By electronic submission

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Biotechnology Industry Organization

Preliminary Testimony:

The Biotechnology Industry Organization (BIO) is a non-profit organization with a membership of more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in all 50 States and a number of foreign countries. BIO's members are involved in the research and development of health care, agricultural, industrial, and environmental biotechnology products. The U.S. life sciences industry, fueled by the strength of the U.S. patent system, supports more than 7.5 million jobs in the United States, and has generated hundreds of drug products, medical diagnostic tests, biotech crops, and other environmentally-beneficial products such as renewable fuels and bio-based plastics.

The majority of BIO's members are small companies that currently do not have products on the market. As such, BIO's members rely heavily on the strength and scope of their patents, both domestically and internationally to generate the investment necessary to sustain their long product development cycle. On average, it takes more than 10 years to develop a biotechnology invention from its inception to

regulatory approval and market launch. The average, fully capitalized cost of developing a biologic medicine has been estimated at USD 1.2 billion.

For BIO's small companies, pursuing international patent protection occurs early in the company's life cycle. All biotechnology companies understand that the products they hope to develop require robust patent protection abroad. This is because when our small biotechnology companies seek access to capital to sustain their existence, a central factor for their valuation is the strength of the their IP portfolio, which must include, in almost every instance, patents or patent applications in at least the markets of our major foreign trading partners.

In fact, empirically we know that U.S. biotechnology companies are a large exporter of IP. The United States are, by a wide margin, the largest originator of international biotechnology patents in all major markets. Small biotechnology companies, which together hold approximately 80% of the development pipeline for new medicines, diagnostics and other bio-based products, play a significant part in this patenting activity.

As products advance through development, small biotech companies often need larger partners in the United States and abroad to develop their experimental products to a market-ready, approvable stage. And even for market-ready products, U.S.-based biotech companies often find it easier to partner with a foreign affiliate who will secure foreign regulatory approval and market the invention in a foreign market, rather than establishing their own overseas sales force. In each case, such partnering depends on robust patent rights that will secure all partners a return on investment.

Small biotechs often bear the initial burden of procuring international patent protection, since patent rights must typically be sought early, and near-simultaneously in the U.S. and in foreign jurisdictions. This enables the small company to partner with larger companies later in the product life cycle to export their products internationally. It is not an option for a small biotech company to wait to secure foreign patent protection, as possible forfeiture of patent rights is too great a risk in foreign absolute novelty jurisdictions. It is imperative that small biotechnology companies plan ahead, even at their inception, to ensure that over the ensuing 10 to 15 years they have the opportunity to partner with larger companies to export their product internationally.

What then are the challenges small biotechnology companies face when filing for patents internationally? First and foremost, international patent procurement is expensive. Small biotechnology companies face unique challenges, as foreign biotechnology patent prosecution is both complicated and subject to greater nonuniformity of the law than it is in many other technologies. Patent claim scope and what is permitted can differ significantly from country to country, which complicates and increases the cost of international patent filing for biotech inventions. Without procedural or substantive harmonization these problems are likely to increase costs for small biotechnology companies.

In addition to filing and prosecution costs, uncertainty limits the ability of small biotechnology companies to limit patenting costs. Small biotechnology companies must patent early in their development life while simultaneously trying to predict which patents will be valuable in 10 years and

which patents will not. As such, biotechnology companies deal with slowly-developing technology that does not allow them to decide to abandon or maintain a family of applications before the real prosecution costs kick in. For example, a biotech company that files a U.S. patent application today (and a PCT application one year from now) has only 30 months to decide whether to abandon the application if it wants to avoid the cost of entering the national stage in a number of foreign countries. 30 months may be enough in some other industries, but in biotech that's too soon for an informed decision. Including translation costs, the aggregate expense of entering the national stage in Japan, Korea, Europe, Australia, and the NAFTA countries can easily exceed $100,000; if the BRIC countries are added, costs can double. Likewise, even if the company defers foreign examination where that's an option, annuities can accumulate to more than negligible amounts. Foreign attorney fees, once prosecution begins, add another layer of cost. Many such costs must be incurred before a biotech company is able to decide whether to maintain or abandon the application. We have small member companies with 30 or 40 employees who are many years from the market, who must every year reserve several hundred thousand of their sorely-needed cash for patent prosecution.

All of these challenges for small biotechnology companies result in patent filing and prosecution costs that are often far from negligible relative to their R&D budgets. Uniformly, such companies would prefer to spend their money to advance their science. This USPTO study, and other initiatives like it, has the opportunity to provide solutions that would save small biotechnology companies significant money that could be spent on researching life-saving products, hiring technicians, engineers and scientists, and shortening our development timeline.

We are aware of grant or loan programs in various foreign countries aimed at helping small businesses defray costs for both domestic and international applications. China is one such example where the Ministry of Finance started subsidizing patent filings for foreign patent applications made by small and medium-sized domestic enterprises, and public and scientific research institutions in 2009. For our small businesses, securing IP protection is as important as obtaining laboratory equipment, leasing space, or hiring creative, dedicated employees. And because IP business assets are at least as important as other, more tangible business assets, there is no reason to exempt patent rights from publicly-funded small business assistance programs that are available for more tangible assets such as capital equipment, hiring, or leasing space. Extending the range of public assistance programs to patent rights for small businesses would help small biotechs spend money normally allocated to patent filing and prosecution elsewhere.

The mechanism for helping small businesses file internationally requires additional thought and could be in the form of a grant, tax deduction, tax credit, or matching program. A matching program, where e.g. every 2 dollars of the company's money would be matched by 8 dollars of grant funding, has the advantage of providing assistance while keeping the small biotech's 'skin in the game.' The small company would be incentivized to still make a business decision on where they file internationally. However, further thought on these mechanisms and how they would affect small biotechnology companies is necessary.

On behalf of BIO, I would like to thank the United States Patent Office for the opportunity to testify. BIO hopes that the USPTO finds a way to defray the hundreds of thousands of dollars it costs small biotechnology companies to file and prosecute patents internationally so that our small companies can spend more money on research, job creation, and product commercialization.