SUBMISSION FORM University System/Employee Intellectual Property Joint Participation MUSP 407

This form is to be submitted with any Board of Regents item whereby a campus seeks the approval of an agreement with or arrangement regarding an employee pursuant to <u>20-25-109 MCA</u> and <u>Regents Policy 407</u>.

When the submission concerns matters of trade secrets or confidential business information, or any other matter entitled to privacy under state or federal law (e.g., the federal statute known as Bayh/Dole) the submitting campus may request consideration of the submission, in whole or in part, in executive session.

The submitting campus should also provide the Commissioner a copy of the contract(s) that form the basis for the cooperative arrangement for which approval is sought. Submission of the contract does not indicate a conclusion that all or part of the contract is a public document and the question of whether it is in whole or in part protected from public disclosure will be evaluated on a case by case basis.

1. Summarize the nature of the intellectual property that was developed by the employee seeking approval. Indicate the sources of funding for the research that resulted in this invention.

This application seeks BOR 407 approval for two agreements, both concerning the same technology, which aims to enable, fast, reliable, and scalable detection of viruses at the point-of-care. The first agreement is a license to IP recently developed in the Wiedenheft lab. The second agreement is a potential Sponsored Research Agreement ("SRA") between Montana State University ("MSU") and VIRIS Detection Systems ("VDS"). Pending external venture funding currently under negotiation, VDS hopes to sponsor research at MSU. The intellectual property ("IP") involved in the SRA refers to future inventions created at MSU that could be licensed by VDS. Work described in the SRA covers research entitled, "Development of Methods for Rapid, Sensitive, and Accurate Viral Diagnostics."

2.

a. Name(s) of the university employee(s) involved.

- Blake Wiedenheft
 - 1.0 FTE Associate Professor in the Department of Microbiology & Immunology at Montana State University
 - Past and potential inventor of MSU IP
 - Founder and Owner of start-up company

b. Name(s) of business entity(ies) involved.

VIRIS Detection Systems (VDS), is a new start-up based in Bozeman, MT. VDS registered as a Limited Liability Company on April 26, 2020 and has "Active Good Standing" status with the Montana Secretary of State.

3. The university and employee(s) are seeking approval for (check as many as appropriate):

- **a.** 🔀 The employee to be awarded equity interest in the business entity
- **b.** The employee to serve as a member of the board of directors or other governing board of the business entity
- **c.** 🛛 The employee to accept employment from the business entity.
- d. 🗌 Other. Please explain.
- 4.
- a. Summarize the nature of the relationship between the university and the business entity (e.g., the entity is licensing the intellectual property from the university, the entity is co-owning the intellectual property with the university).

VDS is a business entity specifically formed and wholly owned by Wiedenheft to sponsor research at MSU and to option and license IP from MSU for the purpose of commercial development of technologies. VDS has engaged MSU in discussions about an option or license to existing IP, and an SRA to sponsor additional development. This SRA is considered a precursor to an "Option to License." The SRA with MSU can be finalized upon VDS receiving the private venture funding.

The standard MSU SRA contains definitive parameters for ownership of future IP. VDS shall own all rights and title to inventions and improvements created solely by VDS and without use of MSU resources. MSU shall own all rights and title to inventions and improvements created solely by MSU employees. MSU and VDS shall jointly own all rights and title to inventions and improvements made jointly by MSU and VDS.

As to all licenses which may be granted by MSU to VDS, MSU retains for itself and other not-forprofit institutions a perpetual royalty-free non-exclusive right to practice the licensed patents and to use the licensed information for research, testing, and educational purposes of MSU.

b. The proposed duration of the agreement or arrangement.

The duration of a license for existing IP would be at least until the last patent expires, which is expected to be at least 20 years. If the licensing agreement includes transfer of "know-how" (unpatented information), then the licensing agreement could persist after the last patent has expired.

MSU and VDS will mutually decide an end date to complete the SRA activities, though that time period is expected to be roughly 12 to 24 months. The above-mentioned Option to License shall be exercisable by VDS for a period of twelve (12) months after disclosure of any inventions and improvements, unless said option is otherwise declined by VDS in writing.

c. The conditions under which the agreement may be terminated or dissolved.

The licensing agreement may be terminated at any time upon 60 days written notice by the company. MSU may terminate the licensing agreement if the company does and fails to cure, within 30 days of notice, any of the following:

- (i) Is delinquent on any report or payment that is not in dispute.
- (ii) Is in breach of the diligence obligations, to commercialize the technology.
- (iii) Is in breach of any other material provision of the agreement.
- (iv) Violates any laws or regulations of applicable governmental entities that have a material adverse effect on MSU or the company's ability to perform its obligations under the agreement.
- (v) Institutes a legal action challenging the validity of any Licensed Patent.

The SRA agreement may be terminated at any time upon the written mutual consent of the parties, by either party for failure of the other party to cure a breach of the SRA within ten (10) days after having received written notice of the breach, or by MSU for any reason upon thirty (30) days prior written notice to VDS.

All SRAs and possible future licenses as provided for by Option Agreements issued by the MSU Office of Technology Licensing are contingent upon this BOR 407 approval.

5. Explain specifically how the University System or the State of Montana will likely benefit from the agreement or arrangement.

- a. The licensing agreement to a Montana company puts Montana business and Montana research at the cutting edge of a crucial technology, to help Montana, the US, and the world address both the current and future pandemics. It will allow the economic development arising from this technology to occur in Montana rather than elsewhere.
- b. The licensing agreement will include fees, royalties, and/or equity that would generate significant revenue for MSU upon successful commercial development of the technology.
- c. The proposed SRA provides the opportunity for new IP to be developed that will be wholly or jointly owned by MSU, increasing the value of the licensing agreement and the likelihood of commercial success for the technology.
- d. The SRA provides a base of collaboration that may lead to future funding opportunities that benefit MSU.
- e. This SRA will support MSU undergraduate students, graduate students, postdoctoral fellows, and career scientists.

6. Summarize the financial terms of the agreement or arrangement. Include:

a. The value, nature and source of the University's contribution.

The University may front additional accrued patent filing costs for new MSU technologies at its discretion, which would be paid back by the company following the schedule set forth in the licensing agreement.

b. The value and nature of the employee's contribution.

As an employee of MSU, Wiedenheft will contribute to the preparation and completion of MSU patent filings. As a business owner, Wiedenheft plans to sponsor significant research at MSU for the mutual benefit of all parties.

c. The anticipated revenue to be generated by the project and the timeline for generating such revenue.

The licensing agreement is yet to be negotiated so projected revenue is difficult to anticipate at this time. However, the tentative terms under discussion would mean that the company pays all patent costs, so MSU bears no financial risk. It would include a modest annual fee. But the bulk of the consideration to MSU would be in the form of equity. So if/when the company is acquired, goes public, or declares dividends, MSU could receive significant revenue.

d. The manner in which revenue and expenses will be shared by the parties.

The licensing agreement would include provisions that specify that patent costs are paid for, or reimbursed by, the company. Thus, MSU does not incur financial costs under the licensing agreement.

Under the SRA, VDS sponsors (pays for) the full costs of the research to be conducted at MSU. Upon reimbursement for all reasonable costs associated with the filing and maintenance of patent protection for any applicable MSU inventions and improvements, MSU will agree to grant VDS an option to negotiate a royalty-bearing license to practice such MSU inventions and improvements developed pursuant to the SRA (or for jointly owned inventions and improvements, a royalty-bearing license to cover MSU's interest therein). So, again, MSU does not bear the financial costs for the activities to be performed under the SRA.

The SRA is an early stage agreement and has no provision for royalties. Only a full licensee is permitted to conduct commercial sales of products or services containing the MSU optioned technology. Future royalty revenue and expense rates (including standard development fee to MSU and collection of any unreimbursed patent costs) will be determined in a future License Agreement to cover any IP developed under the SRA.

e. The nature of each party's equity interest in the project. If none, so indicate.

Wiedenheft holds 100% equity in VDS.