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Hearing on How Procedural Changes under the America Invents Act Affect Small Businesses and the Impact of Patent Assertion Entities on Small Firms

TESTIMONY

My name is Jeff Grainger. I want to thank Chairman Graves and the other Committee members for the opportunity to testify today. I am a patent attorney with an engineering degree, and have worked continuously in start-up companies over the past 20 years, almost entirely in the medical device field. I am also an entrepreneur, having founded my own start-up company and participated in starting a number of others. Currently I am a partner at The Foundry, which is a small company, often called an incubator, based in Menlo Park, California that develops new medical technologies and starts new companies to pursue those technologies with venture capital funding. The Foundry has started about 15 companies since it was started in 1999. Our companies have not only built value for their investors and created hundreds of jobs, but the medical technologies we have developed have advanced the state of the art in medical treatment and improved the lives of thousands of patients. These technologies now allow heart valves to be repaired using catheters inserted through blood vessels rather than through open heart surgery, high blood pressure to be treated through a single catheter treatment rather than a lifetime of drugs, and blood clots to be removed rapidly from cerebral blood vessels to reduce the damage caused by strokes.

While the dialogue concerning patent reform has been at times dominated by forces arguing to weaken the patent system, I am thankful to be able to speak today to ensure you hear a different view, the view of the innovators and entrepreneurial companies that bring new medical treatments to Americans: We depend upon a strong patent system that provides a fast and efficient examination process, discourages frivolous patent challenges, and imposes serious sanctions on infringers. I have genuine concern for those who are harassed by patent trolls, or "patent assertion entities;" however, in addressing that problem, I urge the Committee to maintain a strong patent system that ensures the American medical device industry will remain on the forefront of innovation and that the most

advanced medical technologies will be available to American patients. It is from this perspective that I approach the topic of today's hearing.

The development of new medical technologies in this country is highly dependent upon the continued ability of small entrepreneurial companies to start and grow. Venture-backed companies founded by biomedical engineers or physicians are more than ever the primary source of groundbreaking new therapeutic and diagnostic devices. The established multinational medical device companies rely more and more upon the acquisition of these companies rather than internal R&D programs for product innovation and expansion into new markets. The availability of venture capital is thus critical to allow new medical innovations to reach patients.

Investing in medical devices is not for the faint of heart. Medical device companies must raise substantial capital in order to develop their products, perform clinical studies, and obtain regulatory approval, all before a single device is sold. Investments of more than $50 million and timelines of ten years or more from invention to commercialization are not uncommon.

Investors in medical device start-ups are thus intensely concerned with the ability to obtain strong patent protection. They need to know that after a company has blazed a trail over many years to bring a new product to market there will be some period of exclusivity before the product can be knocked-off by competitors. When we approach venture capitalists for financing a new company, patent protection is a threshold concern that must be satisfactorily addressed before we have any chance of receiving an investment. Any changes to the patent system that impede our ability to obtain patents or that weaken the protection conferred by them would be a serious detriment to our ability to raise the funds necessary to start medical device companies.

The America Invents Act (AIA) implemented significant changes to the US patent system. These include First Inventor to File, Post Grant Review and Inter Partes Review, special procedures for certain business method patents, third party prior art submissions, supplemental examination, Track One prioritized examination, and USPTO fee setting authority, among others. While it is too early to tell whether the AIA has been successful as a whole, several aspects of the Act clearly improve the patent system for innovators, including medical device entrepreneurs and start-up companies.

The change that has garnered perhaps most attention is the change from a first-to-invent system to a "first inventor to file" system. However, for many patent filers including The Foundry, this has resulted in little change in the way business is conducted. Under the first-to-invent system, if a party was second to file a patent application, the statistical chances of proving earlier invention were extremely low, and counting on it was risky. Our standard practice has therefore always been to file as rapidly as possible. Taking one's time in filing on the assumption one could prove earlier invention was not a rational approach.

While not having a significant effect on how we file for patents, the change to "first inventor to file" is good because it creates greater certainty and reliability in the patent system. Because it revolved around secret information about when and how an invention was made, the first-to-invent system was fraught with uncertainty. The prospect, however unlikely, that someone who filed after us could prove earlier invention created a cloud over who owned the intellectual property. Even if we had filed before another party, there remained a lingering risk that they might have invented first, a risk that could not be clarified except through expensive interference proceedings or litigation. In financings and strategic negotiations, this uncertainty lengthened the due diligence process, increased legal fees, and threatened the ability to reach a deal. Under "first inventor to file," the determination of who is entitled to patent an invention is clearer, simpler, and based

on data available to all parties. Moreover, in the vast majority of cases, the results will be the same as they would be under a first-to-invent system.

Another significant change under the AIA pertains to post-grant proceedings for challenging issued patents. Post-Grant Review allows a patent to be challenged by third parties on almost any grounds during the first nine months after grant, while Inter-Parties Review allows a patent to be challenged beginning nine months after grant on grounds related to novelty or obviousness. Both procedures serve an important purpose in providing a process for overturning patents that should not have been allowed in the first place, without having to engage in costly litigation.

Importantly, the Act establishes a Patent Trial and Appeals Board (PTAB) composed of specialized administrative law judges who will decide Post Grant and Inter Partes Reviews. This is an important change from the former reexamination procedures, which were decided by patent examiners. Many practitioners felt they could not rely on patent examiners to overturn patents in reexamination, even when new information was presented clearly calling into question the validity of the patent. The chances were good that the reexamination would result in an affirmation of the patent, which could then be perceived as stronger since the Patent Office had approved it twice. By establishing the PTAB with specialized judges, it is hoped that the new AIA procedures will result in better and more predictable decisions.

Another important aspect of both types of post-grant proceedings is the estoppel provision that prevents a challenger from later challenging a patent in another proceeding or in litigation on grounds that were raised or could have been raised during the first post-grant proceeding. This is a critical aspect of the procedures, for not only does it prohibit re-litigation of the same issues, but it creates meaningful consequences for those who decide to challenge a patent. The estoppel provisions appropriately cause a challenger to think twice before launching a Post Grant or Inter Partes review. They help to ensure that innovators

will not be forced to defend groundless or serial post grant challenges by those with greater resources.

Of all the AIA changes, perhaps the most impactful for medical device start-ups is "Track One" prioritized examination. Under this provision, for a higher filing fee, our patent applications are examined and either finally rejected or allowed within one year. In some cases we are getting our patent applications allowed within 6 months. This ability to get a decision from the Patent Office rapidly can have a dramatic impact on our ability to get our projects funded. For a new startup, we are able to approach venture capital firms for funding with a patent already in hand, or with an official indication of what is patentable. We are also able to build our patent portfolios much more rapidly, so that when we seek later rounds of funding, we have multiple patents issued protecting various aspects of our technologies. This can eliminate much of the concern investors have about the availability and scope of patent protection. As a result we are more likely to get projects funded and can get through funding negotiations faster, with lower legal costs, and with potentially higher valuations than we have in the past.

The last aspect of the AIA on which I wish to comment relates to the PTO budget. If there is one issue in which all stakeholders in the patent system should be aligned, it is the provision of sufficient funds to the Patent Office so that patent pendency is reduced, patent examination is more competently performed, and patent quality is increased. These goals benefit everyone, including those who would like to obtain patents faster, those who seek a more efficient and intelligent examination process, as well as those who want to reduce the issuance of poor quality patents.

To accomplish these goals, the PTO must receive sufficient funding to hire and train more and better-qualified examiners, update its computer systems, and implement other important programs. Yet, even though the PTO generates a revenue surplus from user fees each year, its revenues are subject to diversion by

Congress for other purposes. The Office is thus unable to rely on receiving the level of funding needed to expand and improve its services.

Establishing reliable funding for the PTO was recognized to be an important issue to address in patent reform legislation. To this end, the AIA gave fee setting authority to the office, allowing it to set user fees at an appropriate level to generate the revenue it needs. But the AIA fell short in failing to prohibit the diversion of PTO revenues by Congress. So long as revenue diversion is a possibility, the PTO's budget will remain uncertain, and the office will be unable to do the planning and hiring that it needs to do to achieve its larger objectives.

A fully equipped Patent Office can focus on improving the quality and rigor of patent examination, so that the patents that are granted have undergone rigorous scrutiny and are appropriately limited in scope. This, more than any proposal to weaken the rights of patent owners, will ensure that patent rights are not unfairly wielded to the detriment of innovation. Therefore I would urge the Committee to make the prohibition on fee diversion a priority for any future legislation aiming to improve the patent system.

In sum, the American medical device industry continues to lead the world in innovation. Much of this innovation arises from entrepreneurs and small companies who depend on strong patent protection in order to raise the substantial funding needed to bring a medical device through clinical trials to commercialization. Streamlining and accelerating the examination process, improving the quality of patents, discouraging frivolous patent challenges, and imposing serious consequences on infringers are essential components of a patent system that protects and encourages such innovation. In order to attain these goals, we must fully fund the Patent Office and end diversion of PTO fees so it can build an organization equipped to handle the changing and expanding landscape of inventions. Further, in order to solve the problem of patent assertion entities, we must avoid diluting the important rights conferred by a patent upon which

innovators rely, but rather focus on improving the quality and rigor of the patent process.

It has been an honor to speak to you today, and I thank you again for inviting me to testify.