Prepared Statement of Brian C. Toohey
Senior Vice President, International Affairs
Pharmaceutical Research and Manufacturers of America

Hearing on "Protecting Intellectual Property Rights in a Global Economy: Current Trends and Future Challenges"

Before the U.S. House of Representatives Subcommittee on Government Management, Organization, and Procurement, Committee on Oversight and Government Reform

December 9, 2009

Chairman Watson, Ranking Member Bilbray, and Members of the Subcommittee: Good morning.

My name is Brian Toohey and I am the Senior Vice President, International Affairs, of the Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA's member companies are leading research-based pharmaceutical innovators devoted to developing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA's membership ranges in size from small start-up research firms to multi-national, multi-billion dollar corporations that employ tens of thousands of Americans, and encompass both research-based pharmaceutical and biotechnology companies. The research-based pharmaceutical sector is one of the most knowledge-intensive enterprises in the U.S. economy, and is responsible for 80% of the world's global healthcare biotechnology R&D.[1] In 2008, the pharmaceutical sector invested $65.2 billion in R&D. The vast majority of their R&D investment —$50.3 billion —was invested by PhRMA's member companies – an increase of over $2 billion from 2007. Of that amount, roughly 70%, or $38 billion, was invested in the U.S.

This sector supports high-quality jobs in the U.S. economy, investing almost ten times more per employee in research and development (R&D) than other manufacturing industries.[2] A 2006 Congressional Budget Office analysis reported: "The pharmaceutical industry is one of the most research intensive industries in the United States."[3] This sector is also the source of high-quality, high-value jobs and economic growth. Analyses showed that the industry supported more than 3 million jobs, and directly employed more than 686,000

[1] Burrill and Company, analysis based on publicly available data, 2009.

[2] R. Shapiro and N. Pham, *Economic Effects of Intellectual Property-Intensive Manufacturing in the United States*, 2007.

[3] Congressional Budget Office, "Research and Development in the Pharmaceutical Industry," October 2006.

Americans in 2006.[4] The pharmaceutical industry's direct contribution to GDP in 2006 was $88.5 billion – more than triple the average contribution of other sectors.[5] As a result, many U.S. states actively compete to attract the pharmaceutical sector. As just one example, North Carolina, the first state to specifically target this sector for economic development, is home to a vibrant and growing pharmaceutical sector that has created more than 118,000 jobs in the state.[6] The state's governor cited the biotechnology industry "as an essential economic engine that can benefit all North Carolinians."[7] These figures highlight the critical importance of the work of U.S. trade negotiators to open foreign markets, encourage the adoption of policies that do not discriminate against foreign-based companies, and promote innovation in the global trading regime. High technology industries such as the innovative pharmaceutical industry are the engine of U.S. growth, and it is more critical than ever that the United States takes a strong stand in favor of the open trading rules that will allow such growth to continue.

To foster continued economic growth and deliver the breakthroughs that will save lives and lower health care costs, our sector relies on public policies that promote and protect pharmaceutical innovation. Patents and data protection are the two mechanisms that have proven essential to allow pharmaceutical companies and their investors to realize the benefits of their significant investments. These complementary mechanisms not only stimulate the early-stage discovery and development of new medicines, but also safeguard the sector's ability to carry out the clinical investigations that are essential for ensuring that those medicines are safe and effective.

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[4] Archstone. The Biopharmaceutical Sector's Impact on the U.S. Economy: Analysis at the National, State, and Local Levels. Washington, DC: Archstone Consulting, 2009.

[5] Archstone. The Biopharmaceutical Sector's Impact on the U.S. Economy: Analysis at the National, State, and Local Levels. Washington, DC: Archstone Consulting, 2009.

[6] Archstone. The Biopharmaceutical Sector's Impact on the U.S. Economy: Analysis at the National, State, and Local Levels. Washington, DC: Archstone Consulting, 2009.

[7] Governor of North Carolina. New Jobs Across North Carolina: A Strategic Plan for Growing the Economy Through Biotechnology, 2008.

This sector faces significant challenges to the discovery, development, testing, production, and ability to commercialize new medical treatments. Adequate protection of intellectual property – both within and outside the United States – is an essential economic prerequisite for continued medical advances against the most challenging and costly diseases. In addition, ensuring market access is critical to ensuring that these innovative pharmaceutical products reach as many patients as possible. Unfortunately, in some countries, significant market access barriers undermine the effectiveness and viability of intellectual property protection, and function to limit patient access to innovative products, distort trade, and, ultimately, discourage innovation, both in the United States and around the world.

Bringing new life-saving and life-improving products to people is the central role of our member companies. Because intellectual property is critical to carrying out this mission, PhRMA members particularly appreciate the continuing efforts of the Office of the United States Trade Representative (USTR), the Department of State, and the Department of Commerce, including the U.S. Patent and Trademark Office, to promote compliance with international obligations by this country's trading partners.

Today, I'd like to talk briefly about some of the medical advances from this sector that would not be possible without intellectual property protection. I would also like to talk about the major issues with respect to intellectual property protection for innovative pharmaceuticals abroad. These include inadequate patent protection and enforcement, patent linkage, inappropriate usage of compulsory licenses, and lack of proper data protection.

I. Intellectual Property Rights Are Essential To Pharmaceutical Innovation

Few advances in the last century have been as important to the preservation and enhancement of life as pharmaceutical innovations. According to University of Chicago economists, "[o]ver the last half century, improvements

in health have been as valuable as all other sources of economic growth combined."[8] New medicines have significantly reduced the socioeconomic burden of disease in the U.S. and around the world. Examples of the impact of medical advances include:

- Cancer. Since 1980, the life expectancy for cancer patients has increased by about 3 years. It is estimated that new medicines account for 50-60% of the increases in survival rates since 1975.[9]

- Cardiovascular Disease. Death rates for cardiovascular disease fell a dramatic 26.4% between 1999 and 2005, according to a recent report by the American Heart Association.[10]

- HIV/AIDS. Since the approval of highly active anti-retroviral treatments in 1995 the annual number of AIDS deaths has dropped by over 70%. Today, patients have a range of treatment options, including different combinations of drugs that often keep them symptom-free for years. Hospitalizations have also decreased between 1996 and 2000 with increasing use of anti-retroviral medicines, despite increases in the number of people infected with HIV/AIDS.[11]

- Alzheimer's Disease. Patients taking cholinesterase inhibitors were 2.5 times more likely to progress slowly after two years compared to untreated

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8 Kenin Murphy, Ph.D., and Robert Topel, Ph.D., Measuring the Gains from Medical Research: An Economic Approach (Chicago: The University of Chicago Press, 2003).

9 F. Lichtenberg, "The Expanding Pharmaceutical Arsenal in the War on Cancer," NBER Working Paper 10328, February, 2004.

10 W. Dunham, "Progress Seen in Heart Disease, Stroke Deaths, However, Obesity Epidemic May Offset Decline in Deaths this Decade," *Reuters,* 15 December 2008.

11 CDC, National Center for Health Statistics, *Health, United States, 2006 With Chartbook on Trends in the Health of Americans,* 2006.

patients, and after five years they were only 1/5 as likely to be placed in a nursing home.[12]

PhRMA's member companies also undertake research, both privately and through public-private partnerships, to develop or improve medicines for diseases that disproportionately affect poor countries. In 2007, the pharmaceutical sector was the third largest source of global R&D investment in neglected diseases after the National Institutes of Health and the Bill and Melinda Gates Foundation.[13]

These pharmaceutical advances — driven by scientific research and creative genius — would have been impossible without a system of laws that provides the structure, stability, and opportunity for the needed investment.

As mentioned earlier, the U.S. pharmaceutical sector is responsible for 80% of the world's R&D in health care biotechnology, and more than 2,900 compounds were in development or seeking regulatory approval in the U.S. in 2009.[14] The compounds in development include 300 potential medicines for rare diseases such as chronic sarcoidosis (an immune system disorder), Lennox-Gastaut syndrome (a severe form of epilepsy) and cystic fibrosis; 750 potential treatments for cancers, particularly lung cancer and breast cancer; 277 new approaches for heart disease and stroke; and 109 new treatments to fight and prevent HIV/AIDS.[15]

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[12] O.L. Lopez et al., "Alteration of a Clinically Meaningful Outcome in the Natural History of Alzheimer's Disease by Cholinesterase Inhibition," Journal of the American Geriatric Society, 2005.

[13] The George Institute. G-FINDER: Global Funding of Innovation for Neglected Diseases. 2008.

[14] PhRMA. PhRMA Annual Member Survey, Washington, DC, 2009; Adis R&D Insight Database, Wolters Kluwer Health, accessed 13 February 2009. Burrill and Company analysis based on publicly available data, 2009.

[15] Pharmaceutical Research and Manufacturers of America, "Medicines in Development for HIV/AIDS," December 2008, http://www.phrma.org/files/New%20Meds%20for%20HIV-AIDS%20report.pdf (accessed 12 January 2009).

In addition, researchers in the innovative pharmaceutical industry are taking full advantage of new insights in genomics (the study of collections of genes and their role in the body and disease), proteomics (the study of the structure and function of proteins), and biomarkers (molecular, biological or physical characteristics that can help identify risk for disease, make a diagnosis, or guide treatment) to develop new treatments and make the most effective use of existing treatments. As just one example, biomarker research has allowed scientists to map proteins in tumors at the sub-cellular level, an important step in the development of personalized and more effective cancer treatments.

Like innovators across the spectrum of American industries, pharmaceutical companies rely on patents to protect their inventions and provide the opportunity to recover their research investments. But patents are particularly important to pharmaceutical innovation given the research-intensive nature of this sector and the substantial investment required to discover and develop products that meet FDA approval requirements. Without patent protection, potential investors would see little prospect of a sufficient return on investment tooffset the accompanying financial risk.[16] It is estimated that without patent protection, 65 percent of pharmaceutical products would never have been brought to market, while the average across all other industries was a mere 8 percent.[17] It is well-established that patents are significantly more important for pharmaceutical firms than for other sectors of industry, in part due to the very high costs and lengthy time required to develop and bring to market new pharmaceutical products.[18]

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[16] Barfield, C., and Calfee, J. Biotechnology and the Patent System: Balancing Innovation and Property Rights. AEI Press, 2007.

[17] Edwin Mansfield, *Patents and Innovation: An Empirical Study*, Management Science (February 1986) at 173-181.

[18] Henry Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, 5 JOURNAL OF INT'L ECONOMIC LAW 849-60 (2002).

Several trends underscore the tremendous costs and, importantly, the commercial uncertainty associated with innovation in the pharmaceutical sector that drive the need for effective intellectual property protection:

- In 1960, the average time to develop a new medicine was approximately eight years. By 2007, that figure had increased to between 10 and 15 years.[19] At the same time, costs to bring new discoveries from laboratory to bedside have increased dramatically. A recent study from the Tufts University Center for the Study of Drug Development estimates the average cost of developing a new medicine (including the cost of capital) at more than $1.2 billion, in 2005 dollars.[20]

- A typical commercial product results from making and screening *thousands* of promising, but ultimately failed molecules – products that never make it to market. For every 5,000-10,000 compounds that enter the R&D pipeline, only 250 reach the pre-clinical stage, and of those, only five progress to clinical study in humans, and only one receives regulatory approval.[21] The following figure illustrates this challenging path.

- Clinical trials have become more complex and more costly to perform. Clinical trials today are longer, have more participants (who are difficult to recruit and retain), and involve more demanding and complex trial design and clinical protocols, including more procedures per patient and difficult-to-measure clinical endpoints.[22]

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[19] *Id.*; Joseph A. DiMasi, *New Drug Development in the U.S. 1963-1999*, 69 Clinical Pharmacology & Therapeutics 286, 292 (2001).

[20] J. DiMasi and H. Grabowski, "The Cost of Biopharmaceutical R&D: Is Biotech Different?," *Managerial and Decision Economics*, 2007.

[21] PhRMA, *Drug Discovery and Development: Understanding the R&D Process* (2007), *available at* http://www.innovation.org/drug_discovery/objects/pdf/RD_Brochure.pdf.

[22] Tufts Center for the Study of Drug Development, "Growing Protocol Design Complexity Stresses Investigators, Volunteers," *Impact Report*, 2008.

- The regulatory environment for pharmaceutical products has grown increasingly complex over the past decade. Significant new requirements are continually introduced. For example, two years ago, enhanced post-market surveillance requirements were enacted,[23] in turn increasing the capital investment necessary to launch many products.

- Increasingly, pharmaceutical innovators face the challenges of developing therapies for some of the most complex diseases for which there are currently no effective treatments.[24]

In light of these complexities, it is not surprising that only two in 10 approved medicines ever produce revenues sufficient to recoup the average cost of drug development.[25]

As the factors discussed above illustrate, research and development for new pharmaceuticals is unpredictable, requires immense investments of human and financial capital, and can take up to 15 years of effort before a product is actually approved. Yet, once a pharmaceutical product has been developed, often it can easily be copied and produced.

Because the costs and technical challenges required to copy new drug products are trivial compared to the resources required to develop them, legal mechanisms have proven necessary to sustain a competitive market for innovation in the pharmaceutical sector. These mechanisms defer the time after which a new pharmaceutical product is introduced into the marketplace that a copy of the pharmaceutical product can be made and sold. These mechanisms, which provide a limited period of exclusivity in the marketplace for innovators, allow innovator companies the opportunity to make a return on their substantial

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23 *See generally* Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85.

24 Tufts University Center for the Study of Drug Development, *Growing Protocol Design Complexity Stresses Investigators, Volunteers*, Tufts Impact Report (Jan./Feb. 2008), *available at* http://csdd.tufts.edu/_documents/www/Doc_309_65_893.pdf.

25 Vernon, J., Golec, JH., and DiMasi, J. Health Economics Letters: Drug Development Costs When Financial Risk Is Measured Using The Fama–French Three-Factor Model. Health Economics; June 2009. www.interscience.wiley.com.

investments (which in turn fosters future R&D investment) and provide legal certainty for all concerned.

Two complementary legal mechanisms in particular provide for periods of exclusive marketing of new therapies. These mechanisms are essential to attract the investment needed to fund the long, uncertain, and costly drug development process. First, patents protect inventions made in the course of research and development of a new medicine by giving the innovator the right to prevent the unauthorized use of the inventions for a defined term. The rights conveyed by a patent correspond to the invention – for example, a new drug molecule, a particular drug delivery system, new uses of a drug to treat different diseases, or a way the drug can be made. Thus, for example, depending on the nature of the patented invention, a patent may have a limited capacity to prevent the unauthorized copying of a new drug product. A patent provides proportionate, but not necessarily absolute, protection against copying.

Second, data protection (also known as data exclusivity), has proven essential. Data protection functions by deferring the date on which a generic pharmaceutical manufacturer can rely on the clinical data produced by the innovator to support approval of a new medicine. Such data often represents the investment of more than a billion dollars in conducting the rigorous and lengthy preclinical and clinical testing that FDA requires – and which is indeed essential to establishing whether a new pharmaceutical in fact is a safe and effective therapy for patients.(add cite for this) Generic drug applicants do not perform and submit full clinical trials on their products, but rather must only demonstrate that their drug is the same and that it is bioequivalent (that is, it is absorbed to the same rate and extent as the innovator in healthy volunteers) to the innovative drug. The generic drug applicant relies on the innovator's data as the basis that its product is safe and effective. Data protection prevents the unfair commercial use of clinical data that would result if a generic manufacturer were entitled to rely on the data as soon as a new product was approved. Data protection is not a patent extension. Rather, it runs independently from the date of approval of the

innovator drug, and thus usually runs concurrently with patent protection (which begins to run when the patent application is filed).

Governments have an obligation to provide for enforcement of patents. This enforcement can be implemented in many ways. For pharmaceuticals, government regulatory agencies are involved in review of products that can infringe patents. Through a patent linkage mechanism whereby the regulatory authority does not grant approvals for products known to infringe patents, governments can avoid having a government agency (i.e., the regulatory approval authority) foster infringement of patents. This rule of law concept is particularly important in countries in which the ability to enforce a patent in court is inadequate.

II. Importance of Effective Intellectual Property Protection by U.S. Trading Partners

During the Uruguay Round negotiations that produced the World Trade Organization (WTO), the United States made significant progress toward more consistent and effective global intellectual property (IP) protection standards. The result of this effort was the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which requires all WTO Members, including the United States and most of its trading partners, to establish functional intellectual property systems. Under the TRIPS Agreement, intellectual property owners must be given rights promptly, must gain certain minimum assurances of the characteristics of the rights, and must have recourse to effective means for enforcing those rights.

One of the concessions made by the United States in the TRIPS Agreement was to provide developing countries with a number of extended transition periods to implement new standards. During the first transition period, which concluded on January 1, 2005, all but the least developed countries were required to comply with the provisions of the TRIPS Agreement. Many of these trading partners have benefited tremendously from the trade liberalizations of the

Uruguay Round in other areas outside the TRIPS Agreement. These countries are also home to industries that aggressively compete with U.S. industries – particularly in the pharmaceutical sector. Yet even now, many developing countries have not fully met their TRIPS obligations to provide effective intellectual property protection for pharmaceutical technology.

Especially troubling is the failure of almost all the developing countries to establish measures in their countries that implement effectively their obligations under TRIPS to prevent unfair commercial use of pharmaceutical test data (i.e., provide data protection). PhRMA member companies believe it is now time to refocus government efforts on steps that will ensure a full implementation of TRIPS, including its provisions concerning protection of clinical test data.

Another important area of concern is counterfeit drugs. Weak regulatory and IP enforcement regimes in some countries contribute to this problem, which increases health risks to patients, particularly those in poor populations. PhRMA believes this problem may increase in significance, and that the assistance of the United States throughout the Special 301 process and through other fora will be essential to ensuring delivery of safe medicines to patients.

III. Market Access Barriers

Many of the countries in which the pharmaceutical sector attempts to do business erect barriers to reduce the access of our products into their markets. Clearly, these reductions in market access adversely affect the health of patients in those countries, but they also have potential negative effects on our industry in the United States and consumers worldwide. That is, these reductions could translate into lost revenues that, in turn, could translate into loss of employment and decreases in the R&D investment critical for continued medical advances. We applaud the U.S. Government for its success in eliminating certain trade-distorting practices in intellectual property systems worldwide with respect to pharmaceutical products. The problems we face from market access barriers grow each year, in part because of this success. When it is not possible to

eliminate our products from markets through sub-standard intellectual property laws, officials in many countries seek alternatives such as imposing market access barriers.

We believe that it is critical for the U.S. Government to take action against measures that deny fair and equitable market access to our products. PhRMA members believe that the Special 301 review process can be a particularly useful trade tool through which these barriers in priority markets can be removed.

A. Types of Market Access Barriers

Market access barriers for pharmaceutical products are not generally found in traditional forms such as quotas or tariffs. Rather, they often materialize as direct government price controls or the discriminatory administration of national health insurance schemes that dominate markets for pharmaceuticals. In respect to the latter in particular, pharmaceutical suppliers cannot market a product to most of the population until the insurance or reimbursement authority approves its use and its price. Consequently, reimbursement officials can erect barriers to access either unintentionally through poor administration or intentionally through protectionist measures.

There are four general types of market access barriers our industry faces. Any or all may be present in a single country. Often, several types work together to effectively deny market access for our companies' products.

First, many government price control and national insurance programs lack transparency and fairness in product approval and price setting processes. While most countries afford manufacturers or sellers some right of participation in pricing or reimbursement decisions, there are significant disparities in the openness and accessibility of the decision-making process. In many countries (such as China, Brazil, and India) governments obtain information from manufacturers or sellers that forms part of the basis for a pricing or reimbursement decision, but the decision-making process itself is largely

conducted in a non-transparent manner. In addition, a lack of reasoned explanations for final determinations and an unwillingness of administrative bodies and courts to scrutinize administrative decisions often prevents stakeholders from challenging adverse decisions.

Another key transparency concern relates to the frequent failure of decision-making bodies to provide rights of participation to all key stakeholders. For example, many governments (including those in highly developed countries such as Australia, France, and Italy) afford patients little or no opportunity to participate in reimbursement decisions, even though these stakeholders often have information that is essential to a fair decision.

In this vein, the recently concluded U.S.-Korea Free Trade Agreement (FTA) sets an important precedent by building on the transparency and due process provisions addressing pharmaceutical pricing and reimbursement systems included in prior agreements. Under the terms of the FTA, Korea must revise its system to provide, among other things, greater rights of participation to stakeholders, issue full explanations for administrative decisions, and establish an independent review mechanism. These FTA provisions should be adopted in other countries that place pricing and reimbursement constraints on pharmaceuticals.

Second, many government price control and national insurance programs are used to unnecessarily delay marketing approval of innovative pharmaceuticals. In many countries, national health insurance schemes dominate markets for pharmaceuticals. As a consequence, a pharmaceutical effectively cannot be marketed in a country until national authorities have determined its reimbursement price. The government entities responsible for pricing and reimbursement in most countries tend to be highly opaque bureaucracies, and the process of obtaining a government-approved price can be lengthy. These delays may be used by governments to delay market entry for other purposes.

For example, governments may use the fact that each day of delay reduces the effective patent life for a new drug (i.e., the time between initial sale of the product in a country and expiration of the patent) as leverage to negotiate lower prices with innovator companies. In fact, some delays may be so lengthy that the patent term could expire by the time marketing approval is granted, thereby depriving the innovator of the benefit of its patent rights altogether. Delays may also be favored to avoid costs associated with offering new treatments, or to reduce competition with existing products offered by local generic companies. Moreover, it is not uncommon for some foreign governments to close reimbursement lists entirely to innovative pharmaceuticals. These processes all operate to delay market access (and to diminish the effective patent life) for many innovative new drug products.

Third, many government price control and national insurance programs routinely establish unreasonable prices. Policies creating market access barriers can also result in market distortion that makes the cost of generic pharmaceuticals – often produced primarily by domestic companies – quite high. (add cite for this point – perhaps OECD report in fn 26 covers it) Many foreign generics markets are characterized by a lack of true market competition, which tends to raise prices of those pharmaceuticals above what they would be in a free market. Indeed, many foreign systems actually mandate high prices for generics products, requiring that they be reimbursed at rates as high has 70% or even 90% of the price of original branded products. (same) In the United States, where there is vigorous price competition in the generics market, prices of generic pharmaceuticals tend to be much lower. In a letter to Congress that accompanied the 2004 Department of Commerce Study, the Secretaries of Commerce and Health and Human Services asserted that "[i]n fact, U.S. consumers would pay, on average, 50 percent more for their generic medications if they bought them abroad."[26]

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[26] U.S. Department of Commerce, "Price Controls in OECD Countries," (2004)

Fourth, many government price control and national insurance programs wish to favor local suppliers over innovative, multinational enterprises. Local interests – such as generic producers, wholesalers and pharmacists – generally occupy a politically-favored position within these systems and have significant sway in the policy decisions of the domestic health system.

These are some of the primary market access barriers faced by PhRMA member companies. We provided details of these and other barriers on a country-to-country basis in our submission earlier this year during the Special 301 Review. The submission can be found at www.phrma.org.

B. U.S. Government Engagement on Market Access Barriers

The Special 301 statute authorizes the USTR to identify foreign countries that deny fair and equitable market access to U.S. persons that rely upon intellectual property protection. PhRMA looks to Congress, the Administration, and USTR specifically, to take action by continuing to develop an effective strategy to address these practices. Such actions would be consistent with Congressional directives found in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and the Trade Promotion Authority Act of 2002. PhRMA believes that the Administration should use the Special 301 process to advance a multi-front strategy. First, as recognized in USTR's 2008 Special 301 Report, bilateral consultations should be pursued to promote sustainable innovation by addressing market access barriers abroad.[27] The market access barriers maintained in even developed countries undermine intellectual property rights, deny patients access to the most innovative medicines, and undermine sustainable innovation.

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[27] The 2008 Report stated that:

> The United States also is seeking to establish or continue dialogues with OECD and other countries to address concerns and encourage a common understanding between developed countries on questions related to innovation in the pharmaceutical sector. The United States already has had such dialogues with Japan and Germany, and is seeking to establish ones with other countries. It also has established a dialogue on pharmaceutical issues with China.

Second, the Administration should continue its use of bilateral and multilateral trade negotiations to pursue a positive agenda on pharmaceutical market access issues. For example, the outcome of the U.S. – Korea FTA negotiations benefited from a two-way discussion on Korea's complex and discriminatory listing system. The outcome was a negotiated text that included provisions on pharmaceuticals and specific steps to improve the transparency and accountability of the pricing and reimbursement listing process. We urge the Administration to build on this success and include similar provisions in agreements with future trading partners.

We look forward to working with you to continue our efforts in securing adequate and effective market access for U.S.-based innovative pharmaceutical companies.

IV. Summary of Selected Countries and Issues

Next, I would like to highlight some priority issues by country that we and our member companies would welcome the opportunity to work collaboratively with you in addressing.

Brazil: PhRMA's member companies operating in Brazil remain concerned by the Government of Brazil's failure to make progress on several important patent and data protection issues. Many of these concerns have been raised in prior years with little apparent impact, including:

- the practice of Brazil's health regulatory agency (ANVISA) of improperly intervening in the patent examination process, whereby they frequently defer action or block patent grants;

- the lack of clarity, transparency and judicial review of actions taken pursuant to the decree that authorizes the Minister of Health to issue compulsory licenses;

- continued concerns regarding the "patent backlog" contributing to unreasonable delays in the granting of patents to deserving inventions despite some efforts by the patent office (INPI) to improve its operations;

- government price control mechanisms that discourage innovation while not addressing the stated goal of improving access to medicines; and

- the often antagonistic positions advanced by Brazil in numerous multilateral *fora* that would, if successful, undermine the international patent system and thereby diminish incentives for critical R&D worldwide.

India: PhRMA and its member companies remain concerned about deteriorating intellectual property protection standards and significant market access barriers in India. India still has not implemented data protection provisions for pharmaceutical test data, as required by TRIPS. The standards for patentability in India need to be amended to conform to India's obligations under the TRIPS Agreement as well as prevailing international practice. In addition, the backlog of patent applications awaiting examination and the patent pendency are of growing concern. Also, India is an increasingly significant source of counterfeit pharmaceutical products and is believed to be a major channel for the export of counterfeits to consumers worldwide. Finally, PhRMA members are concerned about proposals to increase the scope of India's government price control system in a manner that would discriminate against imported products.

China: PhRMA and its member companies operating in the People's Republic of China remain concerned over inadequate intellectual property protections, including a lack of effective data protection and poor enforcement against counterfeit pharmaceuticals. Likewise, PhRMA is concerned about several market access barriers, including: (1) an inadequate government pricing

policy for innovative products; (2) an absence of update of drug reimbursement list for over four years; and (3) a lengthy requirement for clinical trial applications.

Philippines: PhRMA and its member companies operating in the Philippines are increasingly concerned about the deterioration of the intellectual property protection environment and the failure of the Philippine Government to address PhRMA's long-standing issues. PhRMA members' most pressing concerns relate to the implementation of the Universally Accessible Cheaper and Quality Medicines Act of 2008 ("the Act"). PhRMA's concerns were not considered or addressed by the Government during the drafting of the Act and its implementing rules and regulations. As a consequence, the Act and its implementing rules and regulations contain several provisions that undermine the ability to obtain adequate intellectual property protection in the Philippines and are inconsistent with the Philippines' obligations under the TRIPS Agreement. In addition, PhRMA's member companies continue to face numerous issues related to patent linkage, parallel importation, data protection, counterfeit drug enforcement, and regulation of drug prices.

Thailand: PhRMA and its member companies operating in Thailand are very concerned that no progress has been made in addressing the issues PhRMA has previously raised, particularly the inappropriate use of compulsory licenses in Thailand, and the fear that the Government is seeking to further reduce protections of intellectual property rights. Despite previous assurances by the Thai Government that a constructive healthcare dialogue between PhRMA's member companies and Thailand Government officials would occur, numerous good faith attempts by member companies to start this process have been rebuffed. PhRMA's member companies continue to have major concerns related to counterfeit medicines, patent linkage, the lack of data protection, delays in the grant of patents, and inappropriate government procurement policies.

Russia: As Russia prepares to develop its own innovative pharmaceutical industry, major market access barriers remain for the U.S. pharmaceutical sector. Russia still does not provide pharmaceutical data protection, despite commitments to the U.S. Government to implement such protection by May 2007. Moreover, non-transparent market conditions are compounded by new signals that some Russian officials want to use healthcare reform to promote discriminatory policies that further impair market access for PhRMA member companies. Although Russia made significant commitments in the 2006 U.S.-Russia WTO Accession bilateral on intellectual property rights (IPR), the Russian Government has not taken steps to fulfill these commitments.

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Thank you again for the chance to speak with you today. PhRMA and its member companies believe it is crucial for this Subcommittee and other policymakers to support policies that foster incentives for innovation both in the U.S. and abroad. We welcome your interest in this issue, and look forward to working with members of the Subcommittee and others in Congress as you address these and other important policy issues relating to innovation and access to medicines.