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WARF Response to USPTO Request for Information:
Patent Eligibility Jurisprudence Study

The Wisconsin Alumni Research Foundation ("WARF") appreciates the opportunity to offer our perspective on the current state of patent eligibility jurisprudence. We commend the U.S. Patent and Trademark Office ("USPTO") for giving this issue the careful attention it deserves.

WARF is a nonprofit supporting organization for the University of Wisconsin-Madison ("UW-Madison"). Our mission is to support scientific investigation within the UW-Madison research enterprise by providing financial support, actively managing assets, and moving innovations to the marketplace for both financial return and global impact. In service of that mission, we act as the designated patenting and licensing organization for UW-Madison. The guiding vision for everything we do is to enable university research to solve the world's problems.

In short, the current state of patent eligibility jurisprudence has made our charitable purpose more difficult than it needs to be. Strong, reliable, predictable patenting criteria serve both inventors and the public. Inventors can be confident their patent rights will withstand scrutiny and the public can trust that patents will be granted for good reason and publicly disclosed with enabling descriptions. The criteria codified in patents' statutes has stood the test of time. The terms "useful" (§101), "novel" (§102), "non-obvious" (§103) and a "written description" sufficient "to enable" use "by any person skilled in the art" (§112) have been the bedrock of the patent system. Our concern is not with that language but with the misapplication of those criteria to recent advances in scientific fields such as computing and biotechnology. Rather than applying scientific expertise to the existing statute, recent court decisions have introduced terms such as "abstract ideas" and "natural phenomena" that do not appear in the law as written.

These new terms are overly broad, ill-defined as a matter of science, and difficult to apply in practice to actual technological innovations. As our colleagues at AUTM have recently stated,

good science leads to good patent law while bad science leads to bad law. The court decisions at question in the Patent Eligibility Jurisprudence Study have led to robust and proven statutory language becoming watered down by the unscientific vocabulary of legal interpretation.

The result has been an erosion of confidence about what qualifies for a patent, diminished trust in the validity of patents, a hesitancy among investors to take risks on scientific innovations, and the loss of opportunities to develop multiple technological advances. After the rulings of each of the court cases referenced in this Docket Number, our Intellectual Property and Licensing Managers have struggled to navigate the shifting requirements for patent eligibility, which has not only delayed the transfer of innovations to the marketplace but made that transfer more complicated, more expensive, and less likely to succeed.

The recent USPTO guidelines issued in 2019 have clarified the path forward. We would be supportive of further codifying those guidelines as a matter of statute. But, ultimately, our preference would be to see a return to "useful," "novel," "non-obvious" and described "to enable" as the criteria for what can be patented.

To be clear, patents are one method WARF uses to accomplish our mission. We do not patent all the research disclosed to us, nor do we claim that all research should be patent eligible. But patents are a crucial, and many times essential, tool in promising areas of technology development, including human therapeutics and medical diagnostics but also animal breeding and agribusiness as well as energy and manufacturing.

More specifically, patents provide the means for WARF to turn scientific ideas into protected assets. Those assets serve as the basis to negotiate formal agreements with private companies and other entities with the resources to turn our ideas into marketable reality. Patent rights give us something tangible to offer our partners and give our partners the clarity and confidence to invest in further development.

Patent protections also ensure that a portion of the proceeds from commercial development will be returned to financially support future research at our university, thus generating a virtuous and ongoing cycle of innovation. We consider this to be a useful, laudable, and beneficial use of the patent system.

Some have advocated for open-source competition as an alternative to patents, but the opposite of patents is not the free flow of information. The opposite of a strong patent regime would be secrecy and a winner-take-all competition favoring large corporations over small innovators and academic contributors. Such open competition might be viable in hypothetical scenarios in which consumer preference is the only determining factor. In most markets,

however, (and especially in the scientific fields where universities operate) the protection of public health and safety demands require high standards of precision and quality control. In these fields, intellectual property protections are the most reliable and time-tested way to ensure that our university inventors can continue to publish in peer-reviewed academic journals while simultaneously participating in the high-quality development of their inventions, as described in the enabling descriptions. Patents, in other words, are the best method to balance the public dissemination of information that academic freedom demands with the scientific controls that successful technology commercialization requires.

The following examples provide more detailed information on WARF's on-the-ground experiences with the problems identified above. We have anonymized the stories in deference to the interests of our commercial partners and in keeping with standard business practices to not disclose the details of commercial agreements. At the same time, we wish to clarify that the below examples each apply to multiple inventions over the last five years. We have seen these issues arise on multiple occasions and anticipate that they will continue to pose ongoing challenges as long as the current state of patent eligibility persists.

Pharmaceuticals and Biologics

The next breakthrough pharmaceutical compound—the next Taxol, penicillin, or warfarin—will not be eligible in the United States for a patent covering the molecule itself. Because the cost of investment is high and the risk of failure significant, the lack of patentability will dissuade the necessary investment to turn a compound into a tested and approved medicine. If that investment does take place, it will likely come from a European or Asian company operating in one of the many countries where patents are still granted on biochemical molecules that have been isolated or purified (as they once were in the United States).

WARF has already begun to encounter the consequences of this uncertainty in our collaborations with UW-Madison researchers who are studying the naturally occurring substances that could generate the next generation of antibiotics. We have begun to explore foregoing domestic patenting in favor of foreign patent protections, and our contacts with industry suggest operations based overseas will be more likely to attract investors.

In some instances, methods used to manipulate, purify, isolate, or improve these novel substances might be patent eligible, but if so, those new and novel processes constitute a *subsequent* patentable invention, not the *original* invention. The first invention is identifying a useful purpose for the molecule or compound itself. The application of human resources, insight, and ingenuity to identify a useful purpose for a chemical compound constitutes a novel and non-obvious inventive step—whether or not the compound is synthetic or naturally occurring. This would be no different than the identification of a naturally occurring element

identified to be useful as a light bulb filament or a naturally occurring chemical that when isolated or purified offers an improvement for rubber. The substance itself should be patent eligible as a new technological innovation.

Some of these compounds could, at a much later date, be determined to have other medicinal uses, such as anti-inflammatory or anti-carcinogenic qualities. Without early patent protection on the molecule the necessary work to explore these qualities would be difficult to complete, because it would significantly limit commercial investment and private sector engagement. Without that investment and engagement, we are not able to attract the type of companies capable of producing products on the scale necessary for clinical trials and quality testing. Absent patent protections, companies have been reluctant to invest, reluctant to be persuaded that we have intellectual property that can offer sustained value for their investment, and reluctant to pursue an unprotected product that could be co-opted by competitors after the fact. In prior years, a strong patent on a molecule could attract private partnerships, and those partnerships could in turn lead to the subsequent development of additional novel uses and methods. In the current state, when we can only secure patents on those *subsequent methods*, the partnerships necessary to develop those methods are less likely to happen due to a lack of definite intellectual property protection.

We want to emphasize that the question of competition is not solely a matter of economic gain or profit, but about the economic and logistical realities of bringing a new drug to market. The time, investment, and risk of failure for a safe and effective pharmaceutical development makes initial market exclusivity essential. If WARF does not have a patent, most pharmaceutical companies will not be interested in developing novel therapies based on our technologies.

Because our university scientists are named on the patent, our intellectual property protections ensure that the original inventing scientists have direct involvement in crafting the enabling description of the invention. Their expertise is essential in ensuring that the development process proceeds with the highest standards of scientific quality, and because of our ongoing relationship with the inventors, they often remain involved during subsequent stages of development.

Without patent protection, their expertise could be impeded or altogether shut out of commercial applications. A lack of patent protection allows, and even encourages, proprietary trade secrets that prevent anyone not employed at the company (such as our university-employed scientists) from accessing information related to the invention. These circumstances have the potential to increase the likelihood of low-quality, ineffective, and dangerous products making it to market.

Cattle Breeding and Dairy Production

WARF collaborates with researchers in the animal husbandry space who study the genetics of cows to determine mutations associated with the likelihood of birthing twins or the fat content of their milk (both positive traits in the dairy industry). Farmers can apply this science to improve the productivity, quality, and health of their cattle herds.

Prior to recent jurisprudence, WARF was able to secure patents around the correlation of mutations with certain phenotypes and companies had expressed interest in licensing such patents. The current state of patent eligibility casts doubts on our ability to do so and companies' willingness to collaborate.

As with biochemical compounds, the ingenuity and scientific application required to identify the utility of a genetic mutation, in and of itself, constitute a novel and non-obvious inventive step. But the current judicially created standards require additional sequencing and the actual selective breeding of an animal to secure intellectual property protection. This amounts to requiring manufacturers to begin the design and production of a product before they are allowed to patent it. In addition, while a company may provide the sequencing information, a farmer will be doing the selective breeding. Such a situation means that each entity will only be performing one component of the entire patented claim, making it difficult to license or enforce.

Medical Diagnostics

Much like novel pharmaceutical compounds, the development of new diagnostics relies on the novel identification of biological signatures that are useful for the identification of diseases within human tissue samples. Considerable resources and ingenuity are required to identify the utility, for example, of a particular sequence of DNA within human blood. The application of ingenuity to identify utility, in and of itself, constitutes a technological advance regardless of whether the material being studied was biological, chemical, or physical (or combination of one or more) in its original state.

The current state of patent eligibility, however, requires an additional step, such as a manipulation of some sort or the addition of a second chemical, to render the underlying invention patentable. This significantly limits the scope of invention and hinders the potential for commercial development. In some cases, WARF has been fortunate that some of our inventions have required additional manipulation or chemical additives, but that is largely happenstance and dependent on the circumstances of a particular line of research, rather than

a quality fundamental to diagnostic science. In other cases, where an additional chemical or manipulation is not as central to the science, the underlying insights are no less useful or novel and no more obvious than if the science required an additional step.

Besides the technical issues of the science, a lack of patent eligibility for useful biomarkers makes it difficult for WARF to negotiate with potential partners—either commercial, academic, or regulatory. Patents gives us demonstrable proof of ownership of intellectual property. That proof gives us an asset that can serve as the basis for negotiations with the entities who can assist us in performing additional manipulations, testing of chemical combinations, and development of applications.

The clarity of enforceable patents also provides a foundation of trust on which ongoing communication and contractual collaboration can be built. Patented products allow both commercial entities and organization like WARF to openly engage in regulatory processes by sharing information with federal agencies and the hospitals that conduct clinical trials. In other words, patent protections create clear indications of who owns and controls the science and clear assets to guide negotiations.

Once again, we thank the USPTO for undertaking this important study of a concern that is essential, not only to our business model, but to the fulfillment of philanthropic mission. WARF looks forward to continued collaboration with the federal government for the benefit of an innovation system that benefits all Americans.

Sincerely,

Erik Iverson
Managing Director

Michael Falk
Chief IP and Licensing Officer

About WARF

Incorporated as a nonprofit foundation in 1925, WARF has a founding purpose "to promote, encourage, and aid scientific investigation and research at and within the University of Wisconsin-Madison." In pursuit of that mission, we have built an investment portfolio valued at more than $3 billion, which over 93 years has funded more than $3.7 billion in research grants to UW-Madison when adjusted for inflation. As the designated technology transfer office for UW-Madison, WARF has been issued close to 4,000 patents, including 2,000 active patents and generates an additional 375 invention disclosures and 60 revenue-generating licenses each year. WARF's efforts are devoted to furthering the historic outreach mission of our state university known as the "Wisconsin Idea."