



Billy Tauzin

PRESIDENT AND CHIEF EXECUTIVE OFFICER

VIA EMAIL DELIVERY

March 24, 2010

Victoria A. Espinel
U.S. Intellectual Property Enforcement Coordinator
Office of Management and Budget
Executive Office of the President

Dear Coordinator Espinel:

The Pharmaceutical Research and Manufacturers of America (PhRMA) welcomes the opportunity to provide comments on the development of the Intellectual Property Enforcement Coordinator's (IPEC's) Strategic Plan.

PhRMA's member companies represent the country's leading innovative biopharmaceutical companies. Our companies are devoted to inventing medicines that allow patients around the world to live longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for new cures to diseases that afflict all regions of the globe.

Intellectual Property (IP) infringement imperils these efforts. Not only does IP infringement threaten the ideas and innovations that are the lifeblood of our members, and in turn our industry's important stake in the U.S. economy, it also presents a very real public health and safety danger for patients world-wide.

Your initiative to develop an efficient and robust Joint Strategic Plan for combating IP infringement is critical to our industry, and other U.S. knowledge-intensive industries. Only through effective IP enforcement can the United States achieve President Obama's goal of doubling exports over the next five years, bolster the U.S. comparative advantage in ideas, and protect U.S. and global consumers and patients.

PhRMA looks forward to being an active stakeholder in helping your office and the Administration achieve these goals.

Sincerely,

A handwritten signature in cursive script that reads "Billy Tauzin".

Billy Tauzin

Pharmaceutical Research and Manufacturers of America

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Office of Management and Budget

By E-mail

Coordination and Strategic Planning of the Federal Effort Against Intellectual Property Infringement: Request of the Intellectual Property Enforcement Coordinator for Public Comments Regarding the Joint Strategic Plan; 75 Fed. Reg. 8137 (February 23, 2010)

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit these comments in response to the Office of Management and Budget's (OMB's) Federal Register Notice regarding the Administration's landmark effort to develop an intellectual property (IP) enforcement strategy that will more effectively and efficiently combat IP infringement within the United States and abroad.

As recently stated by President Obama, "[o]ur single greatest asset is the innovation and the ingenuity and creativity of the American people. It is essential to our prosperity and it will only become more so in this century. But it's only a competitive advantage if our companies know that someone else can't just steal that idea and duplicate it with cheaper inputs and labor."¹ The President's comments underscore the fact that the Administration's efforts to combat IP infringement are both timely and necessary.

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The recent Federal Register notice raises a number of important issues of significant interest to PhRMA member companies. Therefore, we look forward to engaging in an ongoing dialogue with you as you develop and implement the nation's Joint Strategic Plan (Strategic Plan). In order to combat the reality and threat of IP infringement, PhRMA recommends that the Intellectual Property Enforcement Coordinator's (IPEC's) Strategic Plan seek to reduce the supply of infringing goods domestically and internationally, reduce the number of U.S. trading partners that fail to enforce IP rights, and protect the health and safety of patients at home and abroad by, among other things: enforcing international IP

obligations; advocating at international organizations to defend and strengthen IP rights; and seeking strong measures to combat IP infringement and counterfeiting.

The Biopharmaceutical Sector, IP Infringement, and Potential Costs to the U.S. Economy and Patients World-wide

The U.S. innovative biopharmaceutical industry is a core driver of the U.S. economy, depending on robust enforcement of IP rights to continue to support the jobs and develop the medicines that the United States and the world require. PhRMA members rely on the work of U.S. Government officials, such as the IPEC, to open foreign markets, tackle IP infringement at home and abroad, and promote innovation in the global trading regime in order to maintain and grow U.S. jobs. High technology industries such as the biopharmaceutical industry are an essential engine of the U.S. economy and our future economic growth, and it is more critical now than ever given the current global economic environment that the United States takes a strong position in enforcing IP rules that will allow such growth to continue.ⁱⁱ

U.S. innovation and ingenuity represent our comparative advantage in the global trading arena, and will continue to be essential to America's future prosperity and growth. Capitalizing on this advantage will be critical to achieving President Obama's goal of doubling exports over the next five years. However, the U.S. innovative and IP-related sectors, including the research-based biopharmaceutical industry, continue to face daunting challenges in protecting their IP abroad. In its most recent annual report on IP protection abroad,ⁱⁱⁱ the U.S. Government identified 46 different countries that raise serious concerns over the lack of adequate and effective enforcement of IP rights. It is essential that the Government address these challenges to preserve the U.S. economy and to protect U.S. economic growth.

At the same time, it should be aware that combating IP infringement in these markets is not a one-way street – it ultimately contributes to growing the economic strength of our trading partners in today's increasingly innovation-centric economies. As the National Economic Council states, "[o]ther countries understand that innovation is fundamental to their economic well-being and are finding new ways to advance their innovation agendas.... Innovation is the key to global competitiveness, new and better jobs, a resilient economy, and the attainment of essential national goals."^{iv}

Protecting Innovation and Jobs

PhRMA member companies are an important driver of high-quality job creation in the United States, investing more per employee in research and development than other manufacturing industries. Few industries are more competitive when it comes to providing high-quality, high-paying, and high-productivity jobs.

Industry employment (direct, indirect, and induced) in 2008 totaled 3.2 million jobs,^v including direct employment of over 686,000 Americans. In 80 percent of U.S. locations analyzed, direct employment in the biopharmaceutical sector grew at a faster rate than employment in the rest of the economy in that location from 1996 to 2006.^{vi}

A recent study on the “Economic Effects of Intellectual Property-Intensive Manufacturing in the U.S.” also found that IP intensive areas of manufacturing produce relatively much larger benefits to the U.S. economy, with the most IP-intensive industry, biopharmaceuticals, generating the greatest such benefits.^{vii} According to the study, from 2000-2004, the one manufacturing area that expanded its workforce was the biopharmaceutical sector, and “jobs in pharmaceutical companies increased by more than 8% over this period.”^{viii} Our industry has by no means been immune to the global downturn, however. From January to October of 2009, approximately 58,000 industry jobs were lost, compounding earlier job contraction in 2007 and 2008.^{ix}

At the same time, PhRMA member companies make substantial investments in research and development, further fueling the U.S. economy and advancing public health through the discovery and development of new cures and treatment options for patients. In 2006, our industry invested \$56.1 billion in research and development for new medicines, \$44.9 billion of which was invested in research conducted in the United States.^x This represents an estimated investment of more than \$65,000 on research and development per direct employee – approximately eight times more than published estimates of average spend per employee in all manufacturing industries between 2000 and 2004.^{xi} In 2009, PhRMA estimates industry investment in research and development investment reached \$65.3 billion.^{xii} These investment figures highlight the pressing need to defend our members’ IP rights against infringement.

Protecting Innovation, U.S. Economic Competitiveness, and Growing U.S. Exports

Today, when policymakers talk about the jobs of the future, they talk about innovation and economic competitiveness. Innovation has, in the words of President Obama, traditionally made America the “engine of growth, and progress, and discovery for the entire world.” Promoting and protecting these innovations through IP and prevention of IP infringement is increasingly important to the American economy, maintaining and growing America’s comparative advantage in the global marketplace, and growing U.S. exports in the near and long term.

This is certainly true for the U.S. innovative biopharmaceutical industry, which leads the world in finding new medicines to improve health and prolong lives. For example, more medicines are in development in the United States than in the rest of the world combined,^{xiii} (more than 2,900),^{xiv} in large part due to IP

protections and other strong incentives that foster the environment needed to support continued research and development investment. According to a 2006 Congressional Budget Office report, the U.S. innovative biopharmaceutical industry continues to lead the nation in research and development, investing five times more in research and development, relative to their sales, than the average U.S. manufacturing firm.^{xv} In 2009, 19% of domestic sales by biopharmaceutical companies was invested in research and development.^{xvi} Infringement of IP rights threatens this important dynamic.

PhRMA's member companies lead U.S. efforts to research, develop and manufacture innovative medicines, and are major contributors to U.S. economic growth. As we find ourselves in a period of financial crisis it will be critical to promote those industries that are contributing to our economic well-being. For instance, the biopharmaceutical sector's direct contribution to U.S. GDP in 2006, \$88.5 billion, was approximately triple the average contribution from sectors in the rest of the U.S. economy.^{xvii} Each job in the biopharmaceutical sector contributed approximately 71% more than the average contribution from jobs in the rest of the economy.^{xviii}

For every dollar that biopharmaceutical companies contributed to gross domestic product (GDP) in 2006, the ripple effect of that activity supported another \$2.33 in contribution to GDP from other sectors.^{xix} The impact of the sector's activity has increased since 1996, when each dollar of GDP contribution from the sector supported a contribution of \$1.29 from other sectors.^{xx} On average, U.S. biopharmaceutical employees earned annual wages of \$88,929 (excluding benefits) and paid an average of \$21,858 in federal taxes, and an average of \$3,271 in state taxes, or approximately three times the average amount paid by U.S. workers in the rest of the economy.^{xxi} These statistics and figures are only as secure as the IP rights that underpin the work and ideas of our member companies, making U.S. efforts to combat IP infringement essential to both our industry and economic well-being.

IP Infringement Harms the U.S. Economy

A number of studies have found that patents and other IP protections are significantly more important to biopharmaceutical firms in "appropriating the benefits from innovation compared with other high tech industries."^{xxii} This is due in large part to the highly research-intensive nature of this sector, which contributes to high research and development costs. In knowledge-based sectors, such as the biopharmaceutical sector, intangible assets are often more valuable than tangible assets. This sector is highly reliant on the ability to raise capital to support the substantial investments in research and development needed to develop today's treatments and tomorrow's cures. When IP is infringed, biopharmaceutical companies are unable to recoup their research and development investments, reducing the capital available to reinvest in more research and development. IP rights and their enforcement assure inventors and companies that their investments in time, money, and human capital will be

protected if they are successful, and that they will have the opportunity to potentially earn a return on investment. A clear legal framework provides the certainty, security, and predictability necessary for this sector's sustainability and growth. IP infringement creates uncertainty. As a result, the potential returns from innovation cannot be secure without adequate legal protections and their enforcement. The importance of IP is underscored by a survey of American research and development executives, which found that without patent protections, 60 percent of the projects which ultimately produced discoveries in pharmaceuticals would never have happened.^{xxiii} The fact that biopharmaceutical firms' profitability is reliant on the depth and quality of its IP suggests the harm that can be posed by IP theft and infringement.

As discussed by Shapiro and Hassett (2007), "economic research and analysis have established that economically-powerful forms of intellectual property, embodied in innovations are the largest single factor driving economic growth and development." Shapiro and Hassett estimate that in 2005, U.S. intellectual property accounted for an estimated one-third of the market value of all U.S. stocks -- \$5 trillion to \$5.5 trillion -- equivalent to about 45 percent of America's GDP and greater than the GDP of any other economy in the world.^{xxiv} Further, they estimate that the costs of IP infringement "may well constitute a significant drain on both national and world economies and impede the efficient exchange of goods, services, and ideas."^{xxv} Thus, IP infringement can substantially impact the economic contribution of research and development-intensive sectors such as the biopharmaceutical sector.

Reducing IP infringement is critical to the future of our economy. IP protections provide a clear legal framework for all to work, innovate, and compete within, giving participants a sense of predictability and security necessary to ensure continued research and development investment for tomorrow's cures and new therapies, as well as competition.

Providing Innovative Solutions to Healthcare Access in the Developing World

PhRMA member companies are actively engaged in solving the health problems of the developing world, and America's biopharmaceutical companies are one of the largest contributors of funding for development of innovative cures for diseases affecting developing regions in Latin America, Asia, and Africa. In the last decade, biopharmaceutical companies provided over \$9.2 billion in direct assistance to healthcare for the developing world, including donations of medicines, vaccines, diagnostics, and equipment, as well as other materials and labor.^{xxvi}

Research-based biopharmaceutical companies and global health leaders are currently involved in more than 340 initiatives with more than 600 partners to help shape sustainable solutions that improve the health of all people.^{xxvii} These

companies are among the largest funders of the research and development necessary to cure neglected and major diseases of the developing world, including malaria, tuberculosis, sleeping sickness and dengue fever, investing more than \$365 million into new cures and treatments in 2008 alone – making them the third largest funder in the world, ahead of all countries but the United States.^{xxviii} Without these efforts, which are threatened by the infringement of IP rights, access to effective, sustainable healthcare for the developing world's patients would be impossible.

Recommendations for a Strategic Plan That Improves U.S. IP Enforcement Efforts

In order to stem, and ultimately eliminate IP infringement at home and abroad, the Strategic Plan should focus on, among other things: enforcing international IP obligations; working with international organizations to defend and strengthen IP rights; and seeking strong measures to combat counterfeiting.

Enforcing International IP Obligations

It is vital for the research-based biopharmaceutical and other innovative U.S. industries that the U.S. Government ensure that our trading partners comply with international obligations to protect and enforce IP rights, including patents, trademarks, and regulatory data protection. Failure to do so sets a negative precedent for other countries to follow, and as the most innovative economy in the world, the United States has the most to lose from weak global IP regimes. A lack of commitment to protecting U.S. IP around the world will encourage further IP infringement, hurt U.S. industries' competitiveness by impairing future research and development investment, and discourage the venture capital investments so critical to developing new technologies that can create new jobs for millions of Americans. Lax IP standards abroad and at home foster an environment that encourages IP infringement and squanders the U.S. comparative advantage our trade negotiators have sought to protect.

The Strategic Plan must therefore focus in part on monitoring and enforcing trading partner compliance with international trade rules, including under bilateral and regional free trade agreements (FTAs), and multilateral agreements such as the World Trade Organization (WTO) Agreement. These agreements were thoughtfully crafted to protect U.S. IP, and the United States must ensure that other parties are as committed to complying with agreed-upon rules.

Enforcement of obligations under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), the General Agreement on Tariffs and Trade 1994 (GATT 1994), the Agreement on Trade-Related Investment Measures (TRIMS Agreement), and the Agreement on Technical Barriers to Trade (TBT Agreement), as well as our numerous other bilateral and regional commitments, will be essential to this goal. These efforts must be

closely coordinated with U.S. Government agencies tasked with negotiating and enforcing U.S. international trade rights, including the Office of the United States Trade Representative (USTR), the Department of Commerce, the Department of State, and the United States Patent and Trademark Office (USPTO).

Working at International Organizations to Protect and Defend IP Rights

Any effort to reduce world-wide IP infringement must also recognize that the activities and policy positions a particular country may espouse at home and at international organizations can affect the global IP enforcement landscape. Often countries will take active positions on IP issues within international forums such as the United Nations (UN) system, including the World Intellectual Property Organization (WIPO) and World Health Organization (WHO), as well as the WTO, that seek to diminish IP protections and widen the berth for potential infringement of innovative companies' rights. The United States must remain vigilant in these organizations, and continue to advocate for robust IP protections in the face of mounting attempts to diminish these rights.

To this end, the IPEC Strategic Plan should evaluate U.S. staffing at relevant international organizations and ensure that adequate resources and training are focused on strengthening the Government's presence in these forums. In addition, we must ensure that our rules at home, including those enforced by the USPTO and other U.S. Government agencies, continue to aggressively guard against IP infringement and protect IP rights – our positions abroad will only be as persuasive as our domestic commitment to the cause of protecting innovation.

Combating Counterfeit Medicines – Internationally

In order to ensure that the Strategic Plan protects the public health and safety of U.S. citizens and patients around the globe, it should address the growing menace of counterfeit medicines. Weak regulatory and IP enforcement regimes in several of our trading partners contribute to this problem.

The extent of the worldwide counterfeiting problem is difficult to quantify, but all estimates suggest that counterfeiting of medicines is on the rise.^{xxix} For example, recent estimates indicate that between 10 to 30 percent of medicines sold in developing markets are believed to be counterfeit.^{xxx} Counterfeit medicines are manufactured, marketed and distributed with the deliberate intent to deceive patients and healthcare providers as to the source or nature of the product. As a result, these products threaten the health and safety of consumers throughout the world. According to the OECD, "Today, few jurisdictions, whether developed or developing, are immune from counterfeit pharmaceuticals and the infringement of intellectual property rights, as such activities have been reported on all continents."^{xxxi} Further, the OECD states that "[t]he most significant implications of counterfeit pharmaceuticals for patients are the health hazards from direct use and the loss of confidence in the health system

Pharmaceutical counterfeiting has been described as the "perfect crime" since if the patient's condition improves, there is no investigation and if the patient's condition deteriorates, it will be attributed principally to the medical condition or disease."^{xxxii}

Although the prevalence of counterfeit medicines appears to be greatest in developing and least-developed markets, the counterfeit supply chain has no geographic boundaries. Not surprisingly, countries that lack adequate drug regulatory and oversight systems tend to be most vulnerable to counterfeit medicines. In China, India and other countries with drug manufacturing capabilities, lax oversight not only leads to domestic sales of counterfeits, but also to significant exports of counterfeits. This problem can be exacerbated by the ease with which counterfeiters can offer fake medicines to consumers worldwide over the Internet.

Although most countries recognize counterfeit medicines as a threat to the public health and safety, many lack the comprehensive framework of laws and controls necessary to safeguard the drug supply chain against counterfeit sales and exports. In countries like China, India, Russia, Brazil and Mexico (i.e., markets where pharmaceutical counterfeiting is believed to be a growing threat), several common deficiencies contribute to the growing prevalence of pharmaceutical counterfeiting in worldwide markets.

Weak enforcement due to inadequate remedies, penalties, resources and commitment is the most significant problem, and one that undermines the effectiveness of all relevant laws, including prohibitions against trademark counterfeiting, as well as drug regulatory controls. There is also a need to increase customs controls and international information sharing in a world where counterfeit shipments follow ever-convoluted itineraries, including stops at free trade zones. IPEC's Strategic Plan should assess this threat and dedicate resources to combat this global threat to public health and safety. To this end, IPEC should draw upon the expertise of the Department of Homeland Security, including U.S. Customs and Border Protection and U.S. Immigration and Customs Enforcement, to tailor elements of the Strategic Plan. Moreover, IPEC should build on the work of the IPR Center to coordinate the U.S. Government's domestic and international IP law enforcement efforts.

To combat the global proliferation of counterfeit medicines and active pharmaceutical ingredients (APIs), U.S. trading partners must adopt and implement a comprehensive regulatory and enforcement framework that: (i) subjects drug counterfeiting activity to effective administrative and criminal remedies and deterrent penalties; (ii) adequately regulates and controls each link in the counterfeiting supply chain; (iii) trains, empowers and directs drug regulators, law enforcement authorities and customs to take effective and coordinated action, including against exports and online activity; and (iv) educates all stakeholders about the inherent dangers of counterfeit medicines.

Combating Counterfeit Medicines – Domestically

The regulatory system that governs the development, approval, marketing, and surveillance of new drugs in the United States is the most complex and comprehensive in the world and it has become increasingly comprehensive and robust over time. This regulatory system – often regarded as the “gold standard” – is overseen by the U.S. Food and Drug Administration (FDA), whose primary mission is to protect the public health and safety by assuring the safety and effectiveness of medical products, among other things. Thus, the FDA will be an important partner in the development of the Strategic Plan as it relates to medical products.

In the United States, our relatively closed distribution system plays a critical role in helping to keep the global proliferation of counterfeit medicines from infiltrating the domestic prescription drug supply. In fact, the Prescription Drug Marketing Act of 1987 (PDMA) closed the U.S. prescription drug supply to products that have circulated overseas, beyond the jurisdiction of FDA and outside the control of the manufacturer. This landmark legislation was passed following an investigation of incidents of counterfeit drugs reaching American consumers. Thus, the PDMA, coupled with exacting FDA regulatory requirements such as the New Drug Approval and current Good Manufacturing Practice requirements, has helped significantly minimize the possibility that a U.S. consumer receives a counterfeit drug.^{xxxiii} Maintaining our domestic closed prescription drug distribution system is one critical way to ensure that the public health and safety remains protected against counterfeit medicines.

While the U.S. arguably has the safest system in the world with one of the lowest percentages of counterfeit drugs in the market, no system is perfect. The proliferation of Internet drug sellers and the ease of ordering medicine online, without even a prescription in many cases, have introduced new threats on which the U.S. Government has recently placed a greater emphasis. FDA Commissioner Margaret Hamburg, M.D., noted that drugs sold over the Internet, “...are often counterfeit, contaminated, or unapproved products, or contain an inconsistent amount of the active ingredient. Taking these drugs can pose a danger to consumers.”^{xxxiv} Thus, the Internet sale of counterfeit pharmaceuticals is a clear threat to the public health and safety.

Federal agencies have recently taken steps to combat the problem. For example, in November 2009, five U.S. federal agencies participated in a coordinated action targeting the Internet sale of counterfeit pharmaceuticals. Over the course of a week, U.S. agencies targeted over 7,000 suspect packages in seven cities nationwide, with more than 700 suspect packages of counterfeit drugs being detained. Federal agents working at New York’s John F. Kennedy airport inspected suspicious parcels from India, China, Turkey, Taiwan and

Russia, among other countries. Additionally, authorities shut down 90 illegal Internet websites. According to John Morton, Department of Homeland Security Assistant Secretary for ICE, "Counterfeit pharmaceuticals pose a significant threat to the public's health and safety and must be targeted by coordinated global law enforcement action."^{xxxv} The FDA also sent 22 Warning Letters to operators of 136 Internet websites that appeared to be selling unapproved and misbranded drugs to American consumers.^{xxxvi}

In sum, PhRMA believes there is no technological "silver bullet" to protect against counterfeits. The most effective way to combat counterfeiting is to adopt a multi-pronged strategy that addresses weaknesses throughout the distribution system. PhRMA member companies currently employ and routinely enhance a variety of anti-counterfeiting technologies, including covert and overt features on the packaging of high-risk prescription drugs. They have also adopted a range of business processes to better secure prescription drug supply chain and to help facilitate the early detection of criminal counterfeiting activity. These efforts, coupled with the efforts of the U.S. Government and the additional suggestions set forth above, could help reduce the amount of counterfeit pharmaceuticals circulating world-wide.

Combating Counterfeit Medicines – Economic Impact

Just as it is difficult to quantify the extent of counterfeit medicines world-wide, it is also difficult to estimate the losses to the U.S. economy as a result of pharmaceutical counterfeiting. Moreover, estimates vary regarding the other direct and indirect costs for businesses of the sales of counterfeit or pirated goods, such as lost income of companies and the resulting reduction in capital for research and development investment, lost wages, the full socioeconomic impact from counterfeit pharmaceuticals, and the costs of enforcement. The National Association of Manufacturers (NAM) estimates that, in general, "counterfeiting and piracy cost the U.S. economy nearly \$250 billion a year, resulting in the loss of more than 750,000 jobs."^{xxxvii} Another organization, America's Watchdog, estimates that the world's top 10 pharmaceutical companies and the world's top five tobacco companies each lose a minimum of \$1,000,000+ per day due to product counterfeiting.^{xxxviii} In 2009, U.S. Customs and Border Protection estimated the value of seized counterfeit pharmaceuticals had increased 34% from the prior year.^{xxxix} The above statistics illustrate that, while estimates vary, in sum, the impact on the U.S. economy from pharmaceutical counterfeiting is very real.

Conclusion

PhRMA appreciates the opportunity to provide initial thoughts on the development of the IPEC Strategic Plan. As a stakeholder in the process of developing a U.S. enforcement strategy against IP infringement, and in light of

the wide-ranging request for input on elements of the Strategic Plan, we look forward to continuing to collaborate with the IPEC Coordinator as the Strategic Plan is developed and implemented.

⁷ Remarks by the President at the Export-Import Bank's Annual Conference, March 11, 2010.

⁸ Adapted from L.R. Burns, *The Biopharmaceuticals Sector Impact on the U.S. Economy: Analysis at the National, State, and Local Levels* (Washington DC, Archstone Consulting LLC, March 2009).

⁹ U.S. Trade Representative 2008, Special 301: PhRMA submission. Issued 2008.

¹⁰ *A Strategy for American Innovation: Driving Towards Sustainable Growth and Quality Jobs*, Executive Office of the President, Office of Science and Technology Policy, September 2009.

¹¹ *The Biopharmaceutical Sector's Impact on the U.S. Economy: Analysis at the National, State, and Local Levels*, Archstone Consulting, Lawton R. Burns, March 2009.¹² Battelle Technology Partnership Practice, "State Bioscience Initiatives 2008" (June 2008).

¹³ *Id.*

¹⁴ Shapiro, R. and Pham, N. "Economic Effects of Intellectual Property-Intensive Manufacturing in the United States." *World Growth*, July 2007.

¹⁵ *Id.* at 3.

¹⁶ Matthew Herper, "Layoffs Sting Big Pharma." *Forbes*, November 13, 2009.

¹⁷ *The Biopharmaceutical Sector's Impact on the U.S. Economy: Analysis at the National, State, and Local Levels*, Archstone Consulting, Lawton R. Burns, March 2009.

¹⁸ *Id.*

¹⁹ Burrill & Company, analysis for PhRMA, 2005-2009, includes PhRMA research associates and nonmembers; *Pharmaceutical Research and Manufacturers of America, PhRMA Annual Member Survey* (Washington, DC: PhRMA, 1980-2009).

²⁰ U.S. Food and Drug Administration, Office of Orphan Products, "Cumulative List of Designated and Approved Orphan Products" (Washington, DC: FDA, 4 October 2007), <http://www.hhs.gov/orphan/designat/allap.rtf> (accessed 3 March 2008); B. Silverman, "FDA First-Cycle Approval Rate is Silver Lining in Cloud of Low NME Count," *The Pink Sheet* 70, no. 2 (14 January 2008) and B. Silverman, "Year in Review: New Biologics Total Seven in 2007, But Only Four Will See Market," *The Pink Sheet* 70, no. 3 (21 January 2008). Food and Drug Administration, www.fda.gov.

²¹ *Adis Research and Development Insight Database*, Wolters Kluwer Health, accessed 13 February 2009. U.S. Food and Drug Administration, Office of Orphan Products, "Cumulative List of Designated and Approved Orphan Products" (Washington, DC: FDA, 4 October 2007), <http://www.hhs.gov/orphan/designat/allap.rtf> (accessed 3 March 2008); B. Silverman, "FDA First-Cycle Approval Rate is Silver Lining in Cloud of Low NME Count," *The Pink Sheet* 70, no. 2 (14 January 2008) and B. Silverman, "Year in Review: New Biologics Total Seven in 2007, But Only Four Will See Market," *The Pink Sheet* 70, no. 3 (21 January 2008). Food and Drug Administration, www.fda.gov.

²² Congressional Budget Office, *Research and Development in the Pharmaceutical Industry* (Washington, DC: CBO, October 2006).²³ See also, R. Shapiro, et al., *Economic Effects of Intellectual Property-Intensive Manufacturing in the United States*, July 2007.

²⁴ *Pharmaceutical Research and Manufacturers of America, 2010 Pharmaceutical Industry Survey*.

²⁵ *The Biopharmaceutical Sector's Impact on the U.S. Economy: Analysis at the National, State, and Local Levels*, Archstone Consulting, Lawton R. Burns, March 2009.

²⁶ *Id.*

²⁷ *Id.*

²⁸ *Id.*

²⁹ *Id.*

³⁰ See, for example, Grabowski, H. Patents, innovation, and access to new medicines. *Journal of International Economic Law* 2002:849-860.

³¹ Edwin Mansfield, "Patents and Innovation: An Empirical Study," *Management Science*, Vol. 32, No. 1, 1986.

³² Shapiro, R., and Hassett, K. *The Economic Value of Intellectual Property*.

³³ *Id.*

³⁴ IFPMA Survey, validated by LSE Health and Social Care at the London School of Economics and Political Science.

³⁵ See www.globalhealthprogress.org.

³⁶ Moran, M. et al, *Neglected Disease Research and Development: New Times, New Trends*, The George Institute for International Health, (2009).

³⁷ See generally, "Incident Trends," at <http://www.psi-inc.org/incidentTrends.cfm>. The Pharmaceutical Security Institute, Inc., a not-for-profit, membership organization dedicated to addressing pharmaceutical counterfeiting issues, is based in Vienna, Virginia.

^{xxx} The World Health Organization. IMPACT. www.who.org 2008.

^{xxxI} OECD, "Economic Impact of Counterfeiting and Piracy: Part III Industry Sectors," 2008.

^{xxxII} *ibid.*

^{xxxIII} The cGMP regulations are applicable to all pharmaceuticals sold in the U.S., wherever they are made, and extend to all components of a finished drug product, including active pharmaceutical ingredients (APIs), without regard to where those ingredients are sourced. FDA's cGMP regulations are based on the fundamental quality assurance principle that quality, safety and effectiveness "cannot be inspected or tested into a finished product," but instead must be designed and built into a product.

^{xxxIV} FDA, "FDA Issues 22 Warning Letters to Web site Operators," November 19, 2009 <

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm191330.htm>>

^{xxxV} ICE, National Intellectual Property Rights Coordination Center partners take part in international week of action on illegal pharmaceuticals: ICE, CBP, FDA, DEA and USFIS target drugs sold illegally on the Internet, November 20, 2009. <

<http://www.ice.gov/pi/nr/0911/091120washington.htm>>

^{xxxVI} FDA, "FDA Issues 22 Warning Letters to Web site Operators," November 19, 2009 <

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm191330.htm>>

^{xxxVII} <http://www.nam.org/Issues/Technology/Intellectual-Property-Rights.aspx>

www.oecd.org/dataoecd/13/12/38707619.pdf

^{xxxVIII} America's Watchdog. Americas Watchdog Warns The World About Chinese Counterfeit Pharmaceuticals & Cigarettes, March 30, 2009, <http://www.pharmaceutical-manufacturingnews.com/article-press-345-chinesecounterfeit-counterfeitpharmaceuticals-globalpiracy-americaswatchdog.html>

^{xxxIX} See U.S. Customs and Border Protection, Fiscal Year 2009 Seizure Statistics, October 2009

http://www.cbp.gov/xp/cgov/trade/priority_trade/ipr/seizure/: