, 930-31 (Fed. Cir. 1991), and *Merck & Co. v. Kessler*, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996). While the PTO may provide guidance to examiners interpreting the law, it may not create substantive tests that go beyond the law. As noted, the Guidance presents a new "significantly different" test for assessing patentable subject matter and applies this test beyond the scope of the Supreme Court cases that established exceptions to subject matter patentability. This exceeds the PTO's statutory jurisdiction.

Even if the PTO can justify its actions as falling within its statutory jurisdiction, at the very least the PTO's procedure relating to the issuance of the Guidance is flawed. The PTO should have developed the Guidance via notice and comment rulemaking procedures. As noted in 5 U.S.C. § 553, formal notice and comment rulemaking procedures must be followed unless the policy changes sought to be implemented apply "to interpretative rules, general statements of policy, or rules of agency organization procedure, or practice." The PTO likely justifies its position on the basis that its Guidance applies to interpretative rules. However, given the creation of a new test for assessing subject matter eligibility and the heightened scrutiny of patentable subject matter issues across a vast range of subject

matter that goes well beyond the Supreme Court case law, it cannot be said that the Guidance merely presents interpretative rules.

Finally, the Guidance does not further the constitutional and statutory goal of promoting the "Progress of Science and the Useful Arts." As noted by the Supreme Court in *Chakrabarty*, 447 U.S. at 315, "[t]he subject-matter provisions of the patent law have been cast in broad terms to fulfill [this] goal." Yet the Guidance is doing the opposite by broadly imposing exceptions to patentable subject matter. The PTO's approach is at odds both with the Constitution and with Supreme Court case law.

Conclusion

The potential negative impact of the Guidance and the PTO's approach to subject matter eligibility analysis cannot be overstated. Pharmaceuticals derived from natural products have been the sources of new drugs and continue to provide great potential for many new therapies. Researchers have identified natural products as being "a major source of new structural leads" for drug development and have suggested that "the potential of microbial diversity remains essentially untapped." *See* Gordon M. Cragg & David J. Newman, "Natural Products: A Continuing Source of Novel Drug Leads" *Biochimica et Biophysica Acta* 1830, Abstract (2013): 3670-3695. However, this potential for new therapies could remain untapped due to uncertainty about the ability to secure patent protection for such therapies while such patents become caught in the PTO's "natural products" scrutiny and patent eligibility analysis. The Guidance is already adding cost and burden to the PTO in its examination efforts, and to PhRMA members in their efforts to secure patent protection on their inventions.

We are grateful that the PTO is reaching out to stakeholders regarding the Guidance. As the United States' agency tasked with implementing the patent system, the PTO should be supportive of innovation in the life sciences. Yet the Guidance fails to provide such support—to the contrary, it discourages such innovation. PhRMA urges the PTO to revise its Guidance in a way that fosters R&D investment and helps deliver to the public the scientific promise of future drug and biological products. Given that the Supreme Court's ruling in *Alice* came after the Guidance and yet *Alice* includes a framework for analyzing claims with abstract ideas, laws of nature and natural phenomena, the Guidance is already outdated and for this reason alone requires revision. The current Guidance should be withdrawn and an appropriately-revised Guidance in accordance with these comments should be presented for consideration by stakeholders by way of formal notice and comment procedures.