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AND THE INTERNET

Hearing on: "International Patent Issues: Promoting a Level Playing Field

for American Industry Abroad"

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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. These products are literally helping to feed, fuel and heal the world. 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 biotech medicine from its inception to regulatory approval and market launch. The average, fully-capitalized cost of developing a new medicine has been estimated at $ 1.2 billion.

To fully understand what is needed to level the playing field for the biotechnology sector in international markets, one must understand the intellectual property (IP) needs of the

biotechnology sector. Biotechnology innovation requires predictable and effective upstream (early stage) and downstream (product) IP protection. Biotechnology innovation generally starts with an early laboratory discovery, and thus upstream protection helps to generate investment and interest in the further, applied research and development of the invention. Upstream protection includes broad patent eligibility for biotech innovations, consistent patent term, flexible licensing practices, and effective patent enforcement.

Downstream protection is just as important. As mentioned above, the research and development of a biological product can take decades and cost more than a billion dollars to complete. A significant portion of this time and money goes towards developing the regulatory data package that is required by the U.S. FDA, USDA, or similar foreign regulatory offices to approve the biotech product. Therefore, downstream protection for biotech products must include sufficient protection against foreign and domestic competitors relying on the innovator's data package to secure abbreviated approval of competitive products in such markets.

IP Challenges Faced by Biotechnology Companies Overseas

For BIO companies, pursuing international patent protection generally occurs early in the company and product's life cycle. All biotechnology companies understand that the products they hope to develop require robust patent protection abroad. Typical biotechnology inventions include modified cell lines, nucleic acids, proteins, monoclonal antibodies, vaccines, and modified plants and animals, some of which are not patentable in many major markets. Nevertheless, when small biotechnology companies seek access to capital to sustain their existence and development program, a central factor for valuation by investors is the strength of a company's IP portfolio, which must include, in almost every instance, patents or patent applications in at least the U.S. market and those of the United States' major foreign trading partners.

In fact, empirically we know that U.S. biotechnology companies are a large exporter of IP. U.S. companies are, by a wide margin, the largest originator of international biotechnology patents in all major markets.[1] 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.

[1] It appears that U.S. dominance as an originator of international patent applications is nowhere as pronounced as in the biomedical arts. For example, for the 2001-2005 timeframe, the 2008 WIPO World Patent Report lists the following numbers of foreign-filed patent families, by country of origin (top 2 countries):

Technology/Originating Country	United States	Japan
Biotechnology	32,139	7,094
Pharmaceuticals	43,317	7,738
Instruments – Medical Technology	57,902	17,611
Telecommunications	34,627	39,479
Semiconductors	20,431	48,369
Instruments - Optics	18,012	54,278
Machine tools	9,207	11,257

As products advance through development, biotech companies often need larger partners in the United States and abroad to develop their experimental products into 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.

BIO's members often bear the initial burden of procuring this international patent protection, since patent rights must typically be sought before such partnerships develop, and near-simultaneously in the United States and in foreign jurisdictions. Early international filing enables these smaller companies to partner with larger companies later in their product life cycle to export their products internationally. It is generally not an option for biotech companies to wait to secure foreign patent protection until after such partnerships, as possible forfeiture of patent rights is too great a risk in foreign "absolute novelty" jurisdictions. It is imperative that 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 products internationally.

What then are the challenges biotechnology companies face when filing for patents internationally? First and foremost, international patent procurement is expensive. A recent *Nature* article finds that "obtaining a valid patent in most of Europe can cost up to $126,000, the majority spent on validating the patent in each country and translation."[2] The European Commission reports that the average costs of patent filing, validation, and translation in the European Union (EU) is approximately €35,000 (≈$46,000) compared to the average cost in the United States, which is €1,850(≈$2,400).[3]

It is often difficult for biotechnology companies to limit these costs due to the inherent uncertainty surrounding biotech innovation and patenting. As noted above, biotechnology companies must patent early in their development life cycles, while simultaneously trying to predict which patents will be valuable in 10 or more years and which patents will not be so valuable. In other words, biotechnology companies deal with slowly-developing technology that does not allow them to decide to abandon or maintain a family of patent 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. 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 (Brazil, Russia, India and China) are added, costs can double. Thirty months may be enough time to allow other industries to decide whether to spend $200,000 on a patent application, but in biotech that's too soon to make an informed decision.

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[2] "Obtaining a valid patent in most of Europe can cost up to $126,000, the majority spent on validating the patent in each country and translation." See http://www.nature.com/nbt/journal/v30/n3/full/nbt0312-200.html.

[3] See http://ec.europa.eu/europe2020/pdf/cm012012_background_en.pdf

Likewise, even if the company defers foreign examination where that is an option, annuities can accumulate to more than negligible amounts. Foreign attorney fees, once prosecution begins, add another substantial layer of cost. Many such costs must be incurred before a biotech company is able to decide whether to maintain or abandon the application. BIO has numerous member companies that are many years away from market approval, but that must, every year, reserve hundreds of thousands of their scarce dollars for purposes of maintaining their ability to secure patent rights. As a result, patent filing and prosecution costs abroad are often far from negligible relative to their R&D budgets. Uniformly, such companies would prefer to spend their money to advance their science to develop a commercial product.

Biotechnology companies also face unique challenges as foreign biotechnology patent prosecution can be complicated and is subject to greater non-uniformity of the law than in many other technologies. What is a permissible patent claim scope can differ significantly from country to country, which complicates and increases the cost of international patent filing for biotech inventions. For example, examiners in China, Japan, and elsewhere impose onerous data requirements not found in the United States or Europe, which can restrict the scope of the patent. This restricted scope makes it easier for competitors to design around the patent. Other examination inequities include interpreting enablement requirements to restrict patent protection to just the working examples of the case (e.g., in China). Other countries like Canada require substantial clinical evidence before filing a drug patent application and extensive data to prove patentability or operability – requirements that are not found in other major industrialized nations.

In addition to restrictions on patent scope, it is often very difficult to obtain patent protection in a timely manner in some countries. As an example, in India, there is a lengthy pre-grant opposition system, which can delay patent issuance by several years. Once a patent is issued, the same patent then can be the subject of a post-grant opposition. In the United States, some of the patent term lost due to administrative delays prior to issuance can be recovered through patent term extensions. Moreover, for U.S.-regulated products, there is patent term restoration for time lost during the regulatory review period. However, neither of these remedies is available in many other countries (including developed countries like Canada), where patent backlogs and other procedural and regulatory requirements significantly reduce patent term for biotechnology inventions. Such lost patent term significantly disadvantages companies with long development times and complex products such as biopharmaceuticals.

Furthermore, some countries like India and China require that a patent be "worked" in their country to maintain the property right, and will issue a compulsory license if the patent owner fails to satisfy this condition. The recent Bayer compulsory license case in India clearly shows how far some countries will take such matters, as the Indian Controller General stated that **all** patents (not just drugs) must be "manufactured to a reasonable extent in India" and that "mere importation cannot amount to working of a patented invention."[4] Given how complicated the production of biologic medicines and other biotech products can be, such provisions are ripe for abuse to the detriment of U.S. companies and citizens.

[4] See http://www.ipindia.nic.in/ipoNew/compulsory_License_12032012.pdf

Finally, others countries refuse to allow patentability for biotechnology inventions altogether. Countries like Brazil refuse to allow patents for claims to "isolated" DNA, proteins, antibodies or "recombinant" inventions, and require that medical inventions go through two-layers of patenting review – by both the patent office and the regulatory office in charge of approving new medicines. Similarly, some countries like India impose "efficacy" requirements applied only to medical innovations without sufficient rationale.[5] Other countries refuse to patent method of medical treatment claims. While many countries will claim legitimate reasons for refusing to patent such inventions, such restrictions do not apply when innovators from those same countries apply for patents in the United States,[6] thus creating an uneven international playing field for U.S. companies.

These are just some of the many patent inequities that biotechnology companies face when trying to protect their innovations.[7] Without procedural and substantive patent law harmonization, these problems are likely to continue to negatively impact the development and growth of U.S. biotechnology companies. As mentioned above however, patent protection is not the only type of IP that is necessary for the American biotechnology industry succeed globally. Sufficient protection for the massively expensive data that is required by regulatory authorities abroad is also critical.

BIO notes that some elements of harmonization can be achieved through bilateral and regional trade agreements. One such agreement in particular, the Trans-Pacific Partnership Agreement or "TPP," is currently being negotiated by the United States and several key Asia Pacific countries. Such a regional agreement can serve as the basis for future agreements in emerging markets and as such has the potential to lay the framework for a harmonized IP system. In this agreement and others, the United States should advocate for IP provisions that are consistent with U.S. law, including the newly-enacted 12 years of data protection for biologics. BIO urges this Subcommittee's engagement in the process to ensure that the outcome includes a strong IP framework for U.S. innovators, consistent with U.S. law and international trade principles of reciprocity.

BIO thanks the Subcommittee Chairman and Ranking Member for the opportunity to submit this written testimony for the record. BIO urges that this Subcommittee, and the United States Congress as a whole, continues its efforts to improve IP protection abroad for American innovation, and to encourage predictability of patent rights across multiple foreign jurisdictions. Simply put, a more harmonized system can help to ensure that an applicant in one major country patent examining office is able to expect that the same patent application with the same claims would obtain the same examination result in another major examining office. Such an

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[5] Novartis is currently litigating a case in which the company was denied a patent on a drug formulation for "efficacy" reasons even though the drug formulation "is widely recognized as one of the major medical breakthroughs of the 20th century." See Novartis Fact Sheet: http://www.novartis.com/downloads/newsroom/glivec-information-center/Fact_vs_fiction_of_Glivec_India_Case.pdf

[6] In 2010, Chinese entities filed 8,162 patent applications in the United States, and Indian entities filed 3,789 such applications. See http://www.bio.org/advocacy/letters/biotech-ip-issues-around-world-bios-2012-special-301-reporthttp://www.wipo.int/ipstats/en/statistics/patents/

[7] For more international IP challenges facing biotechnology companies see Biotech IP Issues Around the World: BIO's 2012 Special 301 Report

achievement will provide U.S. companies and individual inventors a true level playing field internationally.