The Office Action refuses registration of Applicant's NEXTGEN DEVICES mark based on U.S. Application Serial No. 87/169772 ("the '772 application") for the mark NEXTGEN BIOLOGICS. Applicant respectfully disagrees with this refusal.

Applicant has applied for registration of his NEXTGEN DEVICES mark in connection with "Custom design services, namely, custom design of consumable devices housing lyophilized reagents awaiting hydration" and "Custom manufacturing services, namely, custom manufacturing of consumable devices housing lyophilized reagents awaiting hydration." The '772 application is seeking registration for the NEXTGEN BIOLOGICS mark in connection with "Biochemical catalysts, reagents, diagnostic reagents, and assays all for research use; chemicals for use in the manufacture or product development of biotherapeutics, biosimilars, pharmaceuticals, and therapeutics; nucleic acid products and reagents for laboratory use," "Medical, biological, and pharmaceutical preparations for the treatment of cancer, prevention and treatment of infectious diseases, treatment of genetic diseases; RNA-based therapeutic agents for producing and delivering therapeutic and antigenic proteins; medical diagnostic reagents," and "Scientific research and development in the fields of pharmaceuticals, medicine, biologics, biotherapeutics, biosimilars and therapeutics."

Applicant respectfully submits that his custom design and manufacturing services of consumable devices housing lyophilized reagents awaiting hydration are different than and travel in different channels of trade than the reagents, catalysts, biotherapeutics, pharmaceuticals, nucleic acids, RNA-based therapeutic agents, and research and development in connection with the aforementioned products, of the '772 application. Specifically, Applicant respectfully submits that there is quite a distinction between his design/manufacturing services of *devices* housing reagents awaiting lyophilization, and the pharmaceuticals, catalysts, reagents, and other substances of the '772 application. In short, one is related to *devices* and the other is related to *substances*. Additionally, Applicant respectfully points out that the Office Action has not come forth with any evidence to show that a consumer would expect his highly specialized services relating to consumable devices housing lyophilized reagents awaiting hydration, and the pharmaceuticals, catalysts, reagents, nucleic acids, and other substances of the '772 application to originate from the same source.

Consequently, Applicant respectfully submits that the Office Action has erred in refusing registration of Applicant's NEXTGEN DEVICES mark, and Applicant respectfully requests the withdrawal of the refusal of Applicant's mark.

The Office Action objects to the use of the term "consumable devices" in the identifications of services as allegedly being indefinite, and recommends that this wording be replaced with "consumable cartridges and containers." Applicant respectfully disagrees. First, the term "containers" is simply not a term of art in the lyophilization industry. Second, Applicant respectfully submits that the term "devices" as used in the lyophilization industry is not indefinite. In support of this contention, Applicant points to the Declaration of Applicant Timothy E. Pearcy, a subject matter expert in the lyophilization industry, and the testimony that one of skill in the lyophilization industry is well aware of the meaning of the term "device" in that industry. Applicant further respectfully submits that the knowledge of the term "device" in the lyophilization industry by persons of skill in that industry trumps any general definition in a general-purpose dictionary.

Applicant therefore respectfully submits that the identifications of services in his application are not indefinite, and Applicant respectfully requests the acceptance of the identifications of services in his application.

## **Declaration of Timothy E. Pearcy**

- I, Timothy E. Pearcy, hereby declare as follows:
  - I am the founder and sole owner of BIOLYPH, LLC, of Chaska, Minnesota, in 1993, and to this day continue to run BIOLYPH.
  - 2. BIOLYPH is in the business of developing advanced lyophilization technology.
  - 3. Due to my 40 years of experience in developing lyophilization technology, I am considered a global Subject Matter Expert
  - 4. In the lyophilization industry, those of skill in the art are familiar with the term "devices" and what this term means in the lyophilization industry. Therefore, the term "devices" as used in the lyophilization industry is not indefinite.

I declare under the penalty of perjury of the laws of the United States that the foregoing is true and correct.

Date: <u>December 27, 2018</u>

Timothy E. Pearcy