Statement of

Michael J. Dixon, Ph.D.

# President and CEO, UNeMed

Before the Subcommittee on Commerce, Manufacturing, and Trade

Committee on Energy and Commerce

United States House of Representatives

113<sup>th</sup> Congress, 2<sup>nd</sup> Session

April 8, 2014

# "Trolling for a Solution: Ending Abusive Patent Demand Letters"

#### **Introduction**

Chairman Terry, Ranking Member Schakowsky and Members of the Subcommittee, thank you for the opportunity to discuss patent demand letters, an important issue for America's innovation economy. My name is Michael Dixon, and I am President and CEO of the UNeMed Corporation, the technology transfer and commercialization entity for the University of Nebraska Medical Center (UNMC) and its sister campus, the University of Nebraska at Omaha (UNO).

My testimony today focuses on preventing illegitimate and deceptive patent demand letters without unduly burdening the U. S. patent system or restricting technology transfer efforts by universities. Universities are uniquely positioned interacting with both inventors upstream and commercial partners downstream as innovations make their way from the laboratory to the marketplace.

## **UNeMed and the Technology Transfer Process**

UNeMed improves healthcare by fostering innovation, advancing biomedical research and engaging entrepreneurs and industry to commercialize new technologies created at UNMC and UNO. Similar to many other university technology transfer offices, UNeMed has a large and diverse intellectual property portfolio of new discoveries that represent significant opportunities in biomedical and clinical technology areas such as biotechnology, therapeutics, diagnostics, and medical devices as well as information technology software and hardware.

Last year, the University of Nebraska Medical Center (UNMC) invested nearly \$128 million in research for development of products that improve healthcare and save lives. One such product developed at UNMC was the LeVeen Radiofrequency Ablation Probe, which was the first minimally invasive radiofrequency ablation tool used to treat solid cancer tumors. UNMC researchers Dr. Robert LeVeen and Dr. Randy Fox invented this surgical device which helped to establish the field of interventional oncology. UNeMed and UNMC were eventually able to partner with Boston Scientific to bring this product to market. As a result, thousands of patients' lives have been, and will be, significantly improved. Our experience at UNMC is mirrored at many other universities across the country.

# Patent Certainty and the Role of Demand Letters

For inventions to reach the marketplace, they must have meaningful patent protection. Certainty in patent enforcement is necessary for a company to license the invention and invest significant sums. For biomedical innovations that often means millions or billions of dollars will be invested to bring the product to the marketplace. Our commercial partners depend on patent certainty and strong patent protection to justify the significant financial investments required to transform an invention into a product ready for the marketplace.

As a University technology licensing entity, we have a unique perspective since our downstream licensees have received patent demand letters and upstream, as the holder of patents, we occasionally must send demand letters. We deal with both ends of this issue.

However, before talking about demand letters in detail, it is important to note that there are two types of activities that may be considered demand letters: 1) letters marketing inventions seeking investment, and 2) letters with allegations of infringement seeking compensation. The first, marketing inventions to potential licensees, is one of the primary missions of university technology transfer offices. We feel strongly that such activity is not a demand letter and should not be impacted by legislation aimed at those seeking damages for patent infringement. As a university with a significant patent portfolio, every day we send letters and communications to established companies in an effort to convince them to license and invest in our innovations and technologies. If legislation to standardize patent demand letters is contemplated, it is important to consider the potential impact on the technology transfer process. If, in trying to curb illegitimate patent demand letters, the minimum standard for such a letter constrains the ability of universities to communicate licensing opportunities to potential licensees, a university's ability to transfer technology into the private sector could be greatly harmed. Overly broad federal regulation would hinder legitimate efforts to market and license inventions on their journey to the marketplace.

#### Vague Demand Letters Stall Innovation

Of course, universities not only solicit partners for inventions. We also work with our partners to enforce our property rights and occasionally are also the target of demand letters. Universities and our licensees are negatively impacted by vague, overly aggressive demand letters. These demand letters seek financial gain through intimidation rather than legitimate patent enforcement. They are like rocks thrown in a stream which consume time and money, diverting and slowing the pace of innovations to the marketplace.

According to a 2013 survey by the American Intellectual Property Law Association, the cost of a patent infringement lawsuit for demands of \$1 million dollars or less averages \$970,000 to take the case to final decision (not including appeals). Just taking the case to the end of discovery phase still costs \$530,000. The potential financial risk inherent in patent infringement lawsuits, leaves most legal remedies out of reach for small businesses and inventors who receive a demand letter. For many, a wise business decision is to settle and move on, which further encourages illegitimate demand letters sent in great volume by shadow entities.

As an example, a few months ago, a company with whom UNeMed works received FDA clearance for a device the company patented. Their next step would be to create marketing materials and begin sales of the device. However, almost immediately after receiving FDA clearance, they received a demand letter asserting patent infringement against the company's product and made legal claims without providing sufficient information to evaluate the accuracy of the infringement charge. Ominously the letter ended, "I will be calling you to discuss the forgoing." For a small company with a limited budget having just completed the arduous and expensive FDA process, the prospect of additional time and money to hire attorneys to trace the source of a demand letter and to determine its legitimacy, does not make good business sense. While this letter could be illegitimate, for a small company dependent on an innovation, it is not worth the risk to ignore it. Many companies make a rational decision to pay the demand to make the claim go away.

## A Reasonable Standard for Demand Letters

As we consider the facts above, we must also be careful that the patent enforcement bar is not raised too high. If it is, patent infringers will no longer respect intellectual property. Such a watering down of patent rights could lead to companies reducing investments in new products or resorting to secrecy instead of disclosure. Reducing investment or disclosure would cause significant disruption in our innovation ecosystem.

We seek a balanced approach and respectfully ask the Committee to consider the established best practices used by university technology transfer offices when we send demand letters. We follow our own strict standard to write the demand letter in a manner that, if we received it, we would know what the demand is and to whom to respond. In our judgment, a patent demand letter should contain the following elements:

- Identify the patent being infringed.
- Identify the infringing product or activity being done by the infringer.
- Specify the claim(s) in the patent being infringed.
- Identify the owner of the patent.
- Explain the role of the entity contacting the infringer.
- Provide a knowledgeable point of contact for discussing options for resolution.
- State a follow-up time which allows the infringer time to seek counsel and consider options before taking any next steps.

Unfortunately, illegitimate patent demand letters that have caused so much confusion and concern among businesses and researchers often lack many of these essential elements. Their ambiguity and lack of key information are essential elements contributing to their power to extract significant financial concessions.

If all demand letters were held to a standard that required due diligence, patent owners would be more likely to carefully target specific infringers rather than blanket businesses with demand letters. Infringers would have a clear understanding of the claims asserted by the patent owner and the entity contacting them. This would maintain the legitimate role that patent demand letters have in the patent enforcement process while curbing excessive behavior by those seeking financial gain through deceptive practices.

#### A Balanced Approach

The Bayh-Dole Act, the 1980 legislation widely credited with creating the university technology transfer industry has paid tremendous dividends to the U.S. economy. A 2012 study by the Biotechnology Industry Organization (BIO) found that technology transfer from academia and other non-profit institutions added more than \$385 billion to the GDP of the United States and created more than three million jobs and 650 new companies between 1996 and 2010. In 2013

alone, U.S. universities executed over 5,000 licensing agreements and generated \$2.6 billion in licensing revenue.

The America Invents Act, the most comprehensive reform in patent law in over 60 years, was only fully implemented a little over a year ago. Many of the reforms in this new law were targeted to eliminate overly broad low quality patents. More recently, the President directed the United States Patent and Trademark Office to take additional specific measures to address overly broad low quality patents. Changes are happening, but they will take time. Just as the Bayh-Dole Act has yielded tremendous returns over time, the America Invents Act and the changes in the courts and Administration should be given some time to achieve the intended purposes before additional burdens are placed on patent holders. Over time, these activities will reduce the number of questionable patents and reduce the incentives for illegitimate financial gain.

I applaud the Committee for exploring this issue, as there are still issues to be addressed, but I urge the Committee to take a balanced approach and be cognizant of the possibility of overcorrection. Universities are uniquely positioned interacting with both inventors upstream and commercial partners downstream as innovations make their way from the laboratory to the marketplace. America's universities are interested in continuing to work with you to ensure that the American innovation system remains the best in the world.

Thank you Chairman Terry, Ranking Member Schakowsky, and Committee members for the opportunity to offer my perspective to the Subcommittee. I welcome any questions you have.