

STATEMENT OF VERN NORVIEL WITH REGARD TO INTERNATIONAL PATENT
PROTECTION FOR SMALL BUSINESSES

November 1, 2011

Palo Alto, California

Madam Deputy Under Secretary of Commerce for Intellectual Property and Deputy Director of the United States Patent and Trademark Office.

My name is Vern Norviel and I am a partner in the law firm Wilson Sonsini Goodrich and Rosati. I also am a past member of the Patent Office Public Advisory Committee, an adjunct professor at the University of California Berkeley, and have been intimately involved with the early formation of many life science startup companies, many of which I believe are significantly impacting health care today.

I am pleased to have the opportunity to present a perspective on the subject of international patent protection for small businesses, for purposes of the United States Patent and Trademark Office preparing a report on the subject, as required by the America Invents Act. I will be speaking today almost exclusively from the point of view of a small life science startup company. I will not be representing any company or my firm specifically today, but wish to offer my personal views, based on my experience, on the manner in which the subject of foreign patent protection impacts a life science startup company. I would like to focus on the manner in which foreign patent protection could directly affect the delivery of health care to patients.

Wilson Sonsini Goodrich and Rosati is a Silicon Valley based firm with offices throughout the US and has represented entrepreneurial companies ranging from Genentech to Google. I personally represent exclusively life

science companies. I am very proud to be a part of the life science industry and the companies with which I am associated. They represent technologies that show great promise in many disease and technology areas including:

- Cancer therapeutics
- Cancer diagnostics and drug selection
- Blindness
- Lou Gehrig's disease
- Next generation DNA sequencing technology
- Non invasive pre natal diagnostics
- Parkinson's disease, and many others

A first question in the Notice is "how important is international patent protection to small businesses?"

Let me begin this answer by addressing *the* major problem faced by life science startup companies today. That problem is, *Access to capital*. As a result of many factors, not the least of which is the economy, venture capital has become more and more difficult to access. In life science, a large fraction of the companies that are founded arise from University funded/NIH funded research. Often these research efforts are considered too early and too risky for today's venture capital industry. Just last week a forum was held, called the "BIO Investor Forum" in San Francisco. The last session at the conference was, tellingly, called "Opportunity or Apocalypse? Prophecies for 2012."

As a result of the difficulty in raising capital from venture capitalists, many young life science companies have turned to a process by which they obtain small investments (on the order of less than a million dollars) from "angel" investors. They then use this money to move their drug or

diagnostic technology forward to the point it is “de-risked” and can actually be financed in a larger way by the venture capital community.

But there is another problem. In the life science industry, *very much unlike the high technology and software industry*, the need for patent protection is absolutely essential to obtain venture capital investment. Tufts university now projects that the cost of developing a single significant drug is now over a billion dollars. It is common knowledge that essentially no drug is moved through this development process without strong patent protection. And, since the US market now is typically only about half of the world market for most drugs, foreign protection is also essential to obtain venture capital investment in a drug.

So, where does this leave us? A new startup with a promising cancer drug, or another drug that could change the face of health care, is required to live on a few hundred thousand dollars during the first years of its existence. But, without foreign protection, at the end of this initial phase, the startup cannot get venture money to continue moving the drug to patients. Moreover, the cost of foreign protection can often be so high that much or all of the money from an angel investment would be eaten up by foreign filings.

And, therefore, the answer to the question “how important is foreign protection?” in the life science industry is “INCREDIBLY.” As to the second question, at what point to health care companies does it become important, the answer is simple. The answer is “IMMEDIATELY”, simply because the patent filings are required to support the venture investment. Importantly, the consequence of these companies not receiving adequate funding as a result of lack of patent protection is more than just commercial-- it will significantly impact health care. Just today as I was preparing my remarks I worked on two such companies working only on angel investor money. One has a drug that could dramatically improve the efficacy of radiation therapy

for cancer victims. Another has a drug that could be the first real treatment for blindness. Both were founded by incredibly well respected scientists (at the University of Colorado and MIT in this case) and have great promise. The victims of these health conditions could be harmed significantly if these health care technologies are not translated into the clinic.

I know that AIPLA submitted answers that are colored differently than my answers today. One would wonder how the positions could be different. I think I would tend to agree with the AIPLA positions as they applies to high tech and software companies. I tend to focus more directly on health care.

Question 3 asks how prior user rights would impact protection. Roughly, I do not believe this is a significant question in the health care area- patents must be filed in health care as early as possible in the research and development process to maintain protection in Europe, Japan and China, or there is no company, and no drug is moved forward with significant third party infringement risk in any event. Question 4 asks "What specific role does international patent protection play in the successful internationalization strategies (such as franchising, exporting or foreign-direct investment) of small businesses? Does this role differ by industry or sector?" I believe I have addressed this question by way of my answer to the first and second questions.

Question 5 asks "How can the USPTO and other Federal agencies best support small businesses regarding international patents" with regard to acquisition and maintenance and enforcement of patents. In this regard, I would tend to agree with the AIPLA; i.e. through coordination of patent efforts between countries, the cost and barriers created by a lack of cost effective protection would be lowered.

Question 6 asks "What role should the Federal Government play in assisting small businesses to defray the cost of filing, maintaining and enforcing international patent protection?", and questions 8 and 9 ask the

question specifically with regard to loan and/or grant programs respectively. Question 10 asks if there are circumstances where the government should not assist in this effort.

Let me address these questions as a group, with an embedded response to reasonable concerns about whether the government is in a good position to decide when to give such grants and loans.

With respect to the life science industry, there is a substantial amount of commercial effort around inventions where the government has already conducted a peer review process to determine where the most promising science is found, via NIH or similar grants. The cancer and blindness companies I mentioned earlier have in licensed patents that were developed under NIH grants, and these grants are peer reviewed before award. And, when a company has obtained financing at some level to support moving these health care solutions to the clinic, there is independent validation that this science is commercially translatable. So, whether support is through grants or loans, it would appear to me that many life science startups that would come under consideration for such support have already accomplished a number of things that make government investment worthwhile: first, these inventions are already moving towards treatments for important health care situations, second, outside peer review has validated that the science is compelling via a peer review grant process, and, third, commercial validation of interest is seen via the formation of a company and team, with the initial outside investment. In these cases, it seems particularly compelling to me that startups offering health care solutions should and could be rationally supported via a grant or loan program to support foreign filing of patents such that these solutions can reach the patients that often are desperately in need.

As to whether a grant or loan program is most efficient, I am not personally strongly of one opinion or another. Perhaps as a taxpayer I

would favor a loan or loan guarantee program. I believe either would have a significant impact on the translation of health care from the lab to the clinic. I would note that I have observed that matching programs serve as strong validation that a project is worthwhile, regardless of whether it is a grant or loan program. In the case of health care companies, perhaps it would be best that any grant or loan program would be made as a matching program to ensure that outside investors are putting "skin in the game."

Thank you for the opportunity to submit comments today.