From: JJHU (Jamie Hu)
Sent: Wednesday, July 23, 2014 2:50 PM
To: myriad-mayo_2014
Subject: Comments on Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products

Dear Acting Director Lee:

Attached are comments by Novo Nordisk in response to the USPTO's request for comments on Guidance for determining subject matter eligibility of claims reciting or involving laws of nature, natural phenomena, & natural products.

Best regards,

Jamie Hu

_____

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July 24, 2014

VIA E-MAIL: myriad-mayo_2014@uspto.gov

The Hon. Michelle K. Lee
Deputy Under Secretary of Commerce
Acting Director
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

RE: Comments by Novo Nordisk in Response to the USPTO's Request for Comments on Guidance For Determining Subject Matter Eligibility of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products (Guidance)

Dear Acting Director Lee:

Novo Nordisk A/S and Novo Nordisk Inc. ("Novo Nordisk") respectfully request that the United States Patent and Trademark Office ("PTO") consider the following comments in response to its request for feedback on: Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products ("Guidance").

Novo Nordisk also submits, at the conclusion of this letter, an alternative approach to the overall process for analyzing eligible subject matter under 35 U.S. C. §101 to address the issues raised by the comments submitted herewith.

Novo Nordisk appreciates the PTO's public outreach to solicit feedback on the Guidance, and wishes to assist the PTO in developing additional guidance and update on subject matter eligibility via Novo Nordisk's specific comments and proposed changes to the Guidance.

Novo Nordisk's Background

Novo Nordisk is a pioneer in biotechnology and a world leader in diabetes care with more than 40,000 employees, with offices in the United States, Denmark and many other areas of the world, including Japan, China, India, Africa, and Brazil. For nearly 90 years Novo Nordisk has combined drug discovery with technology to turn science into solutions for people with diabetes. Novo Nordisk also provides treatments for people with hemophilia and growth

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hormone deficiency, and for women experiencing symptoms of menopause. Novo Nordisk manufactures and markets pharmaceutical products, including medical devices, which make a significant difference to our patents' lives, the medical profession, and society.

Novo Nordisk's Comments

Novo Nordisk applauds the PTO on taking the initiative to issue a Guidance on subject matter eligibility in an attempt to apply the recent Supreme Court decisions including *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. __, 133 S. Ct. 2107, 106 USPQ2d 1972 (2013) ("*Myriad*"), and *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. __, 132 S. Ct. 1289, 101 USPQ2d 1961 (2012) ("*Mayo*") to the examination process.

In Novo Nordisk's view, however, the Guidance, including the training materials published shortly thereafter, has serious flaws. The Guidance has gone far beyond what the Supreme Court ruled in recent subject matter eligibility cases and lacks sound legal support from judicial precedents. Novo Nordisk's comments focus on the following several aspects:

(1) The Guidance violates a fundamental principle that patent eligibility be evaluated by considering a claim as a whole

The Supreme Court has long held that a §101 analysis must be performed with respect to a claim as a whole. As firmly stated in *Diamond v. Diehr*, 101 S.Ct. 1048, 1057-58 (1981),

> In determining the eligibility of respondents' claimed process for patent protection under § 101, their claims must be considered as a whole. It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis. This is particularly true in a process claim because a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made. The 'novelty' of any element or steps in a process, or even of the process itself, is of no relevance in determining whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter.

This patent law principle has also been acknowledged in the most recent Supreme Court ruling in *Alice Corp. v. CLS Bank Internationa*l (S. Ct., 2014)[1].

Although the Guidance on its face asks whether a "claim as a whole" recites something "significantly different" than the judicial exceptions, the Guidance fails to instruct an Examiner to weigh the claim as a whole or to consider all claim elements in combination in its 12-factor analysis. The Guidance *de facto* deviates from this long standing tenet; and instead applies the

[1] *See, e.g.*, FN3 of *Alice Corp. v. CLS Bank International* (S. Ct., 2014), "Because the approach we made explicit in Mayo considers all claim elements, both individually and in combination, it is consistent with the general rule that patent claims 'must be considered as a whole.' Diamond v. Diehr, 450 U. S. 175, 188 (1981)...."

exact opposite approach when it dissects claims into individual steps and elements in its analytical framework.

For instance, the second question in the flowchart asks: "does the claim recite or involve judicial exception(s)?" The ambiguous "recite or involve" language implies that each part of the claim, rather than a whole claim, will be subjected to a "judicial exception" scrutiny.

The 12-factor analytical framework set forth in Section II ("how to analyze 'significantly different'") completely ignores the "claim as a whole" principle. Indeed, factors b)-f) and h)-l) direct the Examiner to first determine whether a claim recites "elements/steps *in addition* to the judicial exception(s)" (*emphasis added*) and then to determine whether such elements/steps impart certain limits on the claim (e.g., factor b, whether the elements/steps "imposed meaningful limits on claim scope"). This assessment necessarily requires a parsing of the claim into parts, such that only the "elements/steps in addition to the judicial exception(s)" are analyzed. Similarly, factors a) and g) instruct the Examiner to evaluate whether "the differences between the recited product and naturally occurring products...rise to the level of a ***marked*** difference in structure." This evaluation requires the Examiner to focus only on structural differences, which involve a parsing of a claimed product into separate components.[2]

The Examples of Section III further reinforce the Guidance's focus on evaluating individual elements or steps in isolation without taking the claim as whole or combination of all elements into consideration. *See, e.g.*, Example C and training slide 55, in which the Guidance concludes that gunpowder is not markedly different from what exists in nature because each individual component of gunpowder (i.e., saltpeter, sulfur and charcoal) has not been changed. The Guidance does not consider gunpowder as a whole, and overlooks the fact that the combination of saltpeter, sulfur and charcoal, does not exist in nature. Furthermore, the Guidance is completely silent with respect to the fact that gunpowder, as a mix of three naturally occurring materials, bears a new property, being explosive, not present in and totally different from any of its naturally occurring components.

In the case of combination claims, like gunpowder, the invention lies in bringing the components together and the resultant combination may be something not occurring in nature and may have a new property, function or use compared with its individual naturally present components.

By instructing an examiner to apply the 12-factor analysis to individual "elements or steps" of a claim, the Guidance departs from the long standing legal principle that patent claims must be considered as a whole, and leads to the absurd outcomes, for example, that gunpowder, one of the most important and world-changing inventions, may not pass muster for patent eligibility.

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[2] The Guidance's failure to weigh functional features of a claim will be addressed *infra*.

(2) The Guidance disqualifies functional features without sound legal justification

The Guidance improperly imposes a requirement that a product claim must recite something that is both non-naturally occurring and markedly different in *structure* in order to be patent eligible. Absent a specific structural difference, no weight is given to functional benefits of the claimed subject matter. The Supreme Court precedents do not support such a restrictive interpretation of the law.

It appears that the Guidance deduces this "structurally different" requirement from *Funk Brothers* and *Myriad*. Both cases, however, stand for the proposition that the existence of a novel functional feature is a factor to be weighed in favor of patent eligibility.

As stated in *Funk Brothers*—

> Each of the species of root nodule bacteria contained in the package infects the same group of leguminous plants which it always infected. No species acquires a *different use*. 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. They serve the ends nature originally provided, and act quite independently of any effort of the patentee. *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948) (*emphasis added*).[3]

This was cited in its entirety in another natural product case, *Diamond v. Charkrabarty*, 447 U.S. 303 (1980). To distinguish from *Funk Brothers*, the *Charkrabarty* court stated that,

> 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...His claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring naturally manufacture or composition of matter—a product of human ingenuity 'having a *distinctive name, character [and] use*.' Hartranft v. Wiegmann, 121 U.S. 609, 121 U.S. 615 (1887) (*emphasis added*).

Both *Funk Brothers* and *Charkrabarty* give great weight to "different use," "range of utility," "significant utility," and "markedly different characteristics" in assessing patent eligibility. In *Funk Brothers*, an inoculant for leguminous plants was found to be patent ineligible because each of the species of root-nodule bacteria does not acquire a new use, expand utility or improve its natural function. In *Chakrabarty*, the modified bacterium was found to be patent eligible due to the additional plasmids and possession of markedly different characteristics-- a "capacity for degrading oil."

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[3] It is noted that *Funk Brothers* preceded the 1952 patent act that separated the definition of patent-eligible subject matter (§101) from the requirements for patentability such as novelty (§102) and nonobviousness (§103); thus the Guidance's overly broad application of *Funk Brothers* in §101 analysis is questionable.

New use, utility, and differentiating characteristics are important considerations in assessing patent-eligibility in Supreme Court precedents and there is no legal ground to limit the §101 analysis to only "structural differences."

Myriad is also consistent with the position that a new characteristic, utility, or function could convert an otherwise "naturally occurring substance" into patent eligible subject matter.[4]

Myriad uses the term "information" to refer to the function of DNA. For instance, *Myriad* states: "Sequences of DNA nucleotides contain the information necessary to create strings of amino acids...." The Court considered both functional (information) and structural changes in assessing whether isolated human genes are patentable. See, *e.g.*, "Myriad did not create or alter either the *genetic information* encoded in the BCRA1 and BCRA2 genes or the *genetic structure* of the DNA;" "...its claim is concerned primarily with the *information* contained in the genetic sequence, not with the specific chemical composition of a particular molecule" (*emphasis added*).

As such, *Myriad*'s analysis takes both structural and functional differences from a natural product into consideration in determining patent eligibility. Myriad is compatible with the proposition that changes in function, use, or characteristics --not just structure-- should be weighed in the §101 analysis.

The Guidance should not interpret *Myriad* and *Funk Brothers* as requiring "markedly different structure," which contradicts Supreme Court precedents collectively. Physical differences, which could include form or purity, not just structure, as well as a new function or use relative to the natural product, could carry significant weight in assessing patent eligibility.[5]

(3) The Guidance improperly conflates §101 analysis with statutory requirements under §§102, 103 and 112

Patent eligibility under §101 is a separate and distinct requirement which should be resolved independently from the patentability conditions under §§102, 103 and 112. Furthermore, §101 should be a threshold inquiry: the claimed subject matter must first meet the minimum

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[4] The Guidance has improperly expanded the analysis of *Myriad*. The Supreme Court's order granting *certiorari* in *Myriad* was limited to the question: "Are human genes patentable?" The Court has limited its holding to genes and has explicitly stated that "we 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." The Guidance has expanded *Myriad* to apply to almost everything that could be derived from a product of nature, in direct contradiction to the Supreme Court's clear intention of a limited holding of *Myriad*.

[5] *See* Dr. Leslie Fisher, Novartis Pharmaceuticals, slide 2 of the presentation in the USPTO's round table forum held on May 9, 2014.

standard for patent eligibility. Then, to be accorded patent protection, the claim must be novel, non-obvious, and adequately enabled and described under §102, §103 and §112, respectively.

Each of these requirements is codified in different sections of Title 35 of the Patent Act *without cross-references*. In particular, the Patent Act of 1952 moved patentable subject matter and novelty inquiries of the old 35 U.S.C. §31 to 35 U.S.C. §101 and §102, respectively, and codified the judicially created "invention" inquiry in 35 U.S.C. §103. It is clear that the legislation intended these requirements to be analyzed separately and distinctly and not to overlap with each other.

The 12-factor analytical framework of the Guidance seems to import §102 and §103 analysis into the §101 inquiry. For instance, factors f, j, k, l relate to analyzing whether a claim recites one or more elements/steps in addition to the judicial exceptions that add a feature that is more than well-understood, purely conventional or routine in the relevant field; or that are insignificant extra-solution activity; or that amount to nothing more than a mere field of use. The terms "well-understood," "conventional," "routine," and "insignificant" all point to canonical §102/§103 analysis.

By conflating patentability considerations under §§102, 103 and 112 with patent eligibility analysis under §101, the Guidance runs afoul of the legislative intent of Congress. The Guidance invites the Examiner to turn all patentability inquiries into a question of patent eligibility under §101, blurring the boundaries among distinct and separate sections of the Patent Act.

In some Office Actions received by Novo Nordisk, the Examiners commingled §103 arguments with §101 reasoning under the new Guidance. The prior art cited in obviousness rejections has also been used in support of the §101 rejections. It is simply inappropriate to perform a prior art analysis to answer the threshold question of patent eligibility under §101.

The Guidance should clearly differentiate the patent eligibility inquiry under §101 from the patentability analysis under §§102, 103 and 112, to honor the patent statute and legislative intent and let each individual section under title 35 do the work which it was meant to do.

(4) The Guidance will stifle innovation and jeopardize the entire Pharma/Biotech industry

§101 of the patent statute broadly defines patent-eligible subject matter, and courts have only created *narrow* exceptions to the statute, including laws of nature, natural phenomena, products of nature and abstract ideas. In recent Supreme Court rulings on subject matter

patent eligibility, the court has been cautious in limiting the scope of its decision to the particular issue before it and warned against overly broad interpretation of its holdings.[6]

The Guidance does exactly what the Supreme Court warned against—interprets this exclusionary principle too broadly by turning a judicial exception into a rule—and consequently could eviscerate patent law, stifle innovation in the Pharma/Biotech industry, and ultimately curtail the public's access to new therapeutics.

Novo Nordisk is extremely concerned by the finding that, among 1355 FDA new drug approvals between 1981 and 2010:
(a) 71% (968) would not be patent eligible under the Guidance;
(b) 50% of all small molecule drugs are natural products (2000-2010);
(c) about 75% of antibacterial drugs are natural products or derived from natural products; and
(d) almost 80% of small molecule anticancer drugs are natural products or derivatives.[7]
Critically, in the next 20 years biologics will be the predominant type of drugs on the market and many of these drugs could be patent-ineligible under the Guidance.[8]

As shown by these statistics, the Guidance casts a shadow over patent protection for a broad spectrum of biotech and pharmaceutical products. A significant percentage of existing products, and even more products under development, which rely on patent protection to attract investments for originating, developing, and transforming innovation into commercially available products, would now be precluded from the patent realm.

Bringing a new drug to market involves a huge commitment of capital, time, and human resources. Patent protection provides a means for the stakeholders to re-capture this investment and thus fuel future innovation. By casting doubt on the availability of such an essential element of the business model, the Guidance creates great uncertainty with respect to future investment in the Pharma/Biotech area.

The Guidance not only adversely affects future innovation and product development; it also creates uncertainty as to the validity of many existing biological/chemical patents. Although the Guidance carries no force of law, as an important policy document promulgated by the PTO, it may influence the public's and the courts' perception of the strength of the patents. Judges may consider the Guidance as persuasive authority when ruling in patent cases, further

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[6] As explicitly stated in *Myriad* (quoted *Mayo*): "The rule against patents on naturally occurring things is not without limits, however, for '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.'" 566 U. S., at ___ (slip op., at 2)."
[7] Sherry Knowles; Kevin Noonan; NIH Natural Product Branch Report (Newman and Craig, J.Nat.Prod. 75(3):311-55(2012)).
[8] *Id.*

weakening confidence in those patents. The value of tens of thousands of issued biological/chemical patents could be compromised.

Since the Guidance is an internal PTO document, there is no effective way to challenge it other than pursuing litigation in court, and it will take years to unravel the negative effects of the Guidance. In the meantime, innovative activities would be discouraged and future development of new products to meet the patients' needs would be at serious risk.

Novo Nordisk's Proposed Alternative

In determining patent eligibility under §101, Novo Nordisk believes that 1) the threshold for eligibility under §101 should be relatively low; 2) the claim should be considered as a whole; 3) the inquiry should not be limited to only "structural differences;" and 4) the §101 inquiry should be separate and distinct from patentability analysis under §102, §103, and §112.

Accordingly, Novo Nordisk proposes a two-step approach to determine subject matter eligibility:

(1) Is the claim directed to one of the four statutory categories, i.e., a process, machine, manufacture, or composition of matter? (Same as the Guidance's first step)
(2) Is the claim as a whole directed to a judicial exception?
    a. As long as the claimed subject matter, as a whole, is different from a naturally occurring product, the claim should pass muster under §101.
    b. The difference relative to the natural product could be any difference in structure, purity, form, function, utility, etc.[9]
    c. The significance of the differences should not be a part of the §101 inquiry but, if applicable, should be evaluated under §102, §103, and §112.

The Guidance instructs the Examiners to weigh 12 factors without giving sufficient guidance on how this should be done. It would be up to each individual examiner to subjectively allocate weight to each factor and use his/her discretion to reach a conclusion. The 12-factor analysis will lead to inconsistent §101 outcomes for similar claims that are examined by different Examiners and risks misapplication of the analysis due to its convoluted nature.

In contrast, Novo Nordisk's proposal addresses all issues raised in this feedback and greatly simplifies the analytical framework for §101 analysis, which could be applied uniformly and reasonably in the examination practice.

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[9] *See also* Dr. Leslie Fisher, Novartis Pharmaceuticals, slide 2 of the presentation in the USPTO's round table forum held on May 9, 2014.

Analysis of Sample Claims Proposed by the PTO at the 2014 BIO International Convention

Following is an analysis of the PTO's sample claims using Novo Nordisk's proposed approach:

All seven sample claims satisfy the requirements imposed by step (1), therefore, the analysis of each individual claim focuses on step (2).

1. Isolated nucleic acid comprising a sequence that has at least 90% identity to SEQ ID NO:1 and contains at least one sequence modification relative to SEQ ID NO: 1.

Analysis: Patent eligible because the claimed isolated nucleic acid is different from naturally occurring SEQ ID NO: 1. The significance of the sequence modification for patentability should be further analyzed under §102 and §103.

2. Polypeptide comprising an amino acid sequence that has at least 90% identity to SEQ ID NO: 2 and contains at least one sequence modification relative to SEQ ID NO: 2.

Analysis: Patent eligible because the claimed polypeptide is different from naturally occurring SEQ ID NO: 2. The significance of the sequence modification for patentability should be further analyzed under §102 and §103.

3. A nucleic acid comprising SEQ ID NO: 1 and a fluorescent label attached to the nucleic acid.

Analysis: Patent eligible because the claim as a whole is directed to a combination of SEQ ID NO: 1 and a fluorescent label and such combination does not exist in nature.

4. A chimeric or humanized antibody to Antibiotic L.

Analysis: Patent eligible because the chimeric or humanized antibody to antibiotic L does not exist in nature.

5. Purified Antibiotic L.

Analysis: Patent eligible because purified antibiotic L is different from the naturally occurring antibiotic L with respect to purity and utility (assuming the purified antibiotic L could be administered to human while the naturally occurring one could not).

6. Antibiotic L, which is expressed by recombinant yeast.

Analysis: Patent ineligible because considering the claim as a whole, the claimed antibiotic L expressed by recombinant yeast does not seem to possess any difference from the naturally occurring antibiotic L produced by bacteria.

7. A human or fully human antibody to Antibiotic L.

Analysis: Patent eligible because human antibody to antibiotic L does not exist in nature according to the factual assumptions.

In conclusion, Novo Nordisk strongly urges the PTO to revise the Guidance so that the Supreme Court's decisions on patent eligibility would be administered in a reasonable and workable way that would lead to the consequence intended by the Patent Act—to spur innovation and promote the progress of science and useful arts.

Respectfully Submitted,

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