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Comments Of Natural Products Association on Patent Eligibility Jurisprudence Study

The Natural Products Association ("NPA") thanks the U.S. Patent and Trademark Office ("USPTO") for the opportunity to submit comments to relating to patent eligibility under 35 U.S.C. § 101. NPA also thanks Senators Tillis, Hirono, Cotton, and Coons for requesting this study.

Founded in 1936, NPA is the nation's largest and oldest nonprofit organization dedicated to the natural products industry. Natural products are represented by a wide array of consumer goods that grow in popularity each year. These products include natural and organic foods, dietary supplements, pet foods, health and beauty products, "green" cleaning supplies and more. Generally, natural products are considered those formulated without artificial ingredients and that are minimally processed. NPA advocates for the rights of consumers to have access to products that will maintain and improve their health, and for the right of retailers and suppliers to sell these products. NPA represents over 700 members, accounting for more than 10,000 retail, manufacturing, wholesale, and distribution locations of natural products, including foods, dietary supplements, and health/beauty aids. NPA unites a diverse membership, from the small health food stores to large dietary supplement manufacturers.

NPA played a key role in the passage of the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), Pub. L. No. 103-417, 108 Stat. 4325. This important legislation struck a balance between the need for consumers to have access to and information about safe and effective dietary supplements while also preserving the government's interest in protecting the public from unsafe products and false and misleading claims. Currently, NPA advocates before Congress, the

Food and Drug Administration ("FDA"), the Federal Trade Commission, and other federal and state agencies, legislatures, state attorneys' general and the courts.

Patents serve a critical consumer safety function in the dietary supplement industry. This is because patents form the sole basis for private causes of action to guard against unsafe knockoffs or adulterated supplements, which frequently originate from overseas, and are distributed throughout the United States. The *Mayo*/*Alice* decisions and their progeny have uniquely impacted the dietary supplement industry. Dietary supplements differ from most chemical and pharmaceutical innovation because many claimed compositions are often derived or synthesized from natural ingredients, as required by the Food, Drug and Cosmetic Act ("FDCA"). *See* 21 U.S.C. 301 *et seq*. That regulatory requirement places these beneficial products squarely in Section 101's crosshairs and subjects the associated innovation to particularized scrutiny. As such, dietary supplements have faced an onerous uphill battle in the face of Section 101 and NPA seeks improvement in the implementation of the law or logical expansion of the types of products deemed patent-eligible.

Patents are critical in assuring consumer safety in the dietary supplement industry for at least three key reasons. First, patents are the sole legal basis for a private cause of action against a knockoff (and likely unsafe) product. The FDCA vests sole enforcement authority of its provisions with the FDA. However, in the event an innovator or supplement company realizes that someone is knocking off its product—likely in an unsafe way—their sole regulatory recourse is to request that the FDA prevent the sale, manufacture or distribution of that product. If a company realizes that a knockoff product is being imported from overseas or distributed within the United States, they can only ask that the FDA prevent that sale or distribution. Most often, the FDA takes no action and these products are left to infiltrate the market and be ingested

by unwary consumers. The FDA regularly takes the position that it has both broad enforcement discretion and limited resources to police the market.

The relief companies in the dietary supplement industry seek from the FDA's enforcement is akin to that under the Patent Act (*see, e.g.*, 35 U.S.C. § 271), but, under the FDCA, the FDA has the sole authority as to when, how, and whether to enforce their powers at all. And along the way, the supplement company taking the appropriate steps to ensure their products are safe are left powerless knowing that a knockoff brand is potentially harming the public with unsafe and misleading products. This outcome arises in spite of thorough research, development, and great effort and expense to bring safe and effective health and wellness products to market.

Without patents and the possibility of their enforcement, knockoff dietary supplements can (and will) proliferate the market, subject only to the FDA's discretion to act. To date, the FDA has been frustratingly unwilling to utilize their statutorily-granted power to keep unsafe products off the market. Therefore, the inability to privately enforce their rights as a result of being knee-capped by Section 101 leaves dietary supplement companies at the whim of the FDA's willingness to enforce its regulation. This outcome casts dietary supplement companies as mere observers while free-riders are at liberty to place unsafe products into the market.

Like pharmaceutical approval in some respects, the FDA has a regulatory approval structure for innovative dietary supplements, though the enforcement has been far more lax than in the pharmaceutical industry. For example, one type of approval is when innovators in the supplement industry can seek approval for a new dietary supplement under the new dietary ingredient ("NDI") approval process. The FDCA provides for approvals for NDIs for ingredients that were not marketed as a dietary supplement in the United States before October 15, 1994.

The associated regulations vest the FDA with the power to keep unsafe products off the market—though it has been visibly reluctant to do so even after the grant of an NDI.[1] Thus, dietary supplement companies are frequently left "holding the bag" knowing that important and beneficial innovation will not be enforced by the FDA, and likely to be rejected by the USPTO under Section 101. This cuts against the incentive to innovate and to commercialize beneficial products for consumers. *See, e.g.*, Amelia S. Rinehart, *Patents As Escalators*, 14 Vand. J. Ent. & Tech. L. 81 (2011).

Second—and despite the FDA's unwillingness to enforce its regulations—patents form the framework for seeking the appropriate regulatory approval for innovative NDIs. Given that these products are definitively "new" under the regulation, innovators and product developers have little incentive to develop new products that can be easily copied without patent protection.

The companies marketing reliable, branded products are nearly always the ones also seeking patent protection because those same companies want to maximize the returns for their investment and have their product recognized to be safe by consumers. Additionally, consumers look to trusted brands knowing that those companies are more likely to sell and manufacture safe products. This assumption is premised on the notion that a reputable brand carries its associated goodwill in the arms of the product's safety—something a company does not want to risk diminishing via consumer harm from a knockoff competitor. The entirety of the dietary

[1] *See, e.g.*, Long, Josh, *Supplement Industry, FDA Clash Over NDI Enforcement*, available at https://www.nai-online.com/news_and_events/supplement-industry-fda-clash-over-ndi-enforcement/ (last visited October 15, 2021); *see also* Long, Josh, *FDA, supplement manufacturer debate NDI import alert request*, Natural Products Insider, available at https://www.naturalproductsinsider.com/regulatory/fda-supplement-manufacturer-debate-ndi-import-alert-request (last visited October 15, 2021); *see also* Montemarano, Mike, *Dietary Supplement Leaders Lament Pitfalls of FDA's Approach to NDIs*, Nutraceuticals World, available at https://www.nutraceuticalsworld.com/contents/view_online-exclusives/2020-12-07/dietary-supplement-leaders-lament-pitfalls-of-fdas-approach-to-ndis/ (last visited October 15, 2021).

supplement product development, claim substantiation, marketing, and subsequent regulatory approval are frequently initiated by the foundational technology contained within the associated patents. Put simply: reputable brands and companies invest in patents, seek parallel regulatory approval, and make safe products. And, as the court held in *Natural Alternatives Int'l, Inc. v. Creative Compounds, LLC*, 918 F.3d 1338 (Fed. Cir. 2019), a supplement patent can be eligible under Section 101.

Third, a patent attorney functions as an early technical advisor and gatekeeper to a dietary supplement company when technology is being developed. In most instances, the patent attorney working with a dietary supplement company is well-versed in the relevant technology and will: (a) suggest additional disclosure that will boost patent claims, such as method of use claims, to become more likely to satisfy the enablement and written description requirements; and (b) demonstrate unexpected results to potentially overcome any obviousness rejections. In either case, the patent attorney is likely pushing for the addition of data that not only justifies the patentability of the claims, but also substantiates the dietary supplement's safety and efficacy when marketed to consumers. Further, the attorney is likely to review the technology and provide oversight regarding how that product can be developed and placed into market. In this way, the early investigation about a product's patentability fosters outcomes that benefit the consumer. These same benefits are likely to be harmed by the current Section 101 landscape.

NPA thanks the USPTO for their consideration and would welcome the opportunity to respond to any questions and potential resolutions of patent eligibility.

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Respectfully submitted,

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