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Thank-you for the opportunity of submitting the attached response to your request for public input for an improved enforcement strategy for intellectual property. This is a very timely initiative that could create or cost jobs both in the U.S and Canada.

*Dr. D. Wayne Taylor*

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**Comments**

**Regarding**

# Co-ordination and Strategic Planning of the Federal Effort Against Intellectual Property Infringement: The Joint Strategic Plan Federal Register 75 (35) 8137

**To**

**The Intellectual Property Enforcement Co-ordinator**
**Office of Management and Budget**
**Executive Office of the President**

**From**

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**March 2010**

Cameron Institute

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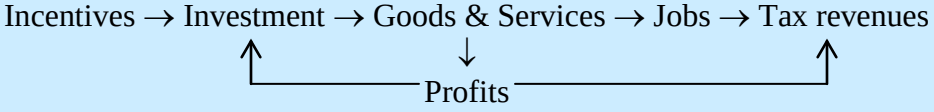
Thank you for the opportunity to comment upon the Joint Strategic Plan designed to co-ordinate and bolster the Federal effort against the infringement of intellectual property rights. Even though we are a Canadian-based think tank this topic and your approach to it is very important to Canadians, as it is to Americans. Over 85% of Canada's international trade is with the United States and, conversely, Canada is America's single largest trading partner. As the American economy goes so does Canada's. So it is of mutual interest that we take this occasion to submit our comments.

**Introduction – Pharmaceuticals and Jobs**

Mixed economies, such as both of ours, need a strong private sector of industry and commerce to support the public sector which supplies defence, justice, public protection, education, healthcare and so on. Incentives are at the very core of this economic symbiosis. Incentives are a bundle of factors present or not within a business environment that offers investors a chance (not a guarantee) of a return on their investment. When the right mix of incentives exists, investment occurs. This investment is used to purchase material, technology and labour to produce goods and services which when sold pays wages or salaries to labour and investment income to the investors. People have jobs, investors make money to then re-invest, and governments reap tax revenues for public programmes (see Figure 1).

Figure 1

**The Incentive-Employment Dynamic**



Amongst incentives can be the legal protection of intellectual property through devices such as trade marks, copyrights and patents. Patents and the other devices represent the material manifestation of an individual's intellectual labours. The United States patent system is grounded in Article I, Section 8, Clause 8 of the U.S. Constitution. This clause was deliberately written to stimulate discoveries and their reduction to practice (innovation) as a means to growing the new nation's economy and providing for its people. The writers of the Constitution were correct. The historical record shows that countries with strong patent protection have experienced stronger economic and employment growth. The Council of Economic Advisors in 1995 estimated that the social rate of return form research and development was over twice that of the rate of return for the innovator.

Currently patents are valid for 20 years from the date of filing. The need for intellectual property protection varies with industry and economic activity. Patents are very important to the chemical and biopharmaceutical industries where patent filings are quite detailed and therefore easier to defend, whereas lead time and strength of the learning curve are more important to the aerospace and semiconductor industries as part of the environmental mix of incentives crucial for survival and success in the marketplace.

President Obama cited in his speech, at the Export-Import Bank's Annual Conference on March 11, 2010, that 20% of U.S. gross domestic product (GDP) is accounted by intellectual property, and nearly 40% of U.S. economic growth, i.e. new jobs. In 2006, the U.S. pharmaceutical industry had a total sector output of $626.6 billion, contributing $294.6 billion, or 2.2% of the U.S. Gross Domestic Product and through its direct sector employees paid $15 billion in total federal and Social security taxes. For an industry such as the pharmaceutical industry that produces tangible, consumer goods, patent protection provides investors with the incentive for investment and, with prudent management and legal enforcement of those patents, profits for reinvestment, high-paying, skilled jobs, and a source for tax revenue. As a result, in 2008, over 20% of pharmaceutical sales dollars in the U.S. were reinvested in research and development. Undermining this rights-based system through lax enforcement of existing rules, lowest-common-denominator, one-size-fits-all, multilateral treaties, or semantic legal work-arounds, jeopardizes the job creation inherent in the system.

Despite the economic downturn of late, the pharmaceutical industry maintained its scale of commitment to the discovery and development of new medicines by investing $65 billion in research and development in 2008 – twice the total budget of the National Institutes of Health, five times more than the average U.S. industry relative to sales, and ten times more than the average industry per employee (Congressional Budget Office, 2009). The Bureau of Labour Statistics (2007) projected that the biopharmaceutical industry will add 69,000 U. S. manufacturing jobs while manufacturing jobs will be lost in computer electronics (-158,000), motor vehicles (-153,000), machinery (-147,000) and most other industries.

We applaud President Obama for publicly recognizing in his radio and Internet address to the nation of August 1, 2009 that, "(i)nnovation has been essential to our prosperity in the

past, and it will be essential to our prosperity in the future" and in his January 22, 2010 Town Hall remarks in Elyria, Ohio that patents are essential to fostering innovation.

We also applaud the Administration's understanding of how innovation spurs job creation just like patents spur innovation. At his press conference of July 20, 2009, U.S. Commerce Secretary Gary Locke stated the Administration's support for the "strong protection for intellectual property" as a means to bring economic recovery to the country as well as significant social contributions.

Discovery (research) is, at best, serendipitous while innovation (development) is difficult and expensive; imitation is easy and cheap (see Figure 2). Intellectual property rights are essential to attracting, growing and retaining knowledge-based industries, the products that they export (nearly 35% of pharmaceuticals produced in the U.S. are exported), and the high-paying jobs of the future (Morris, Mowatt, Reekie & Tren, 2009). According to the United States Trade Representative in talking about the proposed Anti-Counterfeiting Trade Agreement (ACTA):

> "Expertise, innovation, quality and creativity are the main factors for success in knowledge-based economies. Adequate protection and enforcement of intellectual property rights is a key condition for nurturing those factors."

Figure 2

**The Discovery-Innovation-Patent-Employment Dynamic**

Inquiry → Discovery → Patent → Innovation → Commercialization → Jobs

**Pharmaceuticals and the Infringement of Intellectual Property Rights**

For the pharmaceutical industry, willful patent infringements take several forms including but not limited to counterfeit drugs, illegal generics, parallel trade, and compulsory licensing. When legal drug patents are infringed upon and not protected by government and the legal system then the incentive for investment is lost as are the profits, re-investments, jobs and tax revenues. Further, the public's safety is unnecessarily put at risk when illegal or counterfeit drugs are being prescribed and used.

Illegal counterfeiting of pharmaceuticals increased 660% from 2006 to 2007 according to U.S. Customs; 80% of counterfeit product originates in China followed by Pakistan, Egypt, Hong Kong and Taiwan. According to the U.S. Food and Drug Administration (FDA) and U.S. Customs, 88% of the imported pharmaceuticals that they have examined

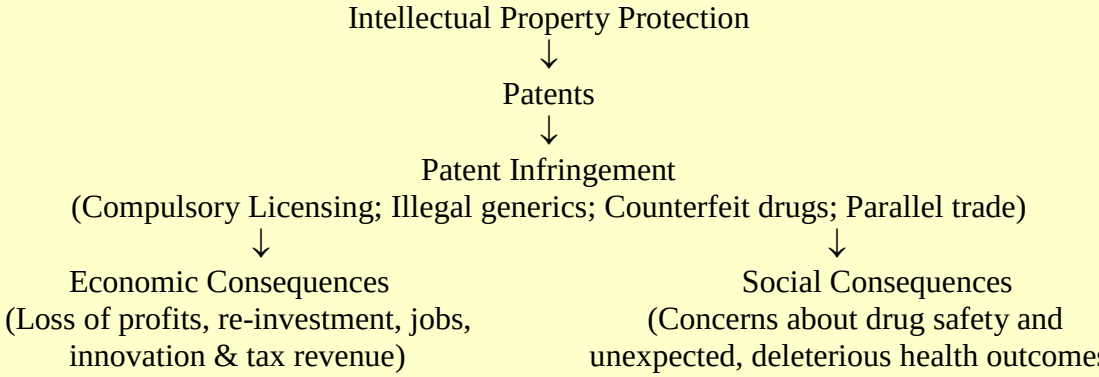
contained potentially harmful contaminants. Many lack the active ingredients that make a drug efficacious; others contain toxic ingredients. Approximately 700,000 people die annually in developing countries just from cheap, counterfeit malaria and tuberculosis drugs (Morris, 2009). Up to 30% of drugs sold in developing countries are counterfeit; two-thirds of which are unsafe.

According to the World Health Organization (WHO) about 1% of the pharmaceuticals sold in the U.S. are counterfeit. Half of Internet drug sales – especially generics - are counterfeit where the Internet pharmacy's address is not identified. These illegal generics are often substandard counterfeits of drugs that have no generic counterparts yet. Counterfeiting is cheaper than, yet as profitable as, the illegal trade in narcotics – with lesser criminal penalties.

The make-up, or characterization, of an illegal or counterfeit drug is not known, and health outcomes from using illegal or counterfeit drugs are unpredictable, such as increased drug resistance (up to 60%) amongst the target population as in the case of compulsory licensed HIV drugs in India and Thailand which may be imported into the United States via the Internet, or life-threatening immunogenicity from follow-on biologics (see Figure 3). According to the WHO, approximately 50% of all seized counterfeit drugs have been deemed unsafe. Unlike other products and industries many counterfeit drugs also infringe upon patent holders' rights. In short, drug patent infringement kills jobs and takes lives.

Figure 3

**The Patent Infringement-Job Loss Dynamic**




The pharmaceutical industry created the Pharmaceutical Security Institute (PSI) in response to this economic and health threat of counterfeiting that knows no national boundaries. The PSI works closely with the World Health Organization's International

Medical Products Ant-counterfeiting Taskforce (IMPACT) on strategies of both prevention and enforcement. The United States government needs to bring its law enforcement and intelligence resources to this battle to keep and grow high-paying, knowledge-based jobs in America.

The lucrative, fast-growing market segment of biologics has attracted a number of counterfeited "biogenerics". By definition there can be no generic version of a biologic, only a similar but not equivalent and non-interchangeable follow-on biologic which may or may not treat the same indications as the innovator product or as well. If approved by the FDA these become legal follow-on-biologics. There are dozens of biogeneric manufacturers in middle income countries such as China that do not follow Good Manufacturing Practices (GMP) and do not have stringent quality control standards. Given the data-intensive nature of regulatory approvals, protection against data disclosure and unfair commercial use of data is vital to incent research-based, innovator pharmaceutical companies to remain in the field of biologics. As biosimilar regulatory pathways are developed and implemented data protection laws and regulations must be upheld and patent terms extended, to compensate for the regulatory times required of biologics.

Generic drugs have an important and acknowledged role to play in reducing health care costs after patents have expired on drugs. There is a clear time and place for generics to enter the market. However, patent infringement complaints have been numerous by innovator companies against generic manufacturers marketing generic formulations of medicines still on patent. Most of these lawsuits are settled out-of-court in favour of the innovator firm. At the time of writing this submission, AstraZeneca filed two lawsuits in New Jersey against India-based Sun Pharma and its U.S. subsidiary for planning to market a generic version of AstraZeneca's intravenous acid reflux disease treatment, Nexium IV. The Federal Drug Administration (FDA) approved Nexium IV in 2005 and its U.S. patents are valid until 2014. Nexium is AstraZeneca's number one selling drug today with 2009 sales of $5 billion, nearly 60% of which was in the U.S. Previously, AstraZeneca had sued Indian drug makers Ranbaxy, Lupin and Dr. Reddy's as well as Israel's Teva Pharma for attempting to do the same thing.

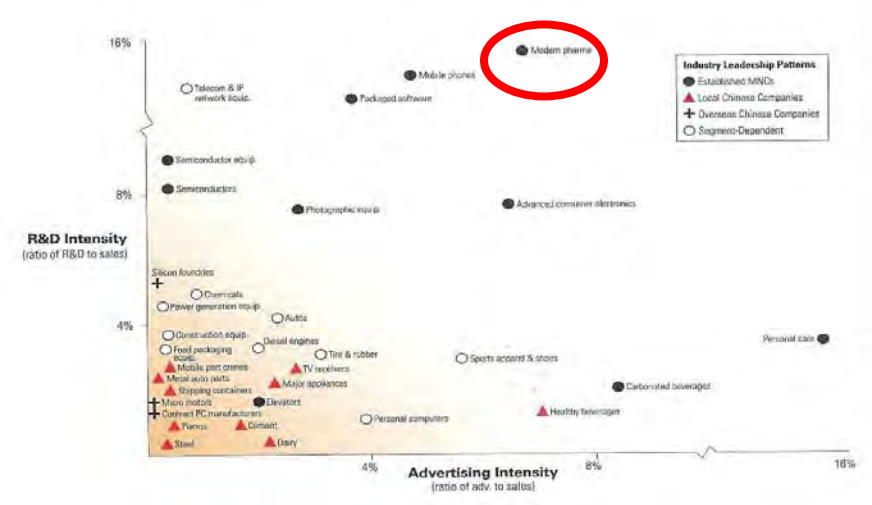
Pharmaceuticals, like most legal products, are sold globally using differential pricing – basically charging what each respective market can bear. This maximizes both the income for the firm as well as patient access to the drug around the world. Differential pricing is a win-win-win for risk-taking innovators, fiscally challenged payers, and patients in need of treatment. Parallel trade – the practical side of the combination of the art of human opportunism and the science of arbitrage - is sometimes referred to as re-importation or the gray market and is used by firms other than those holding patents. Gray market drugs are not counterfeit drugs, but rather are pharmaceuticals manufactured by the patent owner and sold into a foreign market. When these drugs are re-sold and re-imported back into the United States by the foreign buyer, or someone else, the patent holders' rights have been violated under the principle of "national exhaustion of intellectual property rights". Parallel traders rely upon the artifice of "international exhaustion" as giving them permission to resell product wherever they choose. Under

international exhaustion the patent-holding company loses, its investors lose, its workers lose, and its host country loses.

Compulsory licensing, when enacted illegally, is nothing short of piracy. The World Trade Organization (WTO) negotiated 25 years ago in the Uruguay Round its Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). In essence, TRIPS attempted to globally harmonize rights-based protection of intellectual property and the enforcement thereof. This included patents. However, "flexibilities" were written into the agreement – such as the compulsory licensing of pharmaceuticals. This "flexibility" allowed governments to issue a "compulsory licence" to a company, other than the innovator of the drug in question, to produce a patented drug, or use the patented process, under licence, provided that the legitimate interests of the patent holder were safeguarded. Numerous cases arose where compulsory licences were allegedly issued in middle income countries with total disregard for patent holders' rights. Often drugs – still under patent - produced under these "compulsory licences" were not used for the public health of the producer's domestic market but sold for a profit around the world.

Figure 4

**The Biopharmaceutical Industry is the Most Research-Intense**




Source: Harvard Business Review, November 2008, 84.

## The Vulnerability and Value of the Pharmaceutical Industry

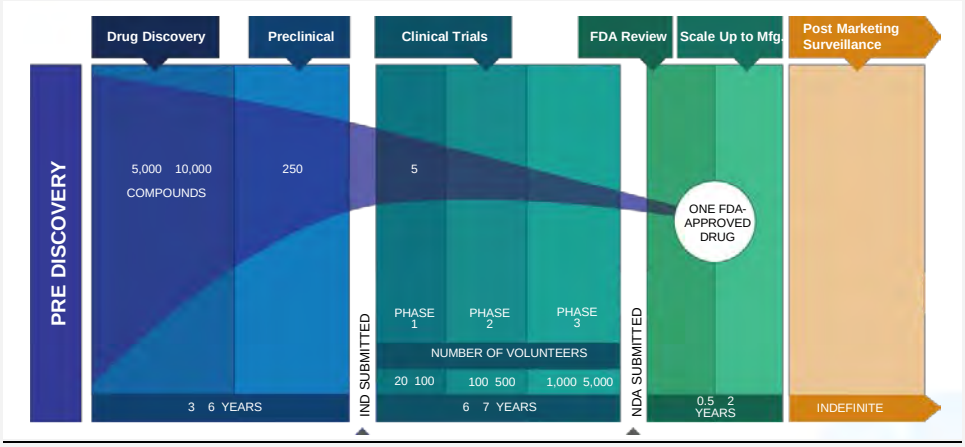
What makes the pharmaceutical industry particularly vulnerable to patent infringement is that it is the most research-dependent industry in the world with individual firms reliant upon research for their very survival (see Figure 4). Whether products are by prescription or over-the-counter, for human use or veterinary use, pharmaceuticals are

developed, produced and sold to either prevent or cure illness, or to provide a better quality of life for those with illnesses for which there is no prevention or cure as of it. Ironically, veterinary drugs and biologics are better protected in terms of intellectual property rights than human medicines thus stimulating innovation in that sector (Manheim, Granahan & Dow, 2006).

Over 700,000 substances will be studied over a 12 year period to yield one marketable, innovative, human drug. According to DiMasi and Grabowski (2007) on average, today, it takes $1.3 billion to bring a prescription drug to market, 90% of which never break-even to recoup all research and development costs thus requiring successful firms to rely upon a "portfolio" of products to realize its revenue needs (see Figures 5 & 6). Even some of these "portfolios" of drugs and biologics take 13-16 years to break-even, according to Grabowski (2007). Between $439 million and $615 million is spent during preclinical research (accounting for about one-third of pharmaceutical jobs) and $626 million to $879 is spent during clinical testing and regulatory phases (two-thirds of employment) – costs the latter of which are borne solely by the firm as documented by the Congressional Budget Office.

Figure 5

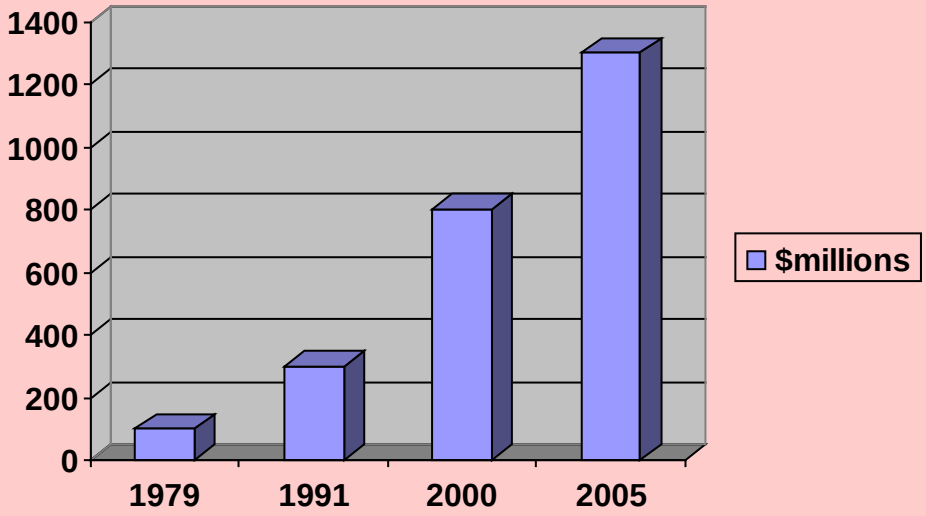
**New Pharmaceutical Product Development of 10-15 Years Versus Patent Life of 20 Years**




Source: Congressional Budget Office, 2006.

Figure 6

**$1.3 Billion to Get One Drug to Market**

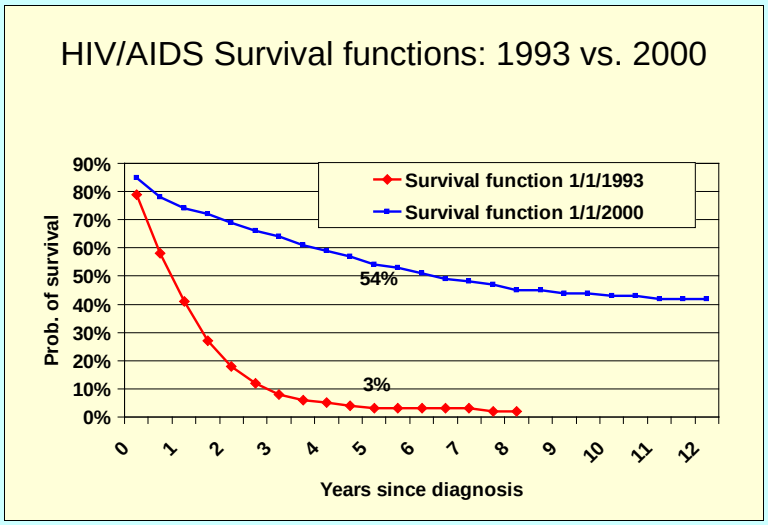



Source: DiMasi and Grabowski, *Managerial and Decision Economics* (2007).

Even though, generally speaking, university laboratory research is government funded and later product development is privately funded there has grown a very significant, job-creating, mutual dependence between universities and firms. Just over half of life science faculty members have some form of relationship with industry – and those faculty members, to the person, were more productive and innovative than faculty without industry support (Zinner et.al. 2009). Industry-assisted research also yields innovative products quicker than research isolated from the marketplace thus getting medicines out to the public faster. The National Institutes of Health (NIH) cannot fund all of the research needed by society therefore the well-being of the pharmaceutical industry is closely tied to the quantity and quality of academic life science research in America.

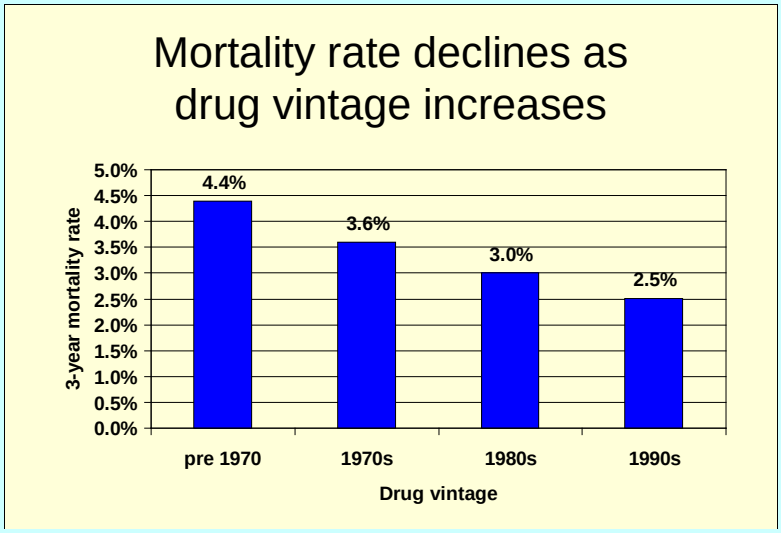
The value of medicines is self-evident. The significant reduction in the mortality due to and morbidity associated with HIV/AIDS, cancer, hypertension, heart disease – just to name a few – due to the greater availability and utilization of newer and better drugs over the past few decades is dramatic (see Figures 7 & 8). Likewise, has been the reduction in costly hospital and nursing home admissions (Cutler 2007). Yet, prescription drugs represented a declining share of health care cost growth from 1998-2006 (National Health Expenditure Accounts, 2007).

Figure 7




Source: Lichtenberg, 2003.

Figure 8




Source: Lichtenberg 2004.

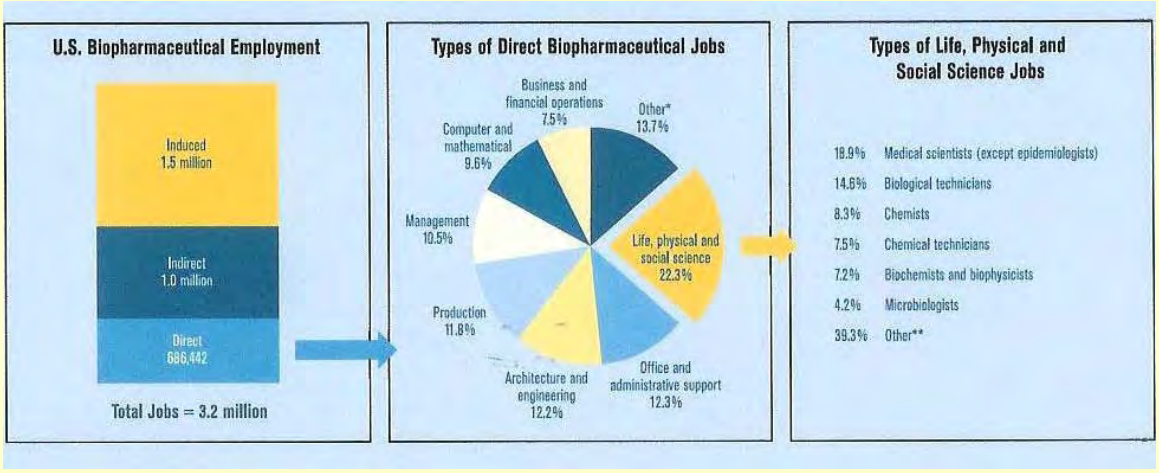
According to a study conducted by Archstone Consulting in 2009 (see Figure 9) the research-based biopharmaceutical industry provides nearly 700,000 jobs directly, and over 3 million jobs indirectly and induced – a multiplier of 4.3 (as compared to a multiplier of ~1.0 for government spending.) Employment growth in the biopharmaceutical industry has been twice that of other industries. If patent infringements are allowed to be continued then hundreds if not thousands of direct high-quality jobs could be lost as well as four times as many indirect and induced jobs.

Nearly 3,000 compounds are currently under development in the U.S. – a 50% increase over a decade ago, and twice that of the rest of all other countries combined. Employment within the pharmaceutical industry, whether scientific, production, marketing or administrative, is divided amongst four segments: small molecule drugs, which comprise 80% or so of the jobs in the industry; large molecule biologics, the fastest growing segment of the industry expanding at twice the rate of small molecule drugs (Grabowski, Cockburn & Long, 2006) and accounting for over 25% of domestic biopharmaceutical research dollars; diagnostics and other chemical and biological screening agents; and the inputs segment of chemicals and biological materials to be further processed into end products.

Patents are integral to the business success of and continued employment in all four segments of the industry but, increasingly, data protection and data and market exclusivity are two other rights that must be protected to help ensure the success of the rapidly growing and extremely high-risk large molecule biologics segment – the future of vaccines, cures, and life-extension therapies that has propelled the United States way

Figure 9

**Direct, Indirect and Induced U.S. Biopharmaceutical Employment, 2006**



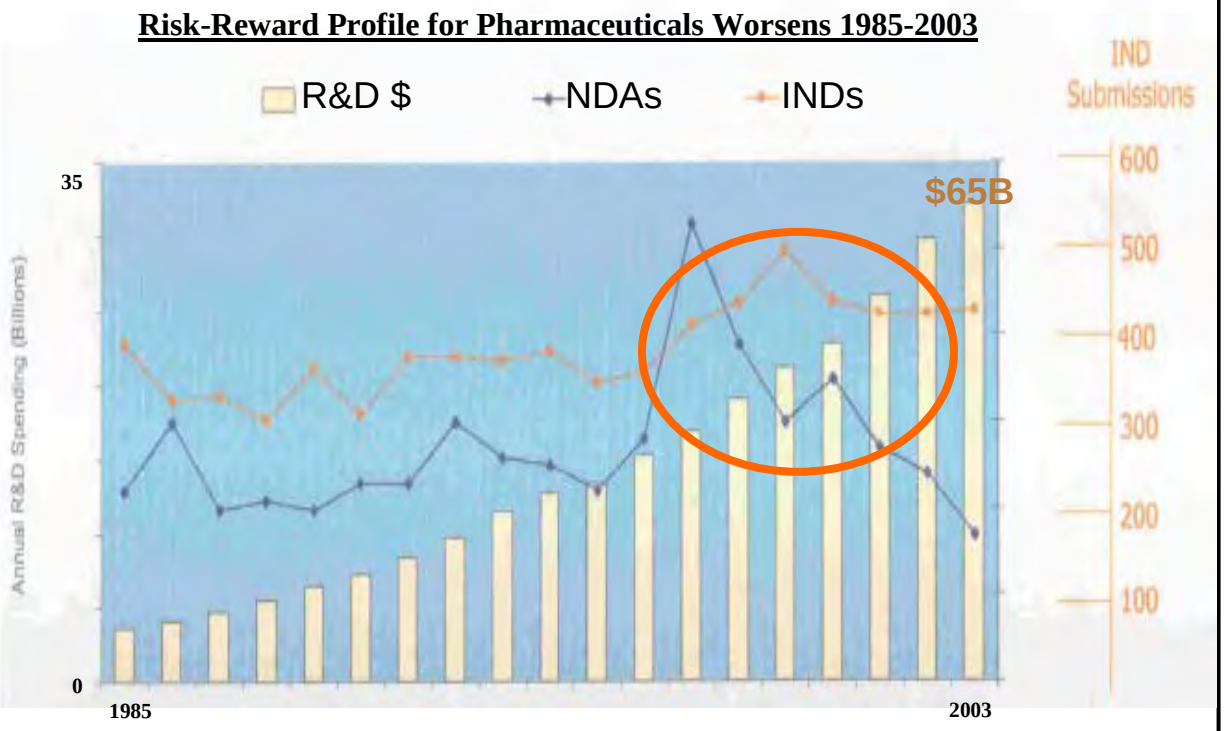

Source: Archstone Consulting, 2009

ahead of Europe in pharmaceutical research and development productivity, innovation and first in-class, global, product launches (Grabowski and Wang, 2006).

Patents may have expired by the time an innovator's biologic comes to market, or may just cover process and not product. Data protection and data/market exclusivity provide certainty for re-investment in this whole new world of biologics with its extended development times and capital needs. Currently the United States accounts for 85% of all research and development spending world-wide in biotechnology and 60% of the jobs in this field (Burrill and Company, 2008).

As the baby boomers age, 46 million more Americans are projected to have at least one chronic condition in 2030 than in 2000 (Anderson 2007). As the pharmaceutical industry evolves from treating acute illness to treating chronic and degenerative diseases, the funds required to develop one efficacious and effective therapeutic product grows each year as the number of products that safely make it to market declines (see Figure 10). Yet the need remains and the potential benefits are huge. It has been estimated that up to 60% of the increase in cancer survival rates had been due to drugs (Lichtenberg 2004). Another reduction of the cancer death rate by 10% would yield roughly $4.4 trillion in economic value to America (Murphy & Topel, 2003).

Figure 10




Source: Pfizer

But each incremental advance becomes costlier than the last. That is why the year-over-year increase in research and development costs exceeds consumer price inflation by about four-fold (DiMasi, Hansen & Grabowski, 2003). Internal rates of return for innovator drug companies are near their cost-of-capital. Return on equity is below average for pharmaceuticals from among the top 20 U.S. industries; return on investment placed pharmaceuticals 41st amongst 46 industries (Fortune Magazine, 5/5/08). Sustained profitability for this industry is questionable in a marketplace where intellectual property rights are not respected and protected; and where there are no profits, there are no jobs. Scherer (2000) has documented that investment in research and development is directly proportional to profitability. As the risk-reward profile worsens for the industry the very need for – if not expansion of – a rights-based intellectual property system increases even more if firms are to survive and continue creating medical breakthroughs and employing thousands of Americans in the process.

Every life-saving and life-giving drug marketed anywhere in the world today has been produced by the private pharmaceutical industry. Successful pharmaceutical innovation has been based upon three pillars:

- Sufficient research capacity, both in terms of capital and human resources, to initiate the quest for innovative therapies;
- An efficient means by which to transfer basic research from laboratories into the hands of those who can further develop it; and
- A sound and strong intellectual property system to incent the risk-taking required to develop these products.

**Pirates, Speculators, Dictators and Terrorists**

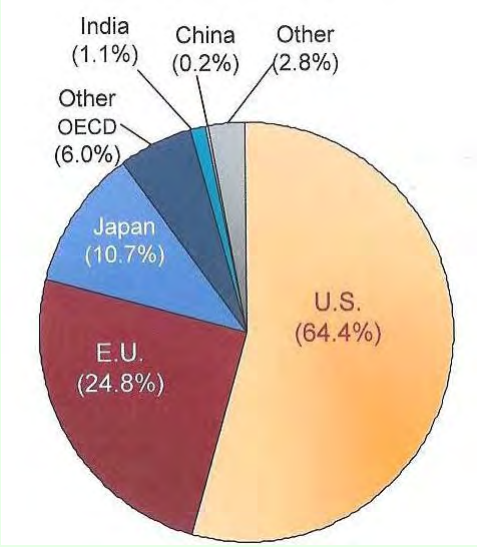
Healthcare as it is today would not exist if it were not for the discovery and innovation driven by this industry, which is only able to do so because its work is protected under the existing rights-based intellectual property system. Historically, the United States has had a very strong, rights-based, intellectual property regime. As a result, two-thirds of the intellectual property associated with new medicines (1990-2002) belongs to Americans (see Figure 11) because the value-chain of research-development-intellectual property protection has been kept relatively intact. In a century where the need for pharmaceutical advances remains urgent and where the cost and time required for innovation both grow, rather than strengthening rights-based, intellectual property protection, the very intellectual property system that has given the world all medical advances is under attack around the world.

Why? *Cui bono?* Who benefits from weakened patent protection, compulsory licensing and all other attacks on intellectual property? Commercial pirates and speculators, whether they be individuals, firms, or other governments and their agents – that's who. Neither invests any money in research, development, job creation or technology. They simply buy and sell product or company shares in a gray market for their own profit. Speculators and pirates thrive when there is market uncertainty, economic fear and the

absence of the rule-of-law. Strictly enforced, rights-base intellectual property laws protect investors, workers and consumers from unfair commercial practices. In the post-TRIPS world, enforcement of existing rules is almost non-existent world-wide, and one of the most at-risk industries - given its huge investment in research and need to protect its data - is pharmaceuticals (Kur, 2009). China, with its 5,000 generic drug manufacturers, allegedly, is the worst violator of intellectual property rights.

Figure 11

**Pharmaceutical Patents (1990-2002) by Country of Innovation**




Source: PhRMA

Pirates and speculators aside, does American protection of American jobs through the enforcement of intellectual property rights harm other countries less able to look after themselves? No it does not; on the contrary (Attaran, 2004). Of the drugs appearing on the World Health Organization's Essential Medicines List, 98.6% are off-patent making them very affordable to all (and even those patents are only used in middle income countries). Only the private pharmaceutical companies are engaged in developing drugs for diseases, such as malaria, tuberculosis and dengue fever, which ravage developing countries. In fact, contrary to what critics of the industry would have the world believe, currently over 100 medicines and vaccines are in development to treat diseases of the developing world (WHO/UNICEF/UNDP/World Bank, 2007). Even Uganda's President Yoweri Museveni, who presided over the world's largest reduction in HIV/AIDS prevalence, has declared that the whole essential medicines argument against patents is a red herring perpetrated by those named above and others. Also, over 400 public-private

partnerships have been very successful at greatly stimulating the research, development, commercialization and distribution of much needed drugs to many patients all over the world who otherwise would not have been treated or cured due to a lack of market potential. According to the Organization for Economic Co-operation and Development (OECD) pharmaceutical companies punch way above their weight in the field of international development assistance contributing over 10% of all monies donated (OECD 2008). From 2000-2006 the research-based pharmaceutical industry made available to developing countries more than 1.3 billion health interventions valued at $6.7 billion.

The real issues confronting public health in developing countries is the lack of potable water for one-third of the world's inhabitants (two-thirds by 2025) as well as the lack of freedom and infrastructure to allow medicines – even if they existed - to be distributed and administered to those who need them. The real barriers to improving the health of the developing nations are barriers that the WHO, World Health Assembly and United Nations continue to ignore: money, power, politics and ideologies. Even if new drugs are commercialized to combat the diseases that plague the developing nations they will be no more effective than existing drugs for other diseases that are not reaching those who need them most, not because of patents or industry location, but because military dictatorships and pseudo-democratic governments (where they pretend to exist) either stockpile them for the elites, sell them on the black market at prices well beyond what was intended, or sell them abroad. Even in situations that exist where the little that can get through to the neediest will get through without interference, there is often inadequate infrastructure, human resources, and transport available to facilitate the timely delivery and use of dated product – even when the price for a product is zero.

As Danzon and Furukawa concluded (2004), drug price differentials among countries roughly reflect income differences as do food prices and prices for consumer electronics. Patents have next to nothing to do with it as speculators and pirates would have you believe. But patents have everything to do with the number of knowledge-based jobs in a country.

Lastly, the unspeakable: how the world of discovery, innovation and progress was turned upside down on September 11, 2001. Never before has the threat of bioterrorism been more real. Only because of the vigilance of the United States and its allies has a serious bioterrorist attack not occurred. Yet the potential for such an atrocity is high if chemical and biological compounds used in the manufacture of pharmaceuticals are not closely protected through a system of secure intellectual property rights and government enforcement of same. Intellectual property protection never played a greater role in global security than now.

## Conclusion

Access to medicines and innovation are not and cannot be mutually exclusive; without access, innovation is meaningless; without innovation, there is nothing to access. The only significant progress that has been made in health care lately has been made in medicine due to five decades of costly pharmaceutical research (Kleinke 2001).

The symmetry amongst innovation, free markets, protection of intellectual property, and democratic societies is no mistake. Patents and other forms of intellectual property protection are just simple, albeit very powerful, devices by which innovation is optimally incented in free societies. It is no accident that the lion's share of the world's innovativeness comes from democratic stalwarts like the United States, Canada and the United Kingdom. And the key to this success has been private property – in this case, patents and other protective devices. Disregard for the protection of intellectual property creates a very real threat to economic growth, jobs creation, and the public welfare – in short, America's competitiveness and well-being.

The United States is the last true and largest free market where medical progress still exists. Threats to intellectual property and medical innovation are unconstructive and not in the nation's best interests. American genius alone is not enough – there must be the potential for return. As President Abraham Lincoln recognized 150 years ago, in words chiseled into the Commerce Building in Washington, D.C.:

> "The patent system added the fuel of interest to the fire of genius."

The Cameron Institute is an alternative, not-for-profit, public policy think tank specializing in the independent study of health, social, and economic issues current in Canada and internationally. The Institute recognizes policy concerns in the health world related to the need for balance between patient safety and access to new, innovative, affordable therapies. It is an objective of the Cameron Institute to provide government decision makers with analyses that will help inform choices. The Institute is also dedicated to educating and better preparing patients, providers, and payers to make appropriate clinical choices.

Dr. D. Wayne Taylor has worked as an executive in the private sector, as a senior civil servant, as a political assistant, and is the Director Emeritus of the Graduate Programme in Health Services Management at McMaster University. He remains a tenured faculty member while serving as the Executive Director of The Cameron Institute and as president of his own private international consultancy.