**Statement of**

**Roy F. Waldron**
**Senior Vice President, Associate General Counsel**
**& Chief Intellectual Property Counsel**
**Pfizer, Inc**

**on behalf of**

**Pharmaceutical Research and Manufacturers of America**

**before the**

**SUBCOMMITTEE ON INTELLECTUAL PROPERTY, COMPETITION, AND THE INTERNET**
**COMMITTEE ON THE JUDICIARY**
**HOUSE OF REPRESENTATIVES**

**on**

# INTERNATIONAL PATENT ISSUES: PROMOTING A LEVEL PLAYING FIELD FOR AMERICAN INDUSTRY ABROAD

**April 26, 2012**

Mr. Chairman and Members of the Subcommittee:

Thank you for this opportunity to appear today and to discuss patent laws and government policies and practices that skew the playing field applicable to the research-based pharmaceutical industry when it attempts to protect its innovative and life-saving products in other countries.

My name is Roy Waldron and I am the Chief Intellectual Property Counsel for Pfizer, Inc. As part of my responsibilities at Pfizer, I oversee the acquisition and enforcement of patents and trademarks worldwide. I am also Chairman of the Intellectual Property Task Force within the International division of the Pharmaceutical Research and Manufacturers of America (PhRMA). This Task Force has the responsibility for reviewing and responding to patent laws and government policies and practices in other countries for the association. It is in my capacity as Chairman of the Task Force that I appear before you today.

PhRMA represents the country's leading pharmaceutical research and biotechnology companies. Its members are devoted to developing medicines that allow patients to live longer, healthier, and more productive lives. Consistent with the Congressional Budget Office's finding that the pharmaceutical sector is one of the nation's most research-intensive sectors, PhRMA members invested an estimated $49.5 billion in research and development in 2011.[1] Medicines developed by member companies have produced large improvements in health across a broad range of diseases, with the rapid growth of biological knowledge creating growing opportunities for continued profound advances against disease. In 2011, 3,240 medicines were in clinical trials or under review by the Food and Drug Administration (FDA) in the U.S., versus about 2,200 medicines in development in the rest of the world combined.[2]

U.S. biopharmaceutical research makes important economic contributions to U.S. gross domestic product, contributions likely to grow if the incentives and underpinnings for large-scale research and development (R&D) investment remain intact. According to a recent study by Battelle Technology Partnership Practice (Battelle), the U.S. biopharmaceutical sector supported a total of 4 million jobs in 2009, including more than 650,000 direct jobs.[3] Battelle also reports that the U.S. biopharmaceutical sector has a high multiplier effect – in 2009, each job in a biopharmaceutical research company supported almost five jobs across the economy, ranging from biopharmaceutical manufacturing jobs to construction and other building service jobs, to contract researchers and child care providers. The U.S. biopharmaceutical industry also exported about $46 billion in goods in 2011, making it the sixth largest U.S. exporting industry for the year.[4] Markets outside of the U.S. are fueling demand for innovative medicines due to their increasing economic growth and rising middle class. Although this creates substantial export opportunities for U.S. companies, there are substantial challenges in many of these countries that impede member companies' ability to grow exports and the high-wage, high-skill jobs that this

[1] Pharmaceutical Research and Manufacturers of America, PhRMA Annual Membership Survey (Washington, DC: PhRMA 1981-2012).
[2] Adis R&D Insight Database, Wolters Kluwer Health (accessed February 10, 2012).
[3] Batelle Technology Partnership Practice, The U.S. Biopharmaceuticals Sector: Economic Contribution of the Nation (Columbus, OH: Batelle Memorial Institute, July 2011).
[4] *See* http://dataweb.usitc.gov/, accessed April 17, 2012 (query run of U.S. domestic exports classified by 4-digit NAIC code 3254).

demand generates. We applaud the Subcommittee's interest in promoting a level playing field and fostering U.S. global competitiveness.

## I. Background and Summary of Testimony

Developing a new medicine takes between 10 and 15 years of work and costs, on average, more than $1 billion of investment in research and development.[5] Like innovators across the spectrum of American industries, pharmaceutical companies make the substantial R&D investments that yield new medicines in reliance on a legal regime that provides protection for any resulting intellectual property. PhRMA members rely on patents to protect their inventions and provide an 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.[6]

Although strong intellectual property protections are provided in the United States, this is not true in many of the developing countries where the greatest growth potential for innovative medicines developed by the U.S. biopharmaceutical industry is expected to occur over the next few years. In many of these countries, local biopharmaceutical companies are owned by or connected to the government and/or supported by the government's industrial policies. The main competitive edge of the U.S. biopharmaceutical industry relative to these local businesses is the innovative nature of their products. While developing and testing innovative medicines requires large investments and a high degree of risk, copying the final product can often occur with relatively small effort or risk in a short period of time. The competitive advantage of the U.S. biopharmaceutical industry and its corresponding ability to increase exports and associated jobs is, therefore, dependent on legal principles and mechanisms which recognize and effectively enforce patents and other forms of intellectual property associated with new medicines. Establishing these principles and mechanisms is often strongly resisted by both local interests and government policies that favor national business interests.

Each year, PhRMA includes a comprehensive list of the barriers faced by member companies in a submission to the U.S. Trade Representative (USTR) as part of the annual "Special 301" review process.[7] Rather than recite this list (PhRMA submits comments on more than 40 countries), we will summarize the major categories of barriers that PhRMA members face with respect to patent systems abroad and cite some of the most significant examples of each. The key categories of barriers that PhRMA members face are:

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[5] JA DiMasi, and HG Grabowski. "The Cost of Biopharmaceutical R&D: Is Biotech Different?" Managerial and Decision Economics no. 28(2007): 469-79; PhRMA. "Drug Discovery and Development: Understanding the R&D Process." (Washington, DC: 2007).

[6] Henry Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, 5 Journal of Int'l Economic Law 849-60 (2002). Without patent protection, potential investors would see little prospect of a sufficient return on investment to offset the accompanying financial risk. Barfield, Claude, and Calfee, John. Biotechnology and the Patent System: Balancing Innovation and Property Rights. AEI Press, 2007. It has been estimated that without patent protection, 65% of pharmaceutical products would never have been brought to market, while the average across all other industries was a mere 8%. Edwin Mansfield, *Patents and Innovation: An Empirical Study*, Management Science (Feb. 1986) at 173-181.

[7] PhRMA's 2012 "Special 301" Submission is available on the "Regulations" website of the U.S. Government at http://www.regulations.gov/#!documentDetail;D=USTR-2011-0021-0010.

- Lack of effective patent enforcement, which includes challenges to obtaining injunctions and damages in patent cases, preventing inappropriate compulsory licenses, and ensuring governments honor patents and regulatory data protection periods before generic products are approved and launched;

- Administrative hurdles in the patent granting process and other administrative procedures, which include delays in examination and grant, use of non-patent related criteria, pre-grant oppositions, additional regulatory procedures and resultant diminution of the effective patent term; and

- Unclear and arbitrary requirements for patent grant, which include expansive utility data support requirements that represent additional standards or hurdles.

Some of these barriers appear to be inconsistent with obligations of governments under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), the North American Free Trade Agreement (NAFTA), or other trade and commercial agreements. Conversely, innovators in other countries receive the benefits of an effective patent system in the United States that meets these international obligations. To improve the competitive environment abroad and move towards a more level playing field, we would greatly appreciate efforts by Members of this Committee to:

- ensure that the U.S. Government articulates and pursues strong intellectual property standards in Free Trade Agreements (FTAs) (including the ongoing negotiations of the Trans-Pacific Partnership) by building on the obligations in the recent Agreement with Korea and the principles found in U.S. law (*i.e.*, 12 years of regulatory data protection for biologics);

- support ongoing efforts of the U.S. Government to secure full implementation of existing and future international obligations under multilateral, regional and bilateral trade agreements; and

- support the system of the IP Attachés administered by the U.S. Patent and Trademark Office and various forms of technical assistance and capacity building programs sponsored by the U.S. Government and other institutions.

## II. Enforcement

Patent enforcement is a basic element needed to provide conditions that support successful growth in exports of innovative medicines. Some of the obstacles in enforcement systems are illustrated here.

### A. Obtaining Injunctions and Damages – China

Many countries have at least one barrier to patent enforcement in their legal regime, and these barriers differ from country to country. China, however, seems to exhibit many of the common barriers – inadequate damages, lack of timely relief, duplicative procedures, time-consuming formalities and ineffective injunctions.

Overall, the level of damages available to a plaintiff is insufficient to deter infringement or make a plaintiff whole. For example, the Patent Law in China sets out four possible methods for calculation of damages in a patent case, but in practice the court in virtually every case reverts to the fourth method, which has a cap of RMB 1 million (roughly $156,000), an amount that often does not compensate the patent owner and does not deter potential infringers.[8] Moreover, other methods for deterring infringement are not available. For example, there is no mechanism for enhancement of the damages in the case of willful infringement and attorneys' fees are not available as a practical matter.

Preliminary injunctions are theoretically available from courts,[9] but they are rarely granted. Judges are reluctant to issue them because they do not have published or precedential standards governing the "irreparable harm" to guide them. Judges are also hesitant to issue preliminary injunctions in cases involving complicated technologies. Preliminary injunctions are more important in China than in some other jurisdictions because money damages are not adequate to compensate the patent owner, as discussed above.

Enforcement of court orders, whether damages or injunctions, is not automatic in China; if the losing party fails to comply, the winning party must apply separately to an enforcement tribunal to compel enforcement. The enforcement tribunals, in turn, have considerable discretion with respect to whether, and how firmly, to enforce an order. While in theory an individual or responsible party (of an enterprise) can be fined or jailed for violating a court order, the fine is trivial, and a jail sentence is rarely imposed.

There are Local Patent Bureaus in China that have the authority to issue an "administrative" injunction against an infringer in their jurisdiction.[10] These Bureaus, however, have no authority to impose sanctions on infringers who do not comply with their injunctions, and patent owners must apply to a court in a separate action to enforce these orders. Furthermore, the local intellectual property authority is also limited to injunctive remedies; it cannot adjudicate damages. In any case, local intellectual property authorities are hesitant to adjudicate patent infringement complaints, at least where the matter is complex, because they lack expertise and resources for these cases. Thus, patent owners are both unable to obtain injunctive relief in a timely manner or obtain reasonable damages during or after these delays.

B. Compulsory Licensing

Many countries have provisions that permit government authorities to issue patent licenses to other entities to exploit the patented invention without the permission of the patent owner under specific circumstances. Such action is usually referred to as a compulsory license although there is no internationally accepted definition for that term.

Compulsory licenses can be granted in extraordinary situations of extreme urgency or other national emergency to meet the legitimate needs of the public. Often, however, compulsory licenses may be used by competitors as a means to obtain authorization to use or transfer

[8] Patent Law of the People's Republic of China, Art. 65, available at http://www.wipo.int/wipolex/en/text.jsp?file_id=178664.
[9] *Id.* at Art. 66.
[10] *Id.* at Arts. 3, 60, and 64.

technology developed by others without having to pay the costs associated with developing and testing the product. These copiers want to obtain a free ride or use the technology at a much reduced cost. Also, compulsory licenses are inappropriately viewed by some governments as part of their industrial policy to establish domestic production or their health policy to reduce government expenditures for medicines.

*1. Thailand*

The Government of Thailand granted compulsory licenses in 2006 to patents covering three major products: two protease inhibitors and one product for preventing strokes and heart attacks.[11] Unofficially, government officials acknowledged that part of the motivation for granting these three compulsory licenses was because the budget could not cover the cost of reimbursing these innovative products. Royalties were set at 0.5 percent of "sales" for products with high volume sales, and up to 2.0 percent of sales for products with lower volume sales.[12] It should be noted that each of the three products were manufactured or acquired by an entity owned and controlled by the Thai Government. The licenses for patents covering two products were renewed in 2011 and the other patent expired.

*2. India*

The Indian Controller General of Patents granted the first compulsory license under the amended Patents Act in March of this year.[13] The compulsory license related to a patent covering a product to treat liver and kidney cancer. The patent owner had only a limited opportunity to market its product given that a local company (Cipla) was successfully marketing a copy of the patent owner's product. The patent owner initiated an infringement action against Cipla, a case which is still pending.[14]

A second local company (Natco) applied for a compulsory license on the basis that the patent owner was not meeting the demands of the public at reasonable prices and that the patent owner was not manufacturing the patented product in India.[15] The Controller agreed that the patent owner was required to manufacture the patented product in India despite the prohibition in TRIPS Article 27.1 to the contrary. In addition, the Controller decided that the patent owner had to supply the entire market in India even though Cipla's product remained in the market. The order granting the compulsory license provided for a royalty to the patent owner of six percent of net sales of the products produced under the license, but established price controls at levels far below even Cipla's price.[16]

[11] The Ministry of Public Health and The National Health Security Office of Thailand. "Facts and Evidences on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand," February 2007.
[12] The Ministry of Public Health and The National Health Security Office of Thailand. "Facts and Evidences on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand," February 2007, p. 11.
[13] Compulsory License Application No. 1 of 2011. Granted March 9, 2012 by P.H. Kurian.
[14] *Bayer Corporation Anr. V. Cipla Ltd.* C.S. (O.S.) No. 523 of 2010.
[15] The Compulsory License Application No. 1 of 2011 from M/S. Natco Pharma Ltd. in Patent No. 215758. Published Office Journal of the Patent Office, Issue No. 32/2011. August 12, 2011.
[16] Compulsory License Application No. 1 of 2011. Granted March 9, 2012 by P.H. Kurian.

C. Effective Enforcement Mechanisms before Generic Approvals

Many countries provide mechanisms in their regulatory approval process to provide for adjudication of patent infringement or validity claims before generic or biosimilar products are marketed. This opportunity to resolve issues early is helpful to patients and generic companies as well as the innovators. Regrettably, many countries have not established effective mechanisms to accomplish this objective.

*1. Mexico*

A Decree in 2003 was intended to "link" the regulatory regime for pharmaceutical products with the patent system. Unfortunately, the Decree is not being applied to a very important class of pharmaceutical patents – formulations. New formulations are often more effective and efficient than the original formulations and usually better respond to a patient's medical needs. For example, a new formulation may allow a patient to take one pill per month (delayed-release to enhance adherence), rather than one or more pills per day, and may have the same or improved therapeutic effect. Yet, these important inventions cannot benefit from the linkage system provided by the Decree.

Moreover, PhRMA and its members are concerned that health authorities in Mexico (*i.e.*, COFEPRIS) are increasingly approving the marketing of copies of patented products without the permission of the patent owner, despite the requirements of the Decree.

*2. Chile*

Chile has not implemented its FTA obligations. Specifically, Article 17.10.2 of the U.S.-Chile Free Trade Agreement requires Chile to implement an effective enforcement mechanism. To date, Chile has failed to establish a satisfactory mechanism to enable effective patent enforcement before marketing approval decisions are made and implemented and PhRMA's members believe that several copied products have received marketing approval despite being covered by a patent.

During 2011, the Chilean Government indicated to USTR and the innovative pharmaceutical industry its recognition of the need to enact new legislation aimed at establishing an effective patent enforcement mechanism that would bring Chile closer to compliance with its FTA obligations. Legislation is pending, but to the best of our knowledge has not yet been enacted.

D. Regulatory Data Protection

The development of test and other data to prove to regulatory authorities that pharmaceutical products are safe and effective requires significant investment (without any guarantees of success) over an extended period. To encourage the development of these data and subsequently the marketing of new pharmaceutical products, TRIPS Article 39.3 requires WTO Members to protect these data from disclosure and unfair commercial use.

It should be noted that although patents and regulatory data protection (sometimes referred to as "data exclusivity") may prevent others from copying a pharmaceutical product, patents and regulatory data protection are very different forms of protection with their own terms, and are

provided for very different reasons. Patents protect the new, useful, and non-obvious inventions. Regulatory data protection encourages the development of the data required to prove that a product is safe and effective, regardless of whether the product is covered by patents.

For products that are not eligible for patents (*e.g.*, products based on naturally occurring materials or compounds which had been known in the past), data protection is the only effective protection available. In countries where the availability of litigation to resolve patent disputes is more theoretical than real, data protection is also the only effective form of protection for pharmaceutical products.

Many countries do not provide effective data protection. Although regulatory data protection is required by the TRIPS Agreement, some countries do not have any effective protection for regulatory data, *e.g.*, India. We also have concerns about the regimes in other trading partners with whom we have FTAs. Several examples follow:

*1. Chile*

Supreme Decree 107 of 2010 provides a regime for the protection of data in Chile, but there are still some significant problems with this regime. For example, data associated with proving the safety and efficacy of new uses, new formulations, and new dosage forms of known products, as well as data associated with new compositions containing known products, are not eligible for protection. In Chile, holders of the data must supply applications to obtain data protection; a formality not provided for in international agreements, which may erode the effectiveness of regulatory data protection.

*2. Mexico*

Mexico has a statute that provides, in essence, that the obligations related to regulatory data protection in the TRIPS Agreement and the NAFTA apply directly in Mexico. Mexico has not, however, enacted any other statutes or promulgated regulations to implement their obligations related to regulatory data protection. As a consequence, there is no Mexican regulatory official specifically authorized to protect data and there is no guidance on important attributes of data protection such as the term of protection. Consequently, adequate steps have not been taken by Mexico to protect these data effectively.

*3. China*

The Implementation Regulation of the Drug Administration Law and the Drug Registration Regulation establish a six-year period of protection for test data of products containing a new chemical ingredient against unfair commercial use. The State Food and Drug Administration (SFDA) is responsible for upholding this Law and Regulation. Unfortunately, the current law is ambiguous as to how data protection should be implemented. For example, particular key concepts such as "new chemical ingredient" and "unfair commercial use" are undefined, resulting in substantial business uncertainty for companies.

SFDA interprets the Law and Regulation to allow it to deny data protection for data associated with obtaining marketing approval for pharmaceutical products first marketed outside of China.

As a practical matter, this interpretation results in the elimination of protection for all but Chinese entities. Moreover, the SFDA allows companies to market copies based on the approvals of an originator's product in another country or published information about the original product. This reliance constitutes not only unfair commercial use, but also typically provides insufficient proof, as a scientific matter, of the safety and efficacy of the copy product.

## III. Patent Granting Process and Other Administrative Procedures

Businesses need reasonable assurance that a patent meets the requirements of the law and that the patent will be granted in a timely manner. Some countries are not able to provide these assurances, as the following examples illustrate.

### A. Delays in Examination and Grant

PhRMA members face significant delays in obtaining an initial examination and the grant of their applications in a number of countries. As a reference point, the U.S. Patent and Trademark Office reports that in March 2012, the average time between filing an application and the first office action on the merits for applications in all fields of technology was 23.3 months. The average total pendency was 34 months.[17] At the moment, the Office estimates that the time until the first office action on applications related to therapeutic compounds will range from 15 to 19 months.[18] Unfortunately, we do not have comprehensive data at hand for other countries, but we have substantial anecdotal evidence, including the following examples:

- For many years, applicants for pharmaceutical patents in Chile have had to wait an average of eight years to obtain final action on their applications by the Chilean patent office. While the National Institute of Industrial Property in Chile instituted a number of procedural reforms to reduce the patent pendency periods, PhRMA members have not yet seen any substantial reduction in the time required to obtain definitive decisions on their patent applications.

- We do not have official statistics from Brazil, but patent counsel in Brazil report that the Brazilian patent office is only now examining applications in the pharmaceutical field filed during the period from 1999 to 2002 – the newest is a decade ago. We are not the only field of technology with delays; we understand that the Brazilian patent office is now examining applications for agrichemicals filed between 2001 and 2003 and applications for other chemicals from 2001 to 2004.

- The lack of qualified examiners may cause significant delays in examination. For example, the last annual report of the Indian Controller General for Patents, Designs and Trademarks states that his office received 34,287 patent applications in all fields of technology, but only examined 6,069 applications in their 2009-2010 year. This low ratio of examinations relative to applications was attributed to several factors, the most important of which was that only 80 patent examiners were available during that period.

[17] Available at http://www.uspto.gov/dashboards/patents/main.dashxml (last visited April 17, 2012).
[18] This estimate is for applications designated in Class 424, entitled "Drugs, bio-affecting and body treating compositions."

More recently, we received reports that there are still only about 200 patent examiners at the Indian Office of the Controller-General but there were 83,686 applications to be examined as of March 2011. Unless some extraordinary steps are taken, it will be years before this backlog of applications will be examined; and new applications will be submitted during those years.

B. Use of Non-patent Related Criteria – Brazil

An amendment in 1999 to the Brazilian Industrial Property Law[19] authorized the agency that regulates pharmaceutical products (ANVISA) to review all patent applications for pharmaceutical products and/or processes. This review is in addition to the examination conducted by Brazil's patent office, the National Industrial Property Office (INPI). This review creates delays in obtaining patents in the pharmaceutical field that do not exist for other fields of technology. Moreover, examiners from ANVISA apply criteria that are different from the criteria permitted by TRIPS Article 27. Often this results in different decisions on patentability or additional delays in the patent process, which does not occur for applications in other fields of technology. At times, the delays and differences in decisions were so severe that it appeared that INPI was not granting patents on inventions in the pharmaceutical field.

This use of non-patent related criteria as instituted by the Government of Brazil is inconsistent with TRIPS Article 27.1, which prohibits discrimination in procedures to grant patents based on the field of technology of the invention. For this and other reasons, Brazil's Federal Attorney General recommended in 2009 that the role of ANVISA in the patent examination process be limited. An inter-ministerial group was supposed to review the role of ANVISA and was supposed to report its findings in January of this year, but the group has not yet released a report.

C. Pre-grant Oppositions

In most countries, applications for patents are examined *ex parte* and published at some point before they are granted. Some countries, however, allow interested parties to "oppose" the grant of the patent after publication but before the date established for the grant of the patent. These countries often set up elaborate *inter partes* proceedings to determine patentability. Of course, these procedures take additional time and resources. Given that the term of patent protection is measured from the date of first filing, these delays erode the effective life of the patent.

If not properly policed, these pre-grant oppositions are opportunities for abuse. Interested parties can effectively delay patent grants for extended periods, often for little cost and without impunity. These delays can eliminate the ability of the inventor to initiate infringement actions to stop copiers already in the market. If the patent is granted after the opposition, the interested party may be able to re-package allegations from the pre-grant oppositions in subsequent infringement actions. This adds burdens on all concerned without adding any significant benefits.

Post-grant proceedings to invalidate patents do not suffer from the same troubles as pre-grant proceedings and are a far superior method for patent offices to determine the patentability more quickly and less expensively than litigation. Nevertheless, some countries still cling to pre-grant

[19] The amendment added a new Article 229-C to the Industrial Property Law No. 9,279 (1996).

opposition procedures. For example, India provides for a pre-grant procedure in Article 25(1) of the Indian Patents Act. Some member companies have reported delays in concluding these procedures for individual applications in several countries, including India, Colombia and Ecuador. Unlike the United States, these countries do not provide for extension of patent terms to compensate for delays in patent processing.

D. Regulatory Procedures and Effective Patent Term

Most countries require that some inventions be reviewed by regulatory authorities before they can be marketed. For example, in the United States, the Food and Drug Administration must review and approve pharmaceutical products before they can be marketed to ensure that they are safe and effective. The time period associated with the regulatory process for marketing approvals can be lengthy. These periods can erode the effective term of the patent and reduce the usefulness of the patent significantly.

Most countries have legitimate safety and efficacy requirements which can cause delays in the ability to obtain approval to market a product. But, there can be issues beyond the determination of safety and effectiveness of the product *per se*, and these can be problematic.

Turkey is a prime example of a country with problematic regulatory procedures. Its legislation requires the Turkish Ministry of Health to assess and authorize the registration of medicinal products within 210 days. Surveys by the Association of Research-Based Pharmaceutical Companies (AIFD) indicate that the regulatory approval period exceeded 850 days in 2011.[20]

The Ministry's revisions to the Registration Regulation have compounded these delays.[21] Effective March 1, 2010, a Good Manufacturing Practices (GMP) certificate that is issued by the Ministry must be submitted with each application to register a medicinal product for each of the facilities at which the product is manufactured. The GMP certificate can only be issued by the Ministry following an on-site inspection by Ministry staff, or by the competent authority of a country that recognizes the GMP certificates issued by the Ministry.

AIFD estimates that approximately 300 innovative products manufactured outside Turkey, including anti-infectives, antipsychotics, vaccines, as well as cardiovascular, diabetes and oncology drugs, are currently awaiting registration by the Ministry. Further, the Ministry has thus far received approximately 550 applications to conduct GMP inspections, requiring inspections at almost 330 overseas sites.[22] The Ministry does not have an adequate number of staff to complete these GMP inspections in a timely manner and there are significant barriers to acceptance of the GMP certificates issued by other countries. The effective term of protection of the patent is eroded by such periods of regulatory approvals.

[20] AIFD Situation Assessment Survey of CTD Applications, June 2011.
[21] Regulation to Amend the Registration Regulation of Medicinal Products for Human Use, Official Gazette No. 27208 (Apr. 22, 2009) (Amended Registration Regulation); MOH, *Important Announcement Regarding GMP Certificates*, (Dec. 31, 2009) (establishing an implementation date for the GMP certification requirement).
[22] AIFD GMP Inspections Survey, September 2011.

E. Lack of Safeguards

We believe that officials of the various patent offices should grant patents in a timely manner and officials of regulatory agencies should provide prompt review and approval of products to prevent the foreshortening of the period of time when the patented invention is protected and used. We understand, however, that the prompt grant of patents and marketing approvals is not always possible. When they are not possible, we believe that it is appropriate and equitable for countries to restore the term of the patents to compensate for delays in marketing due to marketing approval procedures and to adjust the term of patents to compensate for delays in granting patents that were not due to the patent owner, as is the case in the United States.

Most countries refuse to provide either of these safeguards. For example, Members of the Andean Community are expressly forbidden from providing for extension of the patent term to compensate for delays in processing their patent applications covering pharmaceutical products, by Article 1(d) of Decision 689 that amends Decision 486. Members of the Andean Community may extend the terms of patents in other fields of technology. Canada does not provide for restoration of a patent term due to delays in obtaining marketing approval or patent grant.

## IV. Requirements for Patent Grant

Every country with a patent system requires that patents may only be granted for inventions that are new, useful, and non-obvious. In addition, countries require that the invention be disclosed in a manner that enables a person, skilled in the field of technology to which the invention pertains, to carry out the invention. This latter requirement is often called the "enablement" or "sufficiency" requirement. The "utility" requirement demands the invention be useful in that it complies with threshold questions of what is patent-eligible subject matter. Under the TRIPS Agreement, WTO Members are not permitted to add further substantive requirements for patentability.

Countries have different definitions of these four requirements and different rules for determining whether these requirements are fulfilled. Sometimes, these requirements and rules preclude patentability of inventions that would be considered by most countries to be worthy of a patent. We believe that the requirements in these countries are inappropriate and unfair.

A. Patent Eligibility Requirement – Canada

Canadian courts have recently defined one of the patent eligibility requirements, which is often referred to as its "utility" requirement, in a manner that adds a barrier to grant and burdens patent owners. For example, applicants for patents often honestly assert and believe at the time of filing their applications that their inventions have multiple uses. After experience with the invention, they may find that some of the asserted uses were valid, but that others were not. In the United States, the patent would still be valid if any of the assertions were accurate. In Canada, the applicant may be required to demonstrate that all assertions are accurate or the patent will be held invalid because the "promise of the invention" was not met. It makes little sense that a patent should be invalidated when one or more assertions of utility might not have been successful but other life-saving uses that were asserted in the patent application are established

by the inventor. We believe that this practice is unjustifiable in light of the realities of the long, difficult and clinically intense development process for pharmaceutical products.

In Canada, general assertions of utility (*e.g.*, useful as a medicine) do not have to be accompanied by evidence of utility, whereas specific assertions of utility (*e.g.*, treats rheumatoid arthritis) must be accompanied by such evidence. In short, an applicant is penalized for trying to be more precise. This penalty runs counter to the timely disclosure of technology, one of the goals of the patent system. These and other different standards place unreasonable burdens on applicants without any apparent social value.

B. Additional Standards – India

Section 3(d) of the Indian Patents Act, 1970, as amended, requires that applicants who claim certain chemical compounds, which are important in the pharmaceutical industry and based on known substances (*e.g.*, different salts, esters, ethers, polymorphs, and other derivatives), show that these compounds have significantly different properties than the known substances. Many inventions involving known substances, however, require substantial resources to develop and test, and represent significant advances for patients – and in fact may turn what may be merely compounds of interest into a therapeutic treatment for disease. This requirement blocks patents to these valuable inventions and discriminates against them. This requirement is in addition to the four requirements set forth in the TRIPS Agreement and is specific to the pharmaceutical field of technology. As a result, it is inconsistent with India's obligations under the TRIPS Agreement.

## V. Conclusion

Robust intellectual property protections in both the U.S. and around the world are critical to advance U.S. competitiveness, grow knowledge based jobs in-country, increase exports, and ensure that patients have access to innovative medicines. Few industries provide more high-quality, high-paying, and high-productivity jobs in the U.S. than the biopharmaceutical sector. It is vital for the biopharmaceutical sector and the patients they serve that governments comply with international obligations to protect and enforce IP rights, including patents, trademarks, and regulatory data protection.

Today, PhRMA members can at least legally get on the "playing field" of patent protection, which is a vast improvement over the situation 30 years ago. But, the problems discussed illustrate that they are still not playing on a level field in many cases. In some countries, our member companies cannot obtain patents or obtain them in a timely manner. If PhRMA members are able to obtain patents, they face significant problems enforcing them in some countries – which is where the true value lies.

PhRMA and its member companies are working actively to resolve these problems and appreciate the assistance and support of Office of the U.S. Trade Representative, the Departments of State and Commerce, as well as others.

Finally, we appreciate your interest in obtaining more information on level of protection worldwide and would be pleased to provide additional explanations or information. Thank you.