To: myriad-mayo_2014@uspto.gov

Dear Commissioner:

The following submission does not necessarily reflect the opinions of Foley and Lardner, LLP, or its clients.

The "Myriad-Mayo" patent subject matter eligibility guidance issued March 4, 2014 reflects the USPTO's interpretation of Supreme Court cases interpreting and applying 35 USC § 101 to claims involving laws of nature, natural phenomena, and natural products, but the USPTO appears to have issued the Guidance without considering whether it comports with the United States' obligations under international treaties, such as the Uruguay Round Agreements Act (URAA) and the Trade-Related Aspects of Intellectual Property (TRIPS). Here, I highlight how the Guidance is inconsistent with both the requirements of TRIPS in particular and U.S. trade policy in general.

The USPTO Guidance Is Contrary To TRIPS

Article 27(1) of TRIPS states (in part):

[P]atents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. ... patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

Under Art 27(2), members may exclude from patentability those inventions necessary to protect public order, health and the like. For example, Art 27(3)(a) refers to "diagnostic, therapeutic and surgical methods for the treatment of humans or animals." While Art 27(3)(b) refers to "plants and animals other than micro-organisms," there is no categorical exclusion of inventions involving a "product of nature." That is, TRIPS does not permit a *per se* exclusion from patentability of claims involving a "product of nature."

Thus, the USPTO Guidance violates TRIPS when it declares unpatentable such inventions as "isolated amazonic acid" and orange juice formulated with a naturally occurring preservative.

The USPTO Must Follow TRIPS

The U.S. Congress incorporated the provisions of the URAA (and TRIPS) into U.S. law under 19 U.S.C. § 3511-3556. In doing so, Congress made two important reservations:

1. that no provision of the treaty would have effect if it is inconsistent with any U.S. law (19 U.S.C. § 3512 (a))
2. that a violation of TRIPS does not create a direct cause of action in a U.S. court (§ 3512 (c)).

Neither of these reservations shield the Guidance from the obligations of TRIPS. Thus, TRIPS has the force of law that the USPTO, as a federal agency, must comply with, and cannot ignore.

The USPTO should understand that the lack of a *direct* cause of action under TRIPS does not prevent an *indirect* action challenging an interpretation of a statute that violates TRIPS, and should appreciate that a federal court is obligated to construe U.S. statutes and regulations such that they do not conflict with treaty obligations, wherever possible. Indeed, 210 years ago Chief Justice Marshall declared in *Murray v. The Charming Betsy* that "an Act of Congress ought never to be construed to violate the law of nations if any other possible construction remains."

The USPTO may argue that *Charming Betsy* and its progeny have less force in view of decisions that gives greater deference to agency interpretations of statutes, such as the Supreme Court's *Chevron* decision, and the Federal Circuit's *Federal Mogul Corporation* and *Timken* decisions, but the USPTO does not have substantive rule making authority, and both *Federal Mogul* and *Timken* concerned specific issues well with the narrow and specific expertise of the relevant agencies. Those decisions do not support giving deference to USPTO Guidance that has a general and substantive impact across a broad swath of patent applications.

Thus, while the Supreme Court can determine that a U.S. law trumps a treaty obligation, and while TRIPS applies only to the extent that it does not conflict with other U.S. law, the USPTO should not interpret 35 USC § 101 in a manner that violates TRIPS.

Here, the Supreme Court interpreted § 101 to exclude from patentability isolated naturally-occurring DNA (*Myriad*), and method claims reciting natural phenomena (*Prometheus*). Assuming for the sake of argument that these holdings do not violate TRIPS (it does not appear that the Supreme Court was asked to consider the impact of 19 U.S.C. § 3511-3556 when rendering these decisions), they do not justify the USPTO's extension of these holdings contrary to TRIPS. In *Myriad* and *Prometheus* the Supreme Court considered whether specific patent claims satisfied the patent subject matter eligibility requirements of § 101. The Court did not create the sweeping new categories of "judicial exceptions" that are found in the USPTO Guidance.

Because the Guidance exceeds the holdings of *Myriad* and *Prometheus* in a manner that violates TRIPS, the Guidance should be retracted or invalidated as being contrary to law.

The USPTO Guidance Conflicts with U.S. Foreign Policy

The United States is not merely a party to TRIPS, but rather was the *main force behind* TRIPS. Indeed, TRIPS arose from United States' concerns that the lack of uniform intellectual property protection in developing nations put the United States at a competitive disadvantage. The pharmaceutical industry was particularly concerned with patent systems in large developing nations, like Brazil and India. Through TRIPS, India and other developing nations reformed their patent systems and removed numerous barriers to pharmaceutical patents.

The guidelines remove entire classes of subject matter from patentability, and place the USA far outside the mainstream of international practice. Thus, we have the U.S. government erecting *de facto* barriers to pharmaceutical and biotechnology patents, when the United States was such a strong advocate of patent rights in its support of TRIPS. Such inconsistency is not only ironic, but damaging to US leadership in the IP arena.

The USPTO Guidance Could Lead To International Disputes

Notwithstanding the provisions of 19 USC § 3512 (c), a foreign individual denied a patent under the USPTO Guidance may petition its government to bring suit against the United States for violating its treaty obligations. (Indeed, Eli Lilly is pursuing an action against Canada under the North American Free Trade Agreement for its treatment of pharmaceutical patents.) The USPTO should retract its Mayo-Myriad Guidance before it leads to international disputes and undermines the United States' position as a leader and champion of international patent rights.

Sincerely,

Simon J. Elliott, Ph.D. J.D
Associate, Foley and Lardner, LLP
3000 K St. NW, Washington DC, 20007
ph (202) 295 4726
sjelliott@foley.com