Comment Regarding the
Joint Strategy Plan on Intellectual Property Enforcement Strategy

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It is a pleasure to have the opportunity to comment on the Joint Strategy Plan on Intellectual Property Enforcement. I believe intellectual property rights enforcement to be an important issue, both in the context of public health and US job creation/preservation. For more than a decade, my academic research has examined the questions surrounding pharmaceutical innovation and intellectual property (IP) protection, with particular focus on issues of counterfeiting and drug safety. I believe that this provides me with a unique perspective and valuable insights for the development of the joint strategic plan. Due to my research portfolio and expertise, my comments will focus largely on the importance of intellectual property rights and their enforcement to the pharmaceutical and biotechnology industries. Though this focus admittedly limits the breadth of these comments, these industries provide a telling glimpse of the value of IP protection to the US economy. The comments that follow address the importance of intellectual property protection to both public health and safety as well as US jobs.

On the supply side, pharmaceutical innovation is a difficult and expensive process to undertake, but one that is easy to replicate. The fixed costs of research and development are very high [perhaps a billion dollars for a new compound (Danzon 2007, p.176)], while the marginal costs of production are very low [perhaps pennies per dose]. As a result, patent protection is disproportionally more important in the pharmaceutical and chemical industries than in many other sectors to ensure that the researcher appropriates the returns to research and development (R&D).[1] Given the ease of replicating chemical and pharmaceutical innovations, protection is vital for the economic future of these firms.

Economists and other scholars have developed a significant literature on complementary (and substitute) incentive mechanisms for drug development. Historically, innovation is best spurred by the market rather than under government direction or mandate. There is no reason to believe that drug discovery is any different. Accordingly, market incentives, including effective intellectual property enforcement, must be preserved to spur innovation.

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[1] Building on the 1987 "Yale Survey" (Levin, Klevorick, Nelson and Winter 1987), Cohen et al. reexamine the effectiveness of various means of appropriating intellectual property. Echoing the earlier findings, the 1994 "Carnegie-Mellon" survey finds that there are tremendous differences in the effectiveness of various appropriability mechanisms, both among industries as well as within them. Overall, while patents are again seen as "unambiguously the least effective of the appropriability mechanisms," the drug industry regards them as strictly more effective than alternative mechanisms (Cohen, Nelson and Walsh 1996, p.14). This is confirmed by the industry's high propensity to patent both product innovations (overall highest propensity at 99%) and process innovations (fourth highest propensity at 43%) (Cohen, Nelson, and Walsh 1996, pp.21-22). Several other studies report that the protection of intellectual property is disproportionally more important to the chemical and pharmaceutical industries. These include: Levin, Klevorick, Nelson and Winter (1987), Taylor and Silberston (1973), Scherer (1997), Mansfield (1986), Mansfield, Schwartz and Wagner (1981), and Tocker (1988). These studies are echoed by arguments from within the pharmaceutical industry: Mossinghoff (1998), Peretz (1983), Mossinghoff (1987), Santoro (1995), Smith (1990a, 1990b), Mossinghoff and Bombelles (1996), PhRMA (1997), and Bombelles (1999).

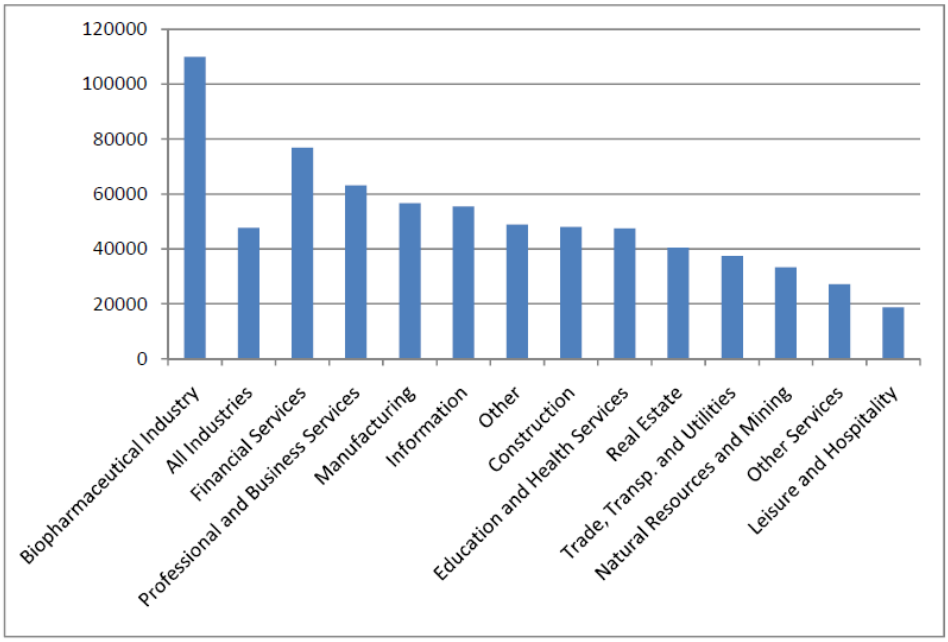
In addition, economic research has established that innovation in high tech industries is enhanced by geographic concentration which facilitates R&D spillovers. Technology is, to a remarkable degree, a local not global asset.[2] Proximity facilitates collaboration, technological spillovers and enhances innovative productivity. All of these benefits are facilitated by an environment of secure intellectual property rights and safeguards for innovation. The success of America's most cutting-edge and technologically sophisticated industries is inextricably linked to strong IP enforcement.

Protecting Intellectual Property Rights Protects US Jobs

The "United States is the epicenter of prescription drug research for the planet producing more new drugs than all other countries combined" (Turner, 2003). The vitality of the pharmaceutical industry and the high-paying jobs available throughout the industry are directly tied to the IP protection granted to pharmaceutical innovations. The continued success of this economic engine depends on intellectual property rights, the industry's lifeblood.

The biopharmaceutical industry is a source of high-paying jobs, with wages markedly higher than those of other industries. As evidence of this, consider the chart below which plots average salaries in Delaware across a variety of industries. The average wage in the biopharmaceutical industry is more than double the average wage across all industries in Delaware. This is true of the industry in other states as well. New Jersey's biopharmaceutical and medical technology industries provided 147,836 jobs in 2008, with an average base salary of more than $110,000. (HINJ 2009, p.1) Notably, biopharmaceutical wage growth is also outpacing other industries. In Delaware, the average biopharmaceutical wage grew 22.8% between 2002 and 2007, while the state average was 15.5% (Brown, Condliffe, Ratledge 2009, p.8).

Figure 1: Delaware Average Annual Salaries, 2008

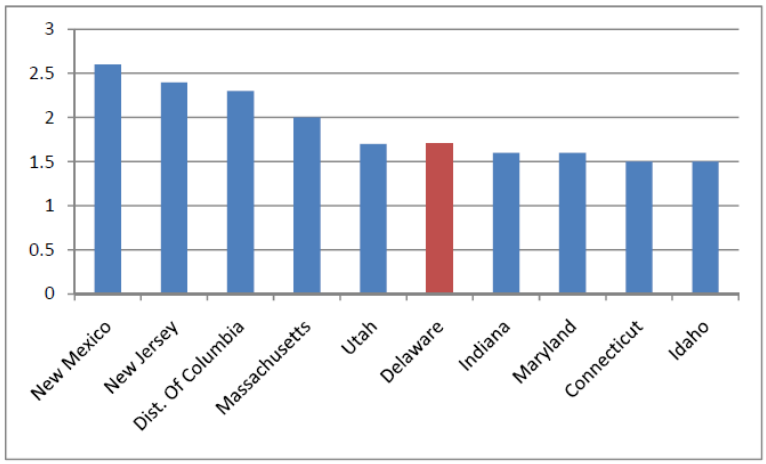


Source: Brown, Condliffe, and Ratledge, 2009, p.8. Data from the Delaware Department of Labor.

[2] Jaffe, Trajtenberg, & Henderson (1993) provide an excellent starting point for exploring this literature.

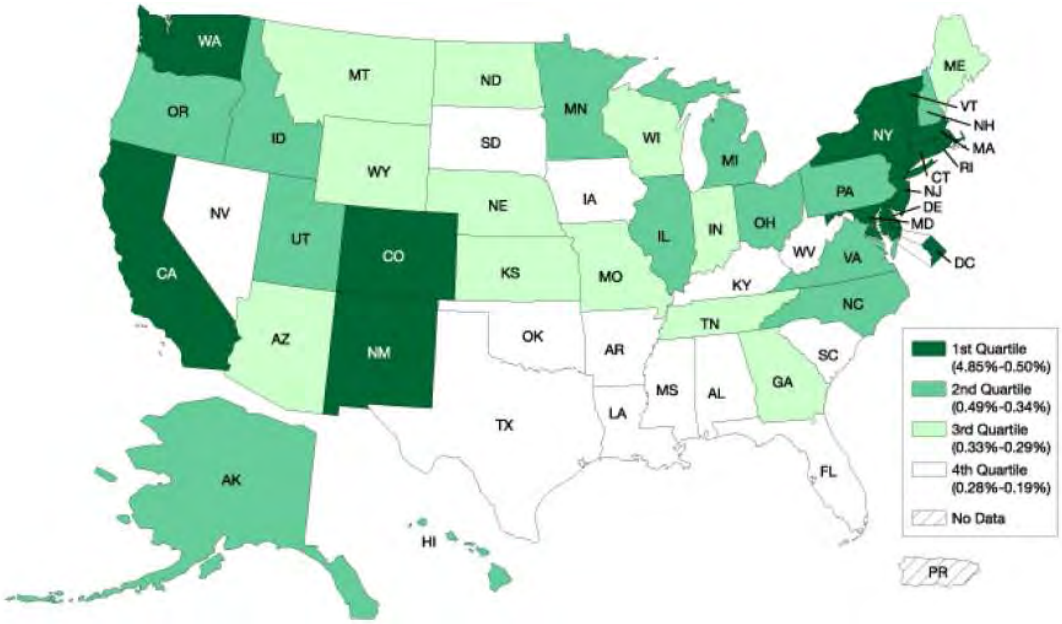
The importance of the biopharmaceutical industry is further exemplified by the industry's share of jobs relative to total private sector jobs. This percentage is shown in Figure 2 below for the top ten states. Perhaps most remarkably, the industry is a significant source of jobs in several states that do not immediately come to mind when considering the biopharmaceutical sector, including the top-ranked state, New Mexico.

Figure 2: Top Ten States, Ranked by Share of Biopharmaceutical-Related Jobs, 2005



Source: Brown, Condliffe, and Ratledge, 2009, p.15.

Figure 3: Science and Engineering Doctorate Holders as a Share of Workforce, 2001



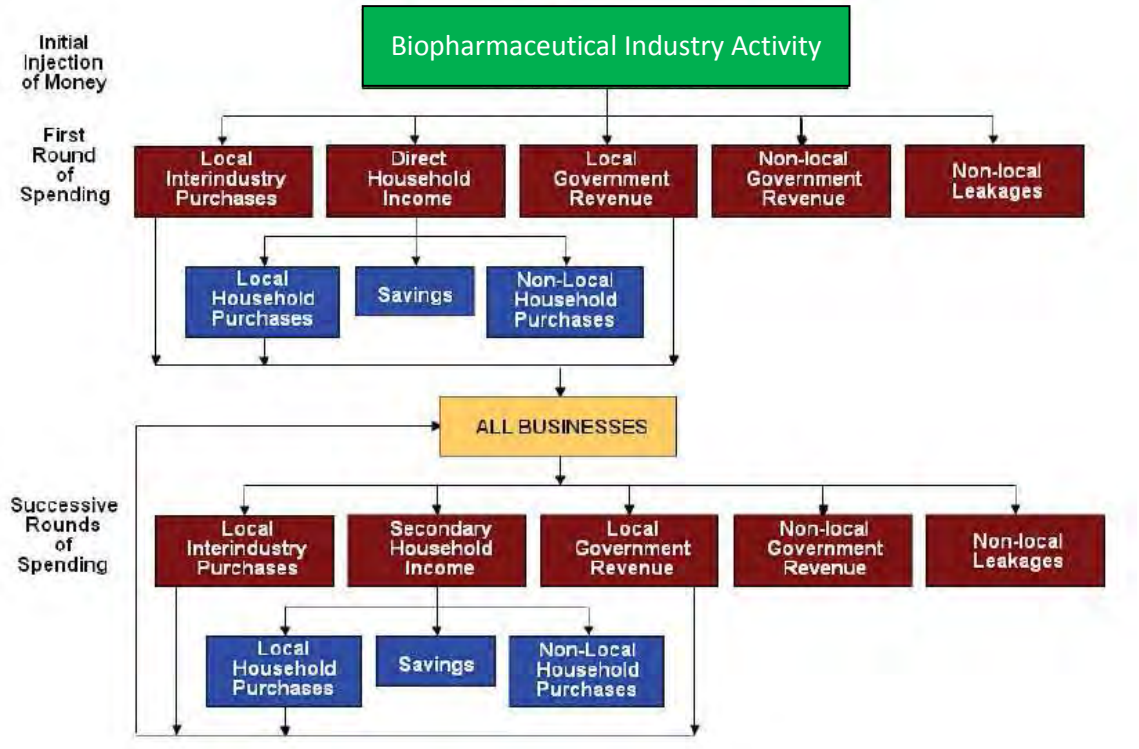
Source: Brown, Condliffe, and Ratledge, 2009, p.42. Data from national Sciences Board, 2004.

Moreover, the biopharmaceutical industry serves as a catalyst, attracting scientists and engineers to the regions in which the industry is most established. Though not a complete explanation, this is evident in Figure 3 above. A comparison of the states with the most patents for drugs also appear as some of those with the largest share of science and engineering doctorate holders: California, New Jersey, Massachusetts, Pennsylvania, New York, Connecticut, and Maryland (Brown, Condliffe and Ratledge 2009, p.19).

The industry serves to draw talented, high-skilled workers to the region. As noted above, economic research has established that innovation in high tech industries is enhanced by geographic concentration which facilitates R&D spillovers. Talent attracts talent and proximity facilitates collaboration, technological spillovers and enhances innovative productivity.

Perhaps the most important characteristic of employment in the biopharmaceutical industry is the multiplier effect. That is, each job created by the industry results in the creation of additional jobs within the economy as a whole. The mechanics of the multiplier effect are likely best conceptualized visually. Figure 4 below maps out the connections between the recipients of industry spending and further economic activity, illustrating the manner in which the industry's initial economic impact is magnified through multiple rounds of purchases. This subsequent economic activity generates new jobs as the expenditure moves through the economy through repeated rounds of spending.

Figure 4: Multiplier Effect through Various Economic Sectors



Adapted from: Brown, Condliffe, and Ratledge, 2009, p.27.

Drawing on the results of studies by the Bureau of Economic Analysis (2008) and the Minnesota IMPLAN Group (2007), Brown, Condliffe and Ratledge (2009) explore how the pharmaceutical industry multipliers in Delaware compare to those of other industries. Table 1 below describes (i) the total dollar change in earnings for households given an additional dollar in earnings for the corresponding industry, and (ii) the total change in employment given an additional job in the corresponding industry.

Admittedly, these calculations describe the specifics of Delaware and the impact on the economy of one state. Nevertheless, it is worth noting that the Pharmaceutical and Medical Manufacturing Industry is associated with the highest earnings multiplier and the largest employment multiplier. This is consistent across both studies, providing evidence, though limited, of the robustness of the result. In a similar vein, a study by the New Jersey HealthCare Institute found that for each job in biopharmaceutical and medical technology member companies, an additional 1.5 jobs were created (HINJ 2009, p.2).

Table 1: Economic Multiplier Calculations across Delaware

		BEA		IMPLAN	
Code	Industry	Earnings ($)	Employment (# of jobs)	Earnings ($)	Employment (# of jobs)
3254	Pharmaceutical and medicine manufacturing	2.68	4.35	2.87	4.72
522A00	Nondepository credit intermediation and related activities	1.90	3.03	1.42	2.26
3391114	Dental equipment and supplies manufacturing	1.88	2.51	2.07	2.59
334510	Electro medical apparatus manufacturing	1.95	3.23	1.79	2.34
541700	Scientific research and development services	1.55	2.29	1.41	2.09
550000	Management of companies and enterprises	1.49	1.89	1.43	1.94
7	Construction	1.67	1.81	1.67	1.81
15	Motor vehicle, body, trailer, parts manufacturing	2.39	4.18	1.70	2.01
27	Wholesale trade	1.61	2.04	1.45	1.95
28	Retail trade	1.63	1.41	1.42	1.21
52	Ambulatory health care services	1.48	1.78	1.66	1.67

Source: Brown, Condliffe, and Ratledge, 2009, p.34. Data from the US Bureau of Economic Analysis' Regional Input-Output Modeling System (2008), and the Minnesota IMPLAN Group (2007).

Beyond the pharmaceutical and medical manufacturing industries, innovation and its protection through the enforcement of intellectual property rights are important to other job-multiplying industries. Although

a nascent industry in 1999, the biotechnology employed 150,800 workers and generated an additional 287,000 jobs for a total of 437,000 jobs attributable to the biotechnology industry in 1999. The employment multiplier in the biotechnology industry was estimated to be 2.9 by Ernst and Young (2000).

Future estimates for employment growth in the pharmaceutical industry are also notably strong. The US Bureau of Labor Statistics projects strong growth in the pharmaceutical and medical manufacturing industries as well as research and development in the physical, engineering and life sciences over the 10 year period, 2006-2016. National forecasts for the pharmaceutical and medical manufacturing industry estimate 23.7% growth, while the employment numbers in research and development in the physical, engineering and life sciences are projected to increase by 9.8% (Brown, Condliffe and Ratledge 2009, p.38).

The continued vitality of the biopharmaceutical industry and these healthy employment statistics are contingent on the future viability of the industry and sustaining its knowledge creation. This in turn, depends on safeguarding innovation through strong intellectual property rights and their effective enforcement.

Contributions to Other Sectors of the Economy

The pharmaceutical and biotech industries are also significant contributors to other sectors of the economy. Their innovations are essential to increasing the efficiency of a variety of other sectors, both directly and indirectly. As a single example, consider the contributions of pharmaceutical technology to modern beef production. A 2006 study by Iowa State University identifies cattle production is the largest agricultural sector in the United States, generating $4.2 billion in revenues in 2005 (Lawrence & Ibarburu, p.1). This industry is present in all 50 states, includes more than 980,000 farms and widely uses pharmaceutical technologies in all segments of the cattle industry. Lawrence and Ibarburu's meta-analysis draws on information from more than 170 research trials, concluding that "the estimated direct cost savings to producers . . . was over $360/head (and selling) prices would have to increase 36 percent to cover the increase in costs without these technologies." (Lawrence and Ibarburu, p.1) Without the pharmaceutical technologies utilized in the cattle industry, the "overall beef industry would be smaller with fewer cattle on feed, reduced slaughter and more beef imports." (Lawrence and Ibarburu, p.13) Accordingly, reduced beef production would eliminate some producers, resulting in a smaller industry and reduced employment in rural communities in particular.

Moreover, the innovations developing in the biopharmaceutical industry are important technologies for the emergence of the new green economy. Consider the changes taking place in agricultural biotechnology. They have allowed for "increases in agricultural production, lessening the need for pesticides and other crop inputs which also serves to reduce our dependence on foreign petroleum." (Ernst and Young 2000, p.3) Further, environmental biotechnology products "make it possible to clean hazardous waste, control agricultural pests and reduce the use of chemicals". (Ernst and Young 2000, p.3)

Threats to Public Health and Safety Created by Infringement

Historically the debate over increased protection for intellectual property has centered on the pharmaceutical industry. In particular, infringing and counterfeit drugs gained international prominence during the Trade-Related Aspects of Intellectual Property Rights (TRIPs) negotiations of the Uruguay Round. This focus stemmed from (i) the stark differences in patent regimes across countries in the pharmaceutical sector, (ii) the disproportional importance of patent protection in the pharmaceutical and

chemical industries in ensuring that the researcher appropriates the returns to R&D, (iii) the inelastic demand for pharmaceuticals over a wide price range, and (iv) the pharmaceutical industry's close ties to the emotionally charged issues of public health.

While the higher profile of the problems of counterfeit pharmaceuticals increased public awareness and resulted in some improvements in enforcement, the problem remains significant. According to IMS Health, pharmaceutical sales are estimated to reach $825 billion in 2010 and the large margin between manufacturing costs and market price creates an impressive economic incentive (Alazraki 2009, p.1). Moreover, medicines are very high value products relative to their bulk. While estimates of the share of counterfeit drugs are difficult to come by and imprecise at best, reports place the share in some developing countries as high as 50-70% (PhRMA 2001).[3] The severity of the health risk associated with fraudulent drugs can vary greatly, from inconvenience to fatality.[4] Treatment failure is the foremost cost of fraudulent drugs, but not the only consequence of spurious products.[5] The production of counterfeit pharmaceuticals may also result in a loss in confidence in the system of western medicine and the rise in drug-resistant strains of bacteria.[6]

Although the United States arguably has the safest drug supply chain in the world, on a global scale pharmaceutical counterfeiting encompasses everything from aspirin to Zyprexa.[7] While counterfeiting is more prevalent in the developing world, the US is not immune from the problem. This is increasingly true as technology improves and becomes more widely available. Counterfeit drugs are difficult to detect, even by the individuals taking them. Today's counterfeiters "equipped with the latest technology, can even buy their packaging from the same companies as the legitimate manufacturers, making it impossible for authorities to identify the fakes without expensive chemical analysis" (Schofield 2001).

Moreover, the problem is amplified by existing market conditions. The market for pharmaceuticals is characterized by sizable price differences across countries. These differences reflect distinct demand patterns as well as differences in governmental regulations and healthcare policies. Recent events have drawn attention to the price differential, particularly the gap between the prices in United States and Canada, nations perceived to be very similar. In 2002, "drug prices in the United States were 67 percent higher than in Canada" (Harris 2003(b), p.1). One consequence of the growing price differential is an

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[3] Consider the following examples from specific countries: Brazil, 20% (Land 1992); Nigeria, 70% (Raufu 2003); Mexico, 25% (GlobalOptions, Inc. 2003); Indonesia, 25% (PhRMA 1997); Pakistan, 50% (Hajari 1998); Ukraine, 40% (Akehurst 2005); Russia, 12% (Akehurst 2005); Columbia, 30% (Capell, et. al. 2001).

[4] Medical experts have a difficult time agreeing "…on how many deaths are caused by fake drugs, although most acknowledge that World Health Organization statistics showing more than 500 fatalities caused by contaminated cough syrup over the past 15 years only scratch the surface of the problem" (Hajari 1998, p.265).

[5] It is worth noting that treatment failure may be mitigated by the placebo effect. "[P]lacebos are about 55 percent to 60 percent as effective as most active medications like aspirin and codeine for controlling pain" (Blakeslee 1998, p.D1). The author is grateful to Oliver Williamson for raising the issue and providing the source on current studies of the placebo effect.

[6] Counterfeit drugs that contain a greatly reduced dose of the active constituent have contributed to the increase in this threat. As one study reports, "Antibiotics obtained as over-the-counter products, commonly without a physician's prescription - or even a physician's advice - are frequently used at too low dosages and for too few days. . . One serious result of this widespread, inadequate treatment has been the rise of drug-resistant strains of bacteria" (Silverman, Lydecker and Lee 1992, p.7).

[7] "Because tablet-making machines are easily obtainable, even counterfeit 'aspirin' tablets containing little or no acetylsalicylic acid can be profitable, especially at open-air markets such as those in African villages" (McGregor 1997, p.1690).

increased incentive to transport drugs across national boundaries. Though illegal, this practice persists. Additional enforcement efforts would assist in reducing the cross-border flow of medicines.

Dating back to 2004, pharmaceutical counterfeiting was "branded the 'emerging crime of the 21st century' – the counterfeit medicines business is now worth an estimated $50 billion a year" (Akehurst 2005). That estimate exceeds the 2003 GDP of Morocco, and is greater than the annual GDP of two-thirds of all nations (126 of the 183 listed by the World Bank). Moreover it is equivalent to the combined annual GDP of the 24 poorest Sub-Saharan African nations: Benin, Burkina Faso, Burundi, Cape Verde, Central African Republic, Chad, Comoros, Republic of the Congo, Eritrea, Guinea, Equatorial Guinea, Lesotho, Liberia, Guinea-Bissau, Malawi, Mauritania, San Tome & Principe, Niger, Rwanda, Sierra Leone, Seychelles, Swaziland, Togo and Zambia (author's calculations, World Bank data, 2003).

In a series of blitz exams in 2003, the FDA reviewed packages entering the US containing drugs. The assessment encompassed Miami, New York (JFK), San Francisco, Carson, CA, Buffalo, Dallas, Chicago and Seattle. "They pulled out 1,153 packages that appeared from the outside to contain drugs. . . [finding that] 1,019, or 88%, contained unapproved drugs . . . most were made in countries that did not have plants approved by the FDA and they seemed counterfeit" (Harris 2003(a)). The potential risks to buyers are significant and included the purchase of controlled substances, potentially recalled drugs, improperly labeled drugs, so-called 'foreign versions' of FDA approved drugs, drugs with significant drug-drug interactions, and drugs requiring risk management (US FDA 2003). The enormity of the task is apparent when one recognizes that each year the Miami International Mail facility alone receives close to 7 million packages containing drugs (US FDA 2003). The number of investigative counterfeit drug cases opened by the FDA has increased from 5 in 1998 to 58 in 2004 and 76 in 2005 (US FDA 2005).

Secure intellectual property rights as well as effective enforcement aid the industry in guarding against counterfeit drug production. While the magnitude of the problem is difficult to estimate, experts recognized the growing dimensions of the problem as far back as 1993 when Tavis and Williams wrote "counterfeiting has now assumed such an alarming size that it and associated activities (misbranding, substitution, adulteration, and spurious manufacture) are becoming a major threat to the industry, to future research and development, to employment, individual and community safety, and public health" (Tavis and Williams 1993, p.162). These sentiments were echoed in a paper by Rapp and Rozek (1992) in which they discuss the direct link between denying patent protection to pharmaceuticals and "poorer health for the country's residents" (Rapp and Rozek 1992, p.162). Clearly the threat extends beyond industry profitability and jobs to the heart of public health.

Additional Considerations

While the focus here is the impact of intellectual property rights enforcement on jobs and public health and safety in the United States, it is important to recognize the other contributions made by the industries that so immediately depend on IP protection. The biotechnology and pharmaceutical industries are significant sources of tax revenues to local communities, as well as state and federal coffers. The jobs generated by these industries create not only personal income, but result in tax payments at each level of government. In an era of state budget deficits and declining tax receipts, the preservation of innovative industries and well-paying jobs should be a top priority.

The challenges of the recent economic downturn expose a less obvious contribution of the biopharmaceutical industry as well. Drawing on the specifics of New Jersey, the biopharmaceutical and medical technology industries in the state generated $4.5 billion in global philanthropy in 2008. (HINJ 2009, p.1) Of this, $221 million directly benefited New Jersey causes. The US industry's generosity

extends to global causes and vulnerable populations as well. The Hudson Institute notes the "U.S. based Partnership for Quality Medical Donations (PQMD) recorded the 'value of donated products at $4.3 billion in 2005' for the developing world. This sum alone is greater than the combined annual health budgets of the WHO, UNICEF and the World Bank." (Norris 2007, p.6) The industry is a generous corporate citizen at both the local and global levels, contributing to economy prosperity and greater public health in both.

The pharmaceutical and biotechnology industries are the source of a diverse range of life-enhancing products and services, including drugs, gene therapy, clinical diagnostic products, research and development, molecular biology research, and agricultural products. These industries have developed treatments and cures for diseases, as well as technologies that increase agricultural production, improve crop resistance to insects, disease and weeds, reduce fuel costs, lessen soil erosion, and clean hazardous waste.

While the biopharmaceutical industry produces a diverse range of products, it is also a significant source of innovation and knowledge generation. Though not a perfect measure, patenting-active reflects this contribution. Table 2 below identifies patents from all 50 states, in addition to Guam and the District of Columbia. The sector is clearly vibrant and active, with a nationwide presence.

Table 2: State Ranking by Patents, 2008

(Drugs, Bio-Affecting and Body Treating Compositions)

Code	State-Territory or Country	2003	2004	2005	2006	2007	Total	Rank
CA	CALIFORNIA	772	612	538	722	655	3299	1
NJ	NEW JERSEY	418	264	230	356	280	1548	2
MA	MASSACHUSETTS	343	280	250	270	262	1405	3
PA	PENNSYLVANIA	320	191	165	216	234	1126	4
NY	NEW YORK	197	169	128	167	154	815	5
CT	CONNECTICUT	180	144	171	165	139	799	6
MD	MARYLAND	176	134	108	143	132	693	7
TX	TEXAS	139	108	85	103	105	540	8
NC	NORTH CAROLINA	120	73	76	107	97	473	9
MI	MICHIGAN	112	92	105	79	53	441	10
IL	ILLINOIS	130	73	65	87	75	430	11
WA	WASHINGTON	90	55	66	86	84	381	12
FL	FLORIDA	113	68	55	68	65	369	13
IN	INDIANA	99	70	60	64	68	361	14
OH	OHIO	104	75	57	61	44	341	15
MO	MISSOURI	77	88	53	60	30	308	16
MN	MINNESOTA	84	71	38	61	40	294	17
WI	WISCONSIN	70	32	43	51	43	239	18
GA	GEORGIA	47	31	36	50	45	209	19
DE	DELAWARE	40	38	37	37	25	177	20
CO	COLORADO	47	38	24	28	26	163	21
VA	VIRGINIA	53	18	20	22	28	141	22
TN	TENNESSEE	35	32	25	25	22	139	23
AZ	ARIZONA	29	31	19	30	22	131	24
AL	ALABAMA	35	23	22	20	20	120	25
UT	UTAH	27	34	10	25	19	115	26
IA	IOWA	19	16	12	16	25	88	27
LA	LOUISIANA	24	16	14	16	11	81	28
OR	OREGON	17	15	8	14	11	65	29
KY	KENTUCKY	18	11	11	11	11	62	30
RI	RHODE ISLAND	10	6	13	12	4	45	31
NH	NEW HAMPSHIRE	12	8	7	9	8	44	32
SC	SOUTH CAROLINA	11	9	6	13	4	43	33
KS	KANSAS	12	12	5	7	6	42	34
OK	OKLAHOMA	11	5	6	7	9	38	35
AR	ARKANSAS	13	5	8	7	3	36	36
NE	NEBRASKA	7	8	4	6	6	31	37
ID	IDAHO	8	3	3	8	6	28	38
MT	MONTANA	8	3	5	6	4	26	39
MS	MISSISSIPPI	5	5	6	4	3	23	40
HI	HAWAII	4	3	4	5	4	20	41
VT	VERMONT	2	2	3	5	3	15	42
WV	WEST VIRGINIA	6	1	5	3	0	15	43
DC	DISTRICT OF COLUMBIA	4	1	3	4	2	14	44
NM	NEW MEXICO	5	5	2	0	2	14	45
ME	MAINE	1	2	0	2	5	10	46
NV	NEVADA	0	2	0	1	2	5	47
PR	PUERTO RICO	3	0	0	1	1	5	48
AK	ALASKA	2	1	0	1	0	4	49
ND	NORTH DAKOTA	2	0	0	0	0	2	50
SD	SOUTH DAKOTA	0	0	0	1	1	2	51
GU	GUAM	0	0	0	0	1	1	52
WY	WYOMING	0	0	0	1	0	1	52
	-- Subtotal --	4061	2983	2611	3263	2899	15817	

Source: Brown, Condliffe, and Ratledge, 2009, pp.19-20. Data from US Patent and Trademark Office.

Conclusions

Intellectual property rights are at the heart of the pharmaceutical industry and the lifeblood of the US advantage in high technology sectors. Their effective enforcement safeguards the viability of these sectors and the jobs that they provide to the US economy. In addition, it ensures continued growth and job creation for some of America's most valuable producers. Relative to other industries, these sectors generate employment at a more rapid rate, provide greater average compensation to employees, and multiply jobs within the extended economy to a larger extent.

Moreover, the sectors, biopharmaceuticals and chemicals, which rely most heavily upon the enforcement of patents and other forms of intellectual property, are also the sectors that are perhaps best poised to launch the green economy within the United States.[8] These industries facilitate environmental gains in other sectors of the economy, from improving agricultural production to aiding in the cleanup of hazardous waste. America's capacity to generate green energy and foster green industries hinges on the nation's ability to innovate in this realm and capture the returns from these investments. Incentivizing innovation relies on the ability to profitably bring new technologies to market, with secure ownership of the knowledge and enforcement of the IP surrounding it.

Finally, strong intellectual property rights enforcement promotes and protects public health and safety. In the context of the biopharmaceutical industry, robust IP protection incentivizes innovative work to improve health tomorrow and guards against infringement and counterfeiting today. On a global scale, pharmaceutical counterfeiting is a significant source of treatment failure and even death. The profitability of fraudulent drugs makes their production virtually irresistible. Faced with such temptation, their producers have little regard for human life and health. Though the prevalence of fake drugs is limited in the United States, recent years find the FDA opening a growing number of investigations into pharmaceutical counterfeiting. The threat remains and counterfeiters are increasingly technologically savvy. Enhanced enforcement of intellectual property rights will provide valuable protection against the potential for harm.

Strong intellectual property rights and enhanced enforcement will preserve US jobs and health. The defense of our most innovative industries and the security of our drug supply chain depend upon it. As aptly phrased by the adage 'an ounce of prevention is worth a pound of cure', protection of our intellectual property rights and the prevention of infringement is far easier than contending with the consequences of failing to do so.

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[8] For a complete description of studies reporting the importance of patents to the pharmaceutical and chemical industries, please see footnote 1.

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