

Statement of Philip McGarrigle Regarding the Study of International  
Patent Protection for Small Businesses

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My name is Philip McGarrigle and I am the General Counsel and Chief IP Office of Nodality a small biotechnology company located in South San Francisco, CA. I have worked in the San Francisco Bay biotechnology area for over twenty years in small to medium sized life sciences companies. I appreciate the opportunity to speak to you today regarding the difficulties a small company faces in protecting its intellectual property and the possibility of providing assistance to these companies. My testimony will be presented from the perspective of a small company in the life sciences field and I will draw relevant examples from my present company and prior companies.

Nodality has under 40 employees and has been in active research for about 5 years. It is based on a technology originated at Stanford which provides a researcher or clinician with the ability to detect what is going on inside cells to understand the specific biology behind a disease, such as cancer or autoimmune disorders. This approach allows a clinician to personalize a patient's treatment and a researcher to focus on select patient populations in drug trials. Understanding the biology behind disease saves lives and money. Applications for the technology arise in drug screening, as well as providing a disease diagnosis or prognosis. It can also assist in selecting patient populations that may benefit from a drug to provide a personalized medicine approach to disease treatment.

It is clear that foreign patent protection is extremely important to small companies as the bulk of their value is in the IP, especially life science companies. It is clear that the only way small entities can survive in an environment with companies that have more resources is via the patent system. Previous experience has shown me that large companies will act very

aggressively in attempting to capture new markets and patent protection is critical to helping the small company protect itself.

I am sure that you have received testimony regarding the expenses for a US company to foreign file in a small, medium or large distribution of countries. However, the total budget for foreign filing in a moderate number of countries is around \$150,000 and biopharmaceutical companies typically file more broadly. Add to that initial fee the cost of prosecution and issuance which can easily cost an additional \$200,000 for a moderate number of countries. Since the US is about 30% of the world market, international protection becomes very important and expensive.

And this need for cash comes even earlier under the America Invents Act. Since the US will be a first to file country, US filings will come as soon as possible and the foreign filing decisions will be stepped up. Moving expenses up for an early stage small life science company is more difficult and the probability increases that these early inventions are not adequately protected.

Small companies usually do not have much available cash which makes paying foreign filing expenses more difficult. They run leanly and need to periodically raise capital to fund their operations. However, they do not raise more money than necessary in the short term it would require selling too much equity at a low price.

Capital is especially hard to raise in current times. It is this circumstance that Nodality finds itself. We are trying to both prove the technology and protect our inventions, which take substantial amounts of cash. In fact, in the last year Nodality has had to scrutinize costs and the foreign filing expenses are the first to be affected. We recently restricted filing several foreign

applications and we have another foreign decision to make in the next month which may be made strictly on the basis of cost.

Deciding to terminate foreign coverage at an early stage in a company is the most damaging because it is the early patents that provide the most fundamental and broadest coverage. Even though the life sciences industry focuses on smaller numbers of patents to protect its business, they still require an overlapping set of patents to adequately protect the main technology and the market. More patents are required with additional products or multiple ways to attempt to cover workarounds. This is especially true in novel platform technologies like that at Nodality. So, abandoning IP protection at an early stage is the most damaging consequence of insufficient funding.

With that backdrop I would like to address the questions.

## Questions

#1-How important is international patent protection to small businesses? International patent protection is extremely important for smaller life science companies. It is just as important as filing in the US, the only impediment is that it is more expensive. For example, Nodality has filed about 1/3 of its US applications overseas. One immediate benefit is that we are proposing partnerships with several foreign based companies and it is important to them that we have some foreign patent protection that would benefit the partnership.

My previous experience has shown that having international protection is critical to protect and enforce an IP estate. In fact, our efforts led an inventor in my prior company to win the first ever inventor of the year award in the EPO. Additionally, having foreign patents is more important as more litigation is global. If you are sued by an entity in a foreign jurisdiction, you would want to have your own patent to countersue and even the playing field.

#2- At what point does international patent protection become important to a small company? International patents have always been important to the small life science companies that I have been involved in. Our technology was initially licensed in from Stanford and they had the vision to foreign file their first applications. So, they understood its importance even before the company was formed. We have continued to recognize its importance by foreign filing early applications. So, my experience is that the life science companies I have been involved in recognize it early on in their life.

#3-What challenges interfere with the growth and competitiveness of small companies if they do not seek international patents early in the process? The valuation of the small company is adversely affected without international patents. They cannot protect their market and larger companies will be able to use the technology once it is proven to be successful. Oftentimes, outside the US rights are an important source of revenue for small companies through licensing arrangements with other companies. This strategy would not be possible without foreign protection. Also, foreign companies that may wish to purchase the small company need to have adequate patent protection in their jurisdiction.

#4-What role does international patent protection play in successful internationalization strategies? International partners will want to see local protection for their markets if they want to collaborate with the small company or invest/purchase. It is critical. As I mentioned, we are engaged with potential partners who are based overseas and it is important that we foreign filed our applications.

#5-How could the US PTO and other Federal agencies best support small businesses. Some solutions could be the following:

The US PTO can expedite small company applications in the US, prosecute them to a point where they are allowable, then use a mechanism like the patent prosecution highway to file and issue them in foreign jurisdictions. This abbreviated process could reduce the filing, search, examination and expenses attendant in the normal foreign process. The AIA acts to harmonize US law with other laws will help drive to a system where we can avoid performing the same tasks in each country at the expense of the applicants. This solution would be

preferable to others as it works to reduce expenses without setting up systems to provide funding or loans.

Another solution could be to allow small, venture backed companies to compete for SBIR grants, which they cannot do currently. The issue has come up in the past few years. A legislative solution was attempted a few years ago when the House passed a bill (HR 2695) that would have allowed VCs to compete for these grants, but it stalled in the Senate (S 1223). Such grants could be used for foreign filing expenses to help small businesses. In fact, Nodality applied for, and received a very high score for one of these grants, but could not actually receive the money as we are majority owned by venture funds. The SBIR grant examiner was disappointed to not have been able to award us the money. These funds could have helped cover our foreign filing costs adequately for several years. It is my understanding that the bill may be coming up for passage again.

Re: 5 b and c-the USPTO can work with foreign PTOs to achieve a system where redundancies are reduced or eliminated. Additionally, they can seek to eliminate the need for translations into each country's language. Typically this is the most expensive item for foreign filing. With respect to enforcement, much expense could be saved here if different jurisdictions recognized patent judgments of foreign countries. Harmonization would be helpful to clarify this issue more, but it is the most difficult area to resolve. (I wrote an article on the role of foreign judgments in patent litigation and it is not easy to enforce a judgment overseas.)

#6-What role should the Federal Government play in assisting small businesses defray international costs? Rather than set up a new organization to administer funds for foreign filing, it may be more straightforward to have arrangements with other foreign patent offices to simplify and reduce redundancy to eliminate costs first. Additionally, the current grant system, such as with SBIRs could be used to provide funds to small businesses within an existing framework. Grants through the NCI could also be used.

Regarding question 7, I feel strongly that assisting small companies with international expenses is an important idea in whatever way it is funded. It would be better to use existing frameworks to distribute funds. However, as to any loans, I do not have as strong position on

how that may be structured. It may be useful to set up a matching loan program that would pay out money to companies who also invested their own cash. Some questions that I would ask would be how the loans are to be repaid, whether they would be subordinate to other debt, and would they be secured with the IP?

Regarding question #8, my previous responses are relevant.

Regarding question #9, a grant program would be more effective and the structure is in place.

In sum, small entities deserve every opportunity to protect their market and ideas in foreign countries as their technology is typically at its earliest and broadest stage. It is here that it is most vulnerable. External funding is difficult to obtain for these expenses and an alternative mechanism would be welcome. Which mechanism can be subject to debate, however any and all methods should be pursued. Further harmonization should be sought to avoid repeating the same task in each country, thereby reducing fees. Existing organizations such as the Small business administration can provide grant funding for small companies in need. They have the mechanism set up for review of proposals and could simply allow granted money to be used for this purpose.