From: David Korn [redacted]
Sent: Friday, November 19, 2010 4:57 PM
To: HumanitarianProgram
Subject: Attached Comments from PhRMA

Attached are comments in response to the "Request for Comments on Incentivizing Humanitarian Technologies and Licensing Through the Intellectual Property System." Please do not hesitate to contact me if you have any questions.

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PhRMA

November 19, 2010

VIA EMAIL: HumanitarianProgram@uspto.gov

Mail Stop Comments – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attention: Joni Y. Chang

We are writing on behalf of the Pharmaceutical Research and Manufacturers of America ("PhRMA") to convey the views of PhRMA's members in response to the "Request for Comments on Incentivizing Humanitarian Technologies and Licensing Through the Intellectual Property System," 75 Fed. Reg. 57261 [Docket No.: PTO-P-2010-0066]. PhRMA's members are leading pharmaceutical research and biotechnology companies devoted to researching and developing new medicines to allow patients to live longer, healthier and more productive lives. PhRMA members lead the way in finding cures and new treatments as well as in developing critically important improvements in existing therapies.

PhRMA's members appreciate the PTO seeking comments in the area, and would welcome further dialogue on the issues.

Please feel free to contact either of us with any questions or concerns you may have.

Sincerely,

Richard Kjeldgaard
Deputy Vice President For
Intellectual Property, International Division

David Korn
Senior Assistant General Counsel

Enclosure

Comments of the Pharmaceutical Research and Manufacturers of America in Response to the PTO's Request for Comments on Incentivizing Humanitarian Technologies and Licensing Through the Intellectual Property System

The Pharmaceutical Research and Manufacturers of America ("PhRMA") appreciates the opportunity to submit comments in connection with the U.S. Patent and Trademark Office ("PTO") Request for Comments on Incentivizing Humanitarian Technologies and Licensing Through the Intellectual Property System.[1/]

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 consists of small companies and multi-national, multi-billion dollar corporations that employ tens of thousands of Americans, and encompasses both research-based pharmaceutical and biotechnology companies. Analyses show that the industry supported more than 3.2 million jobs, and directly employed more than 686,000 Americans in 2006.[2/] The industry's direct contribution to GDP in 2006 was $88.5 billion – more than triple the average contribution of other sectors.[3/]

The core mission of our member companies is to bring new life-saving and life-improving products to people, and strong patent rights in the United States and around the world are critical to that mission. PhRMA members devote substantial resources to humanitarian initiatives. As such, PhRMA appreciates the laudable goal of the PTO's proposed initiative. Nevertheless, we respectfully raise in these comments some suggestions and concerns shaped by implementation questions and public policy issues.

I. PhRMA Members Devote Substantial Resources to Humanitarian Endeavors

Research-based biopharmaceutical companies have a decades-long commitment to getting medicines to those countries and populations where they are needed most. In the last decade, biopharmaceutical companies provided over $9.2 billion in direct assistance to health care for the developing world, including donations of medicines, vaccines, diagnostics, and equipment, as well as other materials and labor.[4/] Key medicines and vaccines are made more accessible through discounted and affordable pricing as determined by individual manufacturers to help countries without the necessary resources to respond to urgent public health needs.[5/] In many countries, research-based biopharmaceutical companies have undertaken voluntary licensing to enable manufacturers in Africa and Asia to produce and sell generic versions of products needed to treat severe epidemics. Donations by research-based pharmaceutical companies to fight neglected tropical diseases are valued at hundreds of millions of dollars each

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1/ 75 Fed. Reg. 57261-62 (Sept. 20, 2010).

2/ Archstone Consulting LLC, Lawton R. Burns, "The Biopharmaceutical Sector's Impact on the U.S. Economy: Analysis at the National, State, and Local Levels," at 5 (2009).

3/ *Id*. at 8.

4/ Int'l Fed. Of Pharma. Mfrs. & Ass'ns (IFPMA) Survey, validated by LSE Health and Social Care at the London School of Economics and Political Science.

5/ *See* http://www.ifpma.org/healthpartnerships.

year.[6/] Yet experience shows that while product donations and other access programs are critical, long-term success will depend on biopharmaceutical research companies working with governments and others to develop medical innovations that can solve the health challenges confronting the developing world.

In a growing number of research centers around the world, biopharmaceutical research companies are investing in and focusing on the development of innovative medicines and treatment technologies specifically to meet the needs of the developing world. America's biopharmaceutical companies are among the largest contributors to funding for development of innovative cures for diseases affecting developing regions in Latin America, Asia, and Africa, investing more than $365 million into new cures and treatment in 2008 alone and supporting R&D centers around the world dedicated to finding innovative diagnostics, medicine and vaccines for diseases such as malaria, TB, sleeping sickness and dengue fever. This investment makes pharmaceutical companies the third largest funder of such research in the world, and puts them ahead of all countries except the United States.[7/]

As a result of efforts by companies and their partners, for example, Colombia was certified as the first country in the developing world to eliminate river blindness, and the lessons learned in that effort are helping to shape similar efforts to eliminate river blindness globally. Moreover, America's biopharmaceutical companies support innovative efforts to develop drugs and treatments that can be safely and easily administered in situations where there are limited healthcare resources, such as treatments that can be sustained in hot climates where refrigeration is not available.[8/]

II. Patent Rights Are Essential To Pharmaceutical Innovation

The research-based pharmaceutical sector is one of the most knowledge-intensive industries in the U.S. economy, and is responsible for 80% of the world's global healthcare biotechnology research and development ("R&D").[9/] In 2009, the pharmaceutical sector invested $65.3 billion in R&D. The vast majority of this R&D investment – $45.8 billion – was invested by PhRMA's member companies. Of that amount, roughly 74%, or $34.9 billion, was invested in the United States.[10/]

As a knowledge-based industry, like innovators across the spectrum of American industries, pharmaceutical companies rely on patents to protect their inventions and provide the

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6/ *See* www.globalhealthprogress.org.

7/ Morgan, M. et al, Neglected Disease Research and Development: New Times, New Trends, The George Institute for International Health (2009). *See also* www.globalhealthprogress.org, highlight the involvement of research-based biopharmaceutical companies in more than 340 initiatives with more than 600 partners to help shape sustainable solutions that improve the health of all people, including, e.g., (1) the Global Fund to Fight AIDS, Tuberculosis and Malaria; (2) the Accelerated Access Initiative; (3) the Medicines for Malaria Venture; (4) the Global Polio Eradication Initiative; (5) Roll Back Malaria; (6) the Global Alliance for Vaccines and Immunization; (7) the Global Alliance for TB Drug Development; and (8) the Global Alliance to Eliminate Lymphatic Filariasis.

8/ *See* www.globalhealthprogress.org.

9/ Burrill and Company, analysis based on publicly available data, 2009.

10/ PhRMA, Pharmaceutical Industry Profile 2010 (Washington, DC: PhRMA, March 2010), *available at* http://www.phrma.org/sites/phrma.org/files/attachments/Profile_2010_FINAL.pdf.

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.

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.[11/] R&D for new pharmaceuticals is unpredictable, requires immense investments of human and financial capital, and can take up to fifteen years of effort before a product is actually approved.[12/] These investments are made with no guarantee of FDA approval and no guarantee of return. In fact, only two in ten approved medicines ever produce revenues sufficient to recoup the average cost of drug development.[13/] Yet once a pharmaceutical product has been developed, it can often be copied and produced. Patents protect inventions made in the course of R&D – including a new molecule, a particular delivery system, new uses of a medicine to treat different diseases, or a new method of manufacturing a medicine – and give the innovator the right to prevent the unauthorized use of the inventions for a defined period of time. Without patent protection, potential investors would see little prospect of a sufficient return on investment to offset the accompanying financial risk.[14/]

Few advances in the last century have been as important to the preservation and enhancement of life as pharmaceutical innovations. These medical advances – driven by scientific research and creative genius – are made possible by a system of laws that provides the structure, stability, and opportunity for the needed investment.

III. The PTO's Proposed Program, While Laudable in Purpose, Could Stretch the PTO's Limited Resources Beyond its Core Mission, and Raise Significant Implementation Questions and Substantial Public Policy Issues

As we describe below, PhRMA members are concerned that the proposed program if fully implemented, could stretch the PTO's limited resources beyond its core mission, present

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

[12/] In 1960, the average time to develop a new medicine was approximately eight years; by 2007, that figure had increased to between ten and fifteen years. *See id*.; Joseph A. DiMasi, New Drug Development in the U.S. from 1963-1999, Vol. 69 No. 5, Clinical Pharmacology & Therapeutics 286, 292 (2001). 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. Joseph DiMasi and Henry Grabowski, The Cost of Biopharmaceutical R&D: Is Biotech Different?, Managerial and Decision Economics 28: 468-79 (2007). For every one product that receives regulatory approval, there were 5,000-10,000 compounds that entered the R&D pipeline. PhRMA, "Drug Discovery and Development: Understanding the R&D Process," at 5 (2007), *available at* http://www.innovation.org/drug_discovery/objects/pdf/RD_Brochure.pdf.

[13/] John Vernon, et al., Health Economics Letters: Drug Development Costs When Financial Risk Is Measured Using The Fama–French Three-Factor Model, Health Economics (2009), *available at* www.interscience.wiley.com.

[14/] Claude Barfield & John Calfee, Biotechnology and the Patent System: Balancing Innovation and Property Rights (AEI Press 2007).

significant implementation questions, and raise substantial public policy issues. In addition, while a voucher for a reduction in the amount of time required to complete reexamination would have value to companies in certain situations, it is not likely to have material impact on the already substantial humanitarian programs undertaken by PhRMA members or the research and development decisions by PhRMA member companies.

A. The PTO Should Not Lose Its Focus on Fulfilling Its Core Mandate.

The PTO fulfills the mandate of Article I, Section 8, Clause 8, of the U.S. Constitution to "promote the Progress of Science and the useful Arts by securing for limited Times to … inventors the exclusive Right to their respective … Discoveries," a mission that does not distinguish among discoveries. The PTO's proposed initiative would require significant administrative attention to determine what constitutes "humanitarian," and these judgments necessarily would require the exercise of significant discretion outside the mission and core competency of the PTO.

Unfortunately, the PTO today faces considerable challenges in fulfilling its core mission, including lack of necessary resources. The PTO's revenues from user fee collections declined substantially during fiscal year 2009 and the financial constraints carried over into fiscal year 2010.[15/] Due to these constraints, the PTO was forced to hire fewer than the planned number of examiners, limit overtime, and postpone critical upgrades to its information technology systems.[16/] In fiscal year 2010, the PTO lost 127 patent examiners and only replaced nine.[17/] PhRMA is concerned that this proposed initiative would further drain the PTO's already insufficient resources. For example, we are concerned about the resource commitments that would be required by the PTO to establish and manage a process for consultation with outside bodies – on how to define "humanitarian" and to make difficult judgments about whether a given claimed invention or use qualifies as "humanitarian" – and we question whether this is the best use of already stretched resources at the PTO.

B. The PTO Should Consider a Number of Implementation Challenges the Proposed Pilot Program Would Present.

PhRMA members believe the PTO's proposed pilot program raises significant implementation questions and concerns. Below we describe some of these issues, focusing on who would be eligible for a voucher, how a voucher would be used, and how program decisions would be made.

1. Questions Regarding Eligibility Criteria

- Which technologies would be eligible for consideration for a voucher under the program? Should such a program be implemented, we believe all technologies should be eligible,

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15/ *See* Testimony by David J. Kappos, Undersecretary of Commerce and Director of the USPTO, Hearing on USPTO Oversight Before the Committee on the Judiciary, U.S. House of Representatives (May 5, 2010), *available at* www.uspto.gov/news/speeches/2010/Kappos_House_Testimony.jsp.

16/ *See id.*

17/ *See id.*

and that the program should not focus narrowly on biotechnological or pharmaceutical products or otherwise attempt to select a set of technologies that are assumed to have the most potential for addressing humanitarian needs.

- Would the proposed program be limited to incentivizing humanitarian practices with patented technologies, and exclude humanitarian technologies and research that may not, in fact, relate to patented or patentable inventions?
- What criteria would be used to assess whether a technology is "humanitarian," and who would make these judgments? Would applicants be permitted to appeal?
- Would the eligibility criteria be spelled out with sufficient specificity? The program can only influence behavior if innovators know what behavior is necessary to achieve the incentive. Otherwise, the program would serve only as a post-hoc prize system.
- Would consideration for a voucher be limited to applications submitted by technology owners or actors on behalf of their own self-identified humanitarian practices? We would suggest that an application system be used but would be concerned if third parties could submit applications. Automatic consideration for a voucher also would raise concerns. In addition, further thought should be given on how assertions made in an application would be validated and whether applications would be made public.
- With respect to biopharmaceutical products, any eligibility criteria should not be based on therapeutic categories, and no therapeutic categories should be excluded from eligibility.

2. Questions Regarding Use of Vouchers

- Who would be able to use the vouchers? Our view is that, if a voucher program is instituted, their use should be restricted to persons or entities seeking reexamination of their own patents (rather than challenging others' patents).
- We believe that a process of fast-tracking certain reexamination proceedings should not delay the processing of other reexamination applications. How will the PTO ensure that this is the case?

3. Questions Regarding Decision Making

- Would the PTO tie its award decisions to determinations made under other humanitarian incentive programs by agencies and entities with more direct insight into the areas in need of humanitarian attention? If so, how would the PTO do this without simply duplicating the efforts and incentives of those other agencies and programs? How would the PTO identify the agencies and entities to be involved in the program and ensure balance in stakeholder representation?
- Would award decisions be made during patent examination or be independent of it?

- Would award decisions be made on a rolling basis as applications are submitted (in which case the entire quota could be exhausted early in the application period, leaving later deployed, but potentially more promising practices unrecognized simply because they did not submit early in the application period), or would applications be received at several specified periods and then be reviewed collectively and awardees selected at the end of the designated application and review period?
- If the program contemplates that a small number of vouchers would be awarded, how can the program be structured to avoid any negative connotation being ascribed to technology and research efforts that are not recognized by the award of a voucher?

C. The PTO Should Guard Against Unintended Policy Risks.

As in other innovative industries, a well-functioning patent system is an essential incentive for the substantial, long-term private investment in biopharmaceutical innovation, including R&D aimed at solving health challenges faced by developing countries. Intellectual property regimes that provide a clear and certain legal framework within which companies may work, innovate, and compete are able to give market participants the predictability and assurance necessary to foster R&D investment for tomorrow's cures and therapies.

The U.S. patent regime, as implemented by the PTO, creates such a strong and stable innovation environment in the United States. However, foreign markets are also very important to U.S. innovative industries because a key aspect of the sector's economic contributions in the U.S. is through market entry into other countries in the form of exports from the United States. Therefore, in considering the adoption of any incentive program, the PTO should take into account the broader impact such a program could have on foreign patent regimes. If the PTO decides to pursue such a program, it should be structured and explained so as to ensure that the program does not provide a basis for countries to discriminate in ways adverse to any category of technology.

IV. Conclusion

The PTO's goal of incentivizing humanitarian invention is laudable; however, PhRMA questions whether the proposed initiative is the best way to achieve the goal. This proposal may present challenges to the fundamental principle of non-discrimination and the smooth functioning of the patent process. Other incentive programs, such as those undertaken by other government agencies with different core missions, may be better suited to incentivizing R&D or other activities in this area.