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Continuous Electrospinning Prototype Development for Spider Silk

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Items to Be Addressed:

1) Need for an outside technology license could be a liability.

After conducting a prior art search, we have not identified any patents that cover the technology we intend to use, just information published in the literature by Dr. Lin's group. Dr. Lin has been to visit our laboratory and talks have taken place between USU and Deakin University. When we commercialize the resulting instrument for continuous electrospinning with post spin processing capability, a more thorough search to identify relevant intellectual property will be performed and if identified, our established relationship with Dr. Lin and Deakin University's Technology Transfer Office will help secure that license. There is no way to anticipate what the necessary components and their configuration will be at the completion of the project. However, with preliminary discussions occurring and our amicable relationship with Dr. Lin and Deakin University, obtaining a license is thought to pose few challenges should we need to proceed in that direction.

2) Araknitek's relationship with university needs clarification.

When this proposal was submitted, the Araknitek relationship was different than it stands today and I think that perhaps led to some ambiguity. When the proposal was submitted, Araknitek Inc. was a wholly owned spin-out company. Araknitek Inc. was anticipated to be the commercialization partner for USU's spider silk IP portfolio. Subsequently, Araknitek Inc. has been dissolved. Recently, an independent team of experienced and successful entrepreneurs have started Araknitek Holdings with the intent to commercialize the USU spider silk IP portfolio. Mr. Phil Grimm, key contributor on this proposal, is the president/CEO of Araknitek Holdings.

Araknitek Holdings, LLC is registered in Delaware and was formed to commercialize the Spider Silk technology developed at the University. The Company will license the IP portfolio from USU and work closely with the research team to develop products based on the research conducted at USU.

3) The overall market discussion is weak, with no explicit initial focus identified, although several (e.g., surgical sutures, ballistic threads) are mentioned. In particular they are not clear on the unique mechanical properties of their material and where they exceed what is available in the market.

Synthetic fibers like nylon and polyester are the dominant materials used in applications today. The market for Nylon 6,6 is very large and growing. In 2014 7.2 million tons were manufactured, up from 6.4 million tons in 2010. The global nylon monofilaments market is expected to reach \$1.89 billion by 2020. Polyester continues to gain market share and today is a dominant material used in textiles and other applications. In 2014, 42 million tons of polyester were sold resulting in a market in excess of \$73 billion. Uses for these materials cover a broad array of market sectors including automotive, aerospace, industrial applications, consumer products, medical applications, and many others. The product is used in all regions of the world with Asia Pacific accounting for more than 60% of the global supply.

While these materials currently dominate the market, pressures to find alternatives exist as these materials require use of non-renewable resources and toxic manufacturing processes. Our meetings

with industry leaders (identified through NSF sponsored iCORPS program) have indicated interest in materials that not only have improved mechanical properties but especially those that avoid negative environmental impact. Spider silk meets these criteria and could be a direct replacement in premium price applications or blended with nylon, polyester or other materials to keep cost down while offering improved mechanical properties and minimizing environmental impact.

While our fiber materials will have a broad market appeal, our focus for this grant is to provide fibers in two different markets, high performance yarns and surgical sutures. The surgical suture market continues to grow with revenues of \$3.46 billion in 2016. Higher performance yarns are a subset of a market expected to exceed \$12 billion by 2020.

Finally, we've identified a developing trend in the industry where some of the major manufacturers are focused on developing application specific replacement technologies. Our synthetic spider silk offers the technical and environmentally sensitive properties to lead in this movement.

Mechanically, electrospun rSSP yarns will have superior mechanical properties to their petroleum based counterparts. What is known about spider silk, through our research and others, is that the finer the fiber becomes the better the mechanical properties become. In both the suture markets as well as the ballistic yarn markets, improved mechanical performance is desirable. Particularly for sutures, having very fine, strong sutures are ideal in a variety of applications including eye surgeries. From a ballistic yarn perspective, we have heard through customer discovery, that mechanical properties between Nylon and Kevlar are needed but not available or being developed. A yarn that has the ability to give when impacted. Our preliminary research electrospinning blends of Nylon-6,6 and rSSP have shown that we fall between Kevlar and Nylon-6,6 mechanically.

4) It is the opinion of this reviewer that the engineering effort required to achieve commercial scale with this technology is being seriously underrepresented. The project includes 4 major tasks that include every element from initial process design through collection, post processing, and chemistry.

It is understood that to achieve a continuous electrospinning device for rSSP and its polymeric blend is an ambitious proposal. However, the components to accomplish the technical milestones are mostly off the shelf (bell and electric motor) or exist in the laboratory currently (electrospinning instrument and godet system). The essence of what is needed is to assemble the device from these components through design and engineering (TM-1 and TM-2). With information published in the literature we know the basic parameters for how to assemble the device to be successful. Items such as speed of the rotating bell and distance of the needle from the rotating bell are published for other polymers. Additionally, the godet system exists and functions in our laboratory. What is needed to accomplish TM-3, the incorporation of the godets into the process of continuous electrospinning, is to remove the wet-spinning extruder and replace it with the electrospinning device. With it in place, we will then need to test speeds and timing of the spinning godets to coordinate the speeds such as to not pull on the yarn prior to the stretch baths. This will require a combination of matching fiber deposition speed onto the rotating bell and the speed of the initial godet wheel.

Further reducing the scope of engineering in this proposal is that we have electrospun rSSP and its blends in a traditional fiber mat form in the 7 months since this proposal was submitted. Through that work, we have good working knowledge of the process of electrospinning rSSP and its blends. Parameters such as dope concentration and components, voltages and needle distance which will

reduce exploration in the chemistry and process space of this proposal. Additionally, we have been wet-spinning rSSP for >10 years and for roughly 5 years with our current wet-spinner/godet device. This gives a strong working knowledge of the parameters required to stretch resulting fibers produced.

Excerpt from Original Proposal:

Technical Milestones:

The development of a continuous electrospinning device to produce a yarn of rSSp or rSSp/polymer blends necessarily proceeds through four milestones.

TM-1: Design and engineer our existing iME electrospinning device to incorporate a rotating bell to which rSSp and polymer blends of rSSP can be deposited.

TM-2: Design and engineer a yarn retrieval mechanism to remove accumulating fiber from the bell and move it outside the device's shields to avoid errant fiber deposition or interruption of electrospinning.

TM-3: Incorporate existing godet technologies to accept the electrospun yarn for post-spin stretching in baths.

TM-4: Determine the best rSSp proteins and blends for electrospinning and characterize their mechanical ability when post-spin processed.

Additional Requested Updates:

- 1) Are there any changes to the current and pending support information provided for the PI, co-PI, and/or senior personnel? If so, notify me with the specifics and attach an updated declaration of the support information.**

Yes, the current and pending support for Dr.'s Jones and Lewis have changed as well as Mr. Grimm's. Those changes are indicated in the updated current and pending support declarations attached to the email.

- 2) The Data Management Plan needs to be revised. It is too general and brief.**

Data Management Plan

The PI and Co-PI have an established track record of promptly publishing data and results generated by federally funded research as can be seen through their biography's and history of funding. These data have been actively shared with the research community and public through conference presentations as well as media outlets at both the regional and national levels.

Expected Data to be Managed:

Primary data and associated metadata will be managed and made available to the public through Utah State University's digital commons and KUALI system managed by the Office of Research and Graduate Studies and the Merrill Crazier library. These data potentially include device fabrication, experimental parameters, data analysis methods and analyzed data. These data will be published promptly in the form of peer-reviewed research articles, supplementary information to journal articles, thesis, dissertation and other printed forms or electronic communications.

Excluded from this data management plan are; future research plans, personal communications, peer reviews, physical samples, drafts of scientific papers, preliminary data or data that are subject to patenting. Data included in patents will ultimately be publicly available in the form of a patent application or patent publication available free of charge from the U.S. Patent and Trademark Office.

Data Formats:

The data will be available as manuscripts from publishers or electronically in PDF format.

Period of Retention:

Data will be retained indefinitely on Utah State University's digital commons system. Once data is uploaded to these data/metadata systems, the PI and Co-PI have no means by which to remove deposited data.

Data Storage and Preservation:

Data storage and preservation will occur through Utah State University's digital commons (<http://digitalcommons.usu.edu/>) data management system. This program is administered by Utah State University's Office of Research and Graduate Studies and is independent of the PI or Co-PI other than the deposition of data.

Sharing and Access of Primary Data:

Sharing and accessing these data will be through Utah State University's digital commons, which is publically available. Exceptions are data involving proprietary information or patent applications. The public's access to these data is restricted.

Public Involvement:

The PI and Co-PI have actively informed the public regarding their research. Numerous group tours are performed within the laboratory that have included public school classes, public service groups, legislators, college students and administrators. The research has also been presented both locally and nationally through newspaper articles, radio and television interviews as well as several documentaries including the Discovery channel among others. Their laboratory also maintains a social media presence on Facebook (www.facebook.com/ususpidersilk) to further communicate scientific accomplishments and also as a way of promotion to attract top-tier undergraduate and graduate students.

2) Are there any current or pending awards that relate to or overlap the proposed AIR-TT work?

There is one award, the UTAG funding that is indicated in the updated C&PS provided as part of this email. UTAG is a Utah based funding mechanism similar in purpose to the PFI-AIR TT program. As part of this award we included some funding to research continuous electrospinning. Of the seven technical milestones proposed in our UTAG award, 2 covered researching continuous electrospinning of rSSP and its polymer blends. However, the UTAG proposal and subsequent award does not support post spin processing of the produced yarns as has been proposed for our PFI-AIR TT proposal. In addition, these were a minor part of the budget as it only supported a graduate student for one year.