International Roundtable on Trade and Competition Policy

IMPROVING U.S. COMPETITIVENESS; ELIMINATING ANTI-COMPETITIVE MARKET DISTORTIONS

1. Introduction

This paper examines what we believe to be a major challenge in global trade and the ability of the U.S. economy to grow. We believe the issues discussed in this paper constitute a national economic security issue and, if not dealt with, an existential threat to the United States. These issues have been variously described as state capitalism, regulatory protection and state-led economic development. We examine these issues under a more economic-focused paradigm - anti-competitive market distortions ("ACMDs").

2. Attempts to Boost American Economic Competitiveness

In January 2010, the President called for a doubling of U.S. exports in his State of the Union address announcing the National Export Initiative ("NEI"). We discuss the initiative as well as other attempts to boost American economic competitiveness, and how these efforts might be undercut if we do nothing about the threat of ACMDs.

The NEI mandate is a weighty and significant one. As many commentators have noted, it will not be easy to deliver a doubling of U.S. exports, particularly in the current economic climate. As noted in a report by the Alliance for Healthcare Competitiveness, "In 2010, America's exports of goods and services rose by 17 percent; or, in dollar terms, by $265 billion, to a total of $1.84 trillion.[1] In dollar figures this was the largest increase in history. In percentage terms, it was the fastest burst of real-dollar growth since 1987. Exports added 1.3 percent to GDP growth - essentially half of the 2.8 percent total GDP growth. This was the largest export contribution to growth since 1946, and the second-highest recorded since the United States began tallying GDP figures in 1929. But even if

[1] Bureau of the Census, *U.S. International Trade in Goods and Services (FT900)*, December 2010.

exporters match this $265 billion in each of the next four years, the U.S. will still fall short. To double exports will require not $265 billion but $310 billion in export growth in 2011, in 2012, in 2013, and again in 2014."[2]

Thus far, the NEI has demonstrated some potential, despite the crumbling economic climate. Section 1 of the Executive Order that launched the National Export Initiative notes that "remaining trade barriers abroad" was a priority for the Obama administration. As tariffs have come down, many of those trade barriers take the form of behind the border barriers, regulatory protection and ACMD's.

After nine months of the NEI, the Export Promotion Cabinet reported to the President on the NEI and its goals. The report highlights the Administration's drive to remove trade barriers, but does not talk much about anything beyond narrow market access. We believe there is an opportunity to expand the scope beyond narrow market access issues to cover the persistent trade barriers that prevail today. The Report also highlights the "market access" difficulties faced by U.S. companies in the BRICs and other big emerging markets which will be critical to the success of the NEI. All indications are that many ACMDs are on the rise in the BRICs and elsewhere. The Report does address the issues of trade-related regulatory and infrastructure issues (specifically including corporate tax policy, VAT policies in other countries, and R&D tax credits).

The NEI Report notes that the Administration should focus trade promotion efforts on important sectors of the economy with export potential. It cites healthcare technology, biotechnology and medical devices. The NEI Report also noted that protection of intellectual property (specifically patents) was critical for U.S. companies "seeking to secure intangible assets associated with products and services in foreign markets with confidence that their ideas and innovations will not be misappropriated;" [3] Under Priority 6: Macroeconomic Rebalancing, [4]

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[2] America's Health Ecosystem in the Emerging Global Health Market; A Unique Opportunity for Growth, Employment and Better Health, Alliance for HealthCare Competitiveness, Sep. 26, 2011.

[3] National Export Initiative, Export Promotion Cabinet, *Report to the President on the National Export Initiative: The Export Promotion Cabinet's Plan for Doubling U.S. Exports in Five Years*, Sec. I(9)(d), September 2010.

[4] *Id.* at § II(6).

reference is made to foreign countries with trade surpluses doing more to increase domestic demand, which will assist with global imbalance. Domestic demand will be more rapidly increased by eliminating domestic market distortions, and enhancing consumer welfare (this will increase efficiency, lower prices and allow consumer spending to go farther). Priority 7 of the Report deals with reducing barriers to trade, and includes work on non-tariff barriers to trade. This priority is to be commended and built upon.

To achieve this goal will require a substantial re-thinking of trade policy, and trade missions will need to be augmented by crafting a trade policy that more completely deals with the barriers that U.S. exporters actually face now. While the NEI goal is laudable and prioritization of the Administration's attention on it is a very important element of the Obama administration's trade policy, difficult steps need to be taken to break down barriers to U.S. exports. The Alliance for Healthcare Competitiveness notes that "Adding export promotion staff in embassies will not be enough; nor will negotiating agreements with small countries. Instead, trade policy as a whole will have to focus on those sectors of the American economy that can make the most meaningful contributions on a large scale and which satisfy the following criteria:

(a) Domestic production and employment on a very large scale;

(b) Technical excellence and capacity to compete and win worldwide; and

(c) Opportunity to serve a large, rapidly growing global market.[5]

We would add that this new trade policy must be shaped by the particular issues that afflict industries that constitute the U.S.'s comparative and competitive advantage.

In addition, this will also require some reinvention of the U.S. government around the notion of the new global economy – which is one of competing global supply chains.

[5] *See* n.2 *supra* at 3.

3. Growing U.S. Exports

3.1 Composition of U.S. Exports

The U.S. has much to gain from this expansion of exports. However, the gains will not be equally spread among all sectors of the economy. There will be more significant gains in the areas where the U.S. has a comparative advantage. This comparative advantage exists in advanced manufacturing and services, which rely on intellectual property protection. The ability to leverage and achieve those gains will depend on how well these different platforms protected by intellectual property can compete in global markets. This in turn will depend on how well intellectual property is protected around the world. In addition to intellectual property issues, new technologies are also prone to technical barriers to trade as well as the use of standards policy to cripple the ability of these new technologies to gain both market access and market contestability. These new technologies are also prone to a range of other government distortions, which are used to secure advantages for competitor firms, and national champions.

It is well known that export jobs tend to support higher wages than domestic industry jobs. In addition, jobs in the high tech/IP space tend to support even higher wage levels. The following table illustrates that jobs in these sectors are some of the highest paying U.S. jobs.

TABLE 1: Annual Average Wages Per Employee By Sector

Top 5 by Sectors

IP-Intensive

Information software	$110,052
Petroleum, coal products	$70,855
Communications equipment	$70,036
Pharmaceuticals, medicines	$69,689
Navigational, electromedical	$63,667

Bottom 5 by Sectors

Non-IP-Intensive

Textiles, apparel, leather	$26,695
Furniture	$30,625
Wood products	$30,816
Food, beverage, tobacco	$33,444
Plastics, rubber products	$35,602

According to the Alliance for Healthcare Competitiveness,

"In particular, in terms of research and development investments, the healthcare sector, including medical, medical devices and the biopharmaceutical sector accounts for $24 billion of the U.S.'s $56 billion in private sector research.[6] American research universities, as well as public labs like NIH and CDC, dominate the world's public investment in life-science and medical research, with university medical research accounting for 33 percent of all academic R&D - a higher fraction than any other country in the world. In total, American health and medical research accounts for almost ten percent of the $1.15 trillion in global R&D spending.[7]"[8]

The figures are even starker when it comes to R&D spending as a percentage of exports. The table below (Table 2)[9] shows that 96.3 percent of pharmaceutical and medicine exports are R&D. The next highest is 79.3 percent for communication equipment, and after that 38.5 percent for miscellaneous medical equipment. By contrast non-IP intensive industries and R&D as a percentage of exports at 8 percent.

[6] Bureau of Labor Statistics, *Occupational Employment and Wages Release,* May 2011.

[7] OECD, *Science and Engineering Indicators 2010*, at http://www.oecd.org/document/36/0,3343,en_2649_33703_41546660_1_1_1_1,00.html

[8] See FN2 at p.4

[9] Table 2 is taken from Table 7, The impact of Innovation and the Role of Intellectual Property, Competitiveness, Jobs, Wages and Exports, Nam D. Pham, (Apr. 2010) (published by NDP Consulting).

TABLE 2: Annual Average R&D Expenditure per Employee, by Industry, 2000-2007

	R&D ($ millions)	Employment (persons)	R&D Per Employee ($)
All Tradable Industries	**$144,987**	**14,759,400**	**$9,956**
IP-Intensive	**$122,945**	**4,475,166**	**$27,839**
Petroleum, coal products	1,370	102,942	13,319
Chemicals	33,113	832,073	40,341
Basic chemicals	2,161	171,640	12,687
Resin, synthetic rubber, fibers	2,208	97,566	22,416
Pharmaceuticals, medicines	25,718	241,994	105,428
Computer, electronic products	42,043	1,238,549	34,978
Computers, peripheral equipment	4,834	144,205	38,552
Communications equipment	11,722	186,822	62,992
Semiconductor	15,556	435,562	37,980
Navigational, electro-medical	9,121	412,984	22,262
Transportation equipment	25,851	1,658,753	15,693
Motor vehicles, trailers	16,337	1,042,386	15,704
Aerospace products	8,384	403,496	21,162
Miscellaneous medical equipment	4,870	307,356	15,889
Information software	15,698	335,493	46,772
Non-IP-Intensive	**$22,042**	**10,284,229**	**$2,164**
Food, beverage, tobacco	2,519	1,625,869	1,551
Textiles, apparel, leather	480	789,043	702
Wood products	165	551,000	300
Paper, printing, support activities	2,630	1,182,400	2,238
Plastics, rubber products	1,884	934,068	2,027
Nonmetallic mineral products	804	485,865	1,652
Primary metals	612	493,207	1,273
Fabricated metal products	1,446	1,602,107	903
Machinery	7,488	1,183,201	6,411
Electrical equipment, appliances	2,728	477,381	5,663

Furniture	359	570,384	640
Misc non-medical equipment	928	389,705	2,415

High-tech, advanced manufacturing is also in the sweet spot for a major expansion of U.S. exports as developing countries import more and millions of people are added to their middle classes since these types of products are more in demand for these new middle classes. China and India are adding tens of millions of people to their middle classes each year. These new populations have consumption patterns that increasingly demand more and more advanced manufacturing and high technology products. Table 3, drawn from the Alliance for Healthcare Competiveness' White Paper, demonstrates how changing global demographics will drive this trend.

Table 3: Twenty Years to an Urban, Middle-Class, Aging World[10]

	2010	2030	Change
Global Middle Class	1.7 billion	4 billion	135%
Population above 60	0.7 billion	1.4 billion	100%
Urban Population	3.5 billion	4.9 billion	40%
Total Population	7.0 billion	8.3 billion	19%
Population below 15	1.8 billion	1.8 billion	0%
Global Poor*	1.0 billion?	~0.5 billion>	-50%

**Population earning $6,000 to $30,000 per year.*
*** Population below $1.25 per day, in constant 2005 dollars.*

Finally, intellectual property based industries support a large number of direct and indirect jobs. In particular, the biopharmaceutical sector accounts for more than 4 million jobs in the U.S. economy (total including 674,000 direct jobs and an additional 3.4 million indirect and induced jobs in 2009). Together, this biopharmaceutical sector-related workforce received $258 billion in wages and benefits in 2009 (see Table 4).

[10] See n.2 at 8 (*citing* UN Department of Economic and Social Affair, Population Tables, at http://esa.un.org/unpp/index.asp?panel=2).

Table 4: Economic Impacts of the U.S. Biopharmaceutical Sector, 2009

	Total Impacts		
Industry	**Employment**	**Wages, U.S.$B**	**Output, U.S.$B**
Direct Effect	674,192	$80	$382.4
Indirect Impacts	1,403,511	$92.1	$261.6
Induced Impacts	1,935,738	$85.9	$273.8
Total Impact	4,013,441	$258.0	$917.8
Impact Multiplier	5.95	3.22	2.40

Sources: Battelle report on "Economic Contribution to the Nation", Battelle Technology Partnership Practice (Jul. 2011).

3.2 Breakdown of High Value U.S. Exports

Before looking at U.S. exports, and how they are broken down by sector, , it is worth exploring how the U.S. gained this enviable position of dominance among high tech sectors. There are two important stories here. One relates to the development of the software industry as a whole, and the other relates to the development of the U.S. biopharmaceutical industries. The first involved the development of an entirely new industry; the second involved the shifting of the centers of research for a well-established industry that had long and deep European roots. Both make different but very important points.

In the first case, the software industry in the U.S. really took off in the 1970s as a result, among other things, of the ability of software producers to protect the expression of their ideas through copyright. Famously, in that decade, there was a debate among software developers as to whether their products should be "open" or protected by intellectual property protection.[11] The evolution of the U.S. software industry generally reflects the combination of rapid technological changes, together with the intensification of supplier competition brought about by heightened demand for new software products and services.

[11] Carl F. Cargill, "Evolution and Revolution in Computer Systems," *StandardView*, Vol. II, No. 1, p4, March 1994, available at http://www.cib.espol.edu.ec/Digipath/D_Papers/44476.pdf.

Regulatory changes, threat of legal action and government measures have also stimulated the creation of the U.S. software industry. These changes include:

1. Statutory recognition of software as a copyrightable work; and

2. Federal government research and development funding of defense related software.

3.3 Statutory Recognition of Software as Copyrightable Work

The principal vehicle for software-related intellectual property protection traditionally has been copyright.[12] The first software copyright was issued by the U.S. copyright office in 1964.

Since the 1970's, statutory recognition of software as a copyrightable work[13] has offered an automatic, low cost mechanism to software developers to protect their programs from improper adaptation or theft. Intellectual property protection for the underlying raw material of the industry was one of the primary drivers for that industry's growth. Indeed in the 1970s there was a debate between those who advocated for intellectual property protection and those who put a premium on free access to software so that the community could benefit from and build on it (not unlike today's movement for open systems, creative commons and open source).

3.4 Federal Government Research and Development Funding of Defense Related Software

The federal government's policy during the post war period highly influenced the computer software industry.[14] The software industry received considerable

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[12] Office of Industries, U.S. International Trade Commission, "Global Competitiveness of the U.S. Computer Software and Service Industries." June 1995.

[13] The *Computer Software Copyright Act of 1980* amended the 1976 Copyright Act concerning software. In the 1976 general revision of the copyright law, Congress was unable to agree on the proper scope or application of copyright law to computer programs. Accordingly, Congress legislated, in Section 117 of the 1976 Copyright Act, that the state of the law on copyrightability of computer programs would be preserved as it was on December 31, 1977. At the same time, Congress formed the CONTU Commission to make recommendations for copyright legislation on various computer-related matters. Congress enacted legislation recommended in the CONTU Final Report several years later with one exception.

[14] Subah A. AL-Zayani, "Software: A Historic View of its Development as a Product and an Industry" CSIS 550, 04/26/2001 found at:

federal research and development funding throughout the post war for cold war defense, especially strategic air defense. The funding of the defense-related software created an infrastructure that supported the new areas of R&D, training and technology development.

During the early years of the post war period, private industries had been responsible for a great deal of innovation in software. By the 1960s, the industrial innovations drew on research and manpower that had been supported by federal government funds. Direct "spillovers" from defense-related support appeared. These "spillovers" were widely adopted civilian versions of software developed initially for military applications. Advances from the private sector supplemented them. Universities also received federal funding and developed several important programming languages and operating systems.
These types of generalized research and development spending are much less likely to cause consumer welfare damage than R&D spending that is more focused on a particular entity or technology. R&D spending that is technology neutral and more general is less likely to be market damaging.

3.5 Development of Biopharmaceutical Industry in the United States

In the pharmaceutical area, research began in the seventeenth century, with Merck as an old apothecary shop in 1664. Europe was the unquestioned center of research and development for centuries, challenged only by Japan in the post war period. However, regulatory changes in the U.S., specifically regulatory changes brought about by patent legislation and also by court cases started to attract research and development into the U.S. In 1980, Congress passed the Stevenson-Wydler Technology Innovation Act which facilitated the transfer of technology from the federal government to private institutions. Also in 1980, the Bayh-Dole Act allowed universities and businesses operating under federal research contracts to have exclusive rights to their intellectual property. This caused industry and academia to collaborate much more closely. The impact of Bayh-Dole led to the growth of business sponsorship of university research by 74 percent from 1980 and 1985.[15]

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http://www.computinghistorymuseum.org/teaching/papers/research/software_historic_view_of_its_development_Alzayani.pdf

[15] See U.S. General Accountability Office, "Patent Policy; Recent Changes in Federal Law Considered Beneficial"; RCED 87-44, April 87, 3.

Coupled with the Supreme Court decision in Diamond v Chakrabarty,[16] which allowed bio-organisms to be patentable, these measures gave birth to an entirely new sub-division of the pharmaceutical industry, the biotechnology industry. The Drug Price Competition and Patent Term Restoration Act of 1984 extended intellectual property coverage by taking into consideration that considerable patent time could be lost if there were delays in the application process. Attention was also paid to expediting the drug review process, culminating in the Prescription Drug User Fee Act ("PDUFA") (which allowed the FDA to collect fees from industry that could then be used to expedite the drug review process). The medical device industry also received a boost from the 1976 Medical Device Amendments to the Federal Food, Drug and Cosmetic Act creating a class of products called medical devices subject to a different and more straightforward inspection system procedure than drugs.

Meantime in Europe, research firms were struggling with a combination of increased regulatory requirements and cost, reimbursement delays, and price controls. Inevitability these cost increases damaged the ability of European research firms to match their American rivals and research funds shifted across the Atlantic. A study by the Milken Institute shows that in 1990 the global research-based pharmaceutical industry invested 50 percent more in Europe than in the U.S., but by 2006 this had been reversed, and investment in the U.S. was 40 percent higher than in Europe.[17]

The Milken Institute recently released a study which included an analysis of New Chemical Entities (NCEs) produced by headquarter country of inventing firm.

Table 5: New chemical entities
By headquarter country of inventing firm

	1971-1980		**1981-1990**		**1991-2000**		**2001-2010**	
Country	**NCEs**	**% total**	**NCEs**	**% total**	**NCEs**	**% total**	**NCEs**	**% total**
U.S.	157	31	145	32	75	42	111	57

[16] 447 U.S. 303 (1980).

[17] European Federation of Pharmaceutical Industries and Associations, "The Research Based Pharmaceutical Industry; A Key Actor for a Healthy Europe," 2006

France	98	19	37	8	10	6	11	6
Germany	96	20	67	15	24	13	12	6
Japan	75	15	130	29	16	9	18	9
Switzerland	53	10	48	11	26	14	26	13
U.K.	29	6	29	6	29	16	16	8
Total NCEs	508		456		180		194	

However, these numbers underestimate the importance of the U.S. as many of the Swiss companies have moved much of their innovation to the U.S. Examples include the fact that Novartis establishing its research hub in Cambridge, Mass. Roche acquired a majority stake in Genentech in 1990 (Genentech was the company that started the biotech boom in the U.S. in 1976). Sanofi acquired Cambridge-based Genzyme in February, 2011 elevating the Swiss firm's NCE discoveries. In the last decade, while the U.S. had 111 NCEs discovered, Switzerland-headquartered companies were second with 26. This means that actual NCEs discovered that had a significant U.S. nexus for research and development is much higher than the 57 percent of total NCEs discovered, perhaps closer to 65 percent. One other point worth noting from Fig 1 is the reduction in overall NCEs discovered from the decade of the 1980s to now. The U.S. has the vast majority of clinical trials. A similar trend has taken place for medical devices.

Another pioneering move by the U.S. was the research and development tax credit. However other OECD countries have overtaken the U.S. now in terms of the size of the tax credit. The U.S. is now ranked 17th out of 21 OECD member countries, in terms of the magnitude of its R&D tax credit. Corporate income tax rates also are a factor considered by firms in determining where firms locate their production facilities, and here again OECD countries have generally surpassed the U.S. in lowering its overall corporate tax rate. In fact the U.S. corporate tax rate is now the second highest across all OECD countries. The U.S.' federal and state average is 39.2 percent, as compared to an OECD average of 47.2 percent in 1981 and 25.4 percent in 2011. Indeed, even France (34.4 percent) and China (25 percent in 2011) have lower overall corporate tax rates than the U.S. Here again, the pattern is the same. The U.S. started out as a market leader (in the early 1980s) and gradually has been overtaking by other OECD and some non-OECD countries.

Another important factor is the pace of regulatory approvals. Here again a similar pattern emerges. U.S. FDA and other regulatory processes were broadly as expeditious as other OECD members, but have recently slowed in comparison. Clinical trials take much longer than has historically been the case, and the FDA has become much more risk averse in its own process. While the FDA has slowed down in its overall drug approval process (17.8 months average in 2008), the European Medical Agency has speeded up to 15.8 months in the same period. In medical devices, the EMA takes half as long in some cases to grant approvals than the FDA.

Another reason the U.S. has been able to accelerate its development as a research hub is that there is much more access in the U.S. to venture and risk capital. The U.S. captured 68 percent of total global venture capital in life sciences (out of a global $8bn). Part of this is because of the regulatory structure which allows and encourages flows of funds, and part of this is because the rewards (derived from a strong patent environment) stimulate investment and capital flows.[18] When S. Korea improved its patent environment, venture capital increased dramatically.[19]

U.S. immigration policy from the 1980s also encouraged highly skilled, technical workers such as scientists to work on extended visa programs. However the size of these visa categories has declined in the last decade, leading to problems keeping high value scientists in the U.S. There is anecdotal evidence that many scientists are no longer choosing to come to, or to remain in the U.S. but are instead going to other destinations. While the movement of scientists around the world has continued, the U.S. is not the same magnet it used to be.

Pricing policies also differ markedly from country to country. We will discuss pricing policies as an ACMD later in this paper, but suffice it to say here that markets that do not cap prices tend to be the markets where R&D spend occurs, and where investment flows. This is because price caps significantly distort markets and damage the overall risk-return incentive structure which is so sorely

[18] See generally, Ross deVol, Armen Bedroussian, and Benjamin Yeo, The Global BioMedical Industry; Preserving U.S. Leadership, September, 2011, Milken Institute.

[19] See "The Triple Interface Between Intellectual Property, Competition and Trade," Chapter 9, p 323, 327, Shanker Singham, A General Theory of Trade and Competition; Trade Liberalization and Competitive Markets (CMP Publishing, 2007).

needed for development of new technologies and therapies. This has implications not only for overall research flows, but also for the direction of research which will inevitably focus more on U.S. diseases, rather than diseases that particularly afflict other markets.

4. How to Foster an Innovation Ecosystem?

As we have noted above, the overall regulatory system is key to ensuring a vibrant innovation ecosystem. Such a regulatory system consists not only of property and intellectual property protection, but includes a range of other regulatory areas which we set out below when we provide a taxonomy of market distortions. ACMDs can distort the regulatory environment in ways that harm intellectual property based industries. Depending on what the regulatory framework looks like, it can either incentivize the introduction of new technology into the market or it can lead to its disincentivization.

The innovation ecosystem can be regarded as a system which produces new technological breakthroughs if properly nourished by investment and finance. For the ecosystem to truly function and promote innovation, financial flows directed towards it must be maximized. The question is how these flows can be maximized. Money tends to flow fastest in the innovation ecosystem when the property is valued at its highest, consistent with a competitive market. Financial flows are the lifeblood of the innovation ecosystem. The faster finance flows around the system (feeding initial R&D, development programs, and general spending needs), the more innovation we will see across a range of sectors and sub-sectors. The speed with which money circulates in the innovation ecosystem will also decrease as the products themselves face trade barrier restrictions and market distortions, including, critically, behind the border restrictions, as we will discuss below.

4.1 Role of Intellectual Property and High Tech Companies in Exports

Property rights are a fundamental pillar of a market economy. Intellectual property rights are an important part of that pillar. Within the overall subject of intellectual property rights, patents play a very important role. The innovation enhancing aspects of IPRs should be fully considered and evaluated in economic decision-making. The economic literature demonstrates the link between strong intellectual property regimes and economic growth. Robert Solow suggests that

fully 87.5 percent of the growth of American economic output between 1904 and 1949 was related to technological factors.[20] Charles Jones agreed that in the period between 1965 and 1990, over 40 percent of U.S. growth could be attributed to the rise in research intensity.[21] Strong intellectual property regimes allow and promote new technologies. The World Bank has also conducted a number of studies that show that patent protection is very important in supporting domestic R&D. Intellectual property protection is clearly required in order to stimulate investment in innovation technologies. Foreign direct investment in technology also increases as the strength of the patent system increases. A very good example of this is the substantial development of a Korean venture capital sector which invested in technology and greatly contributed to the rise of Korea.[22] By contrast, weak patent regimes prevent developing countries from establishing a robust technology related sector in their countries. This creates a vicious cycle where promising students are forced to seek employment opportunities in developed countries, leaving home usually never to return. While this is no doubt good for developed countries, it is critically damaging to the innovation ecosystem in developing countries. The patent system is the only system that drives academic research into commercial application. When patent systems are weak, this process does not occur. For example, in India, despite the fact that 2-3 percent of the world total of scientific papers originate there, the number of scientists engaged in industrial research is low (and did not increase between 1977 and 1982 when industrial research was increasing rapidly).[23] There is also a symbiotic relationship between research institutions, patent candidates, academic researchers, universities and the private sector. All of these relationships can be characterized as part of the innovation ecosystem. Strong patent protection is the glue that holds these institutional relationships and this ecosystem together. In the U.S., IP intensive industries accounted for 60 percent of total U.S. exports between 2005 and 2007.[24]

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[20] Robert Solow, "Technical Change and the Aggregation Production Function", 39 Rev Econ. & Stat. 312 (1957).

[21] Charles Jones, "Sources of U.S. Growth in a World of Ideas", Stan. Workshop Paper (Sept, 1999).

[22] See Shanker A. Singham, A General Theory of Trade & Competition; Trade Liberalization and Competitive Markets (CMP Publishing, 2007).

[23] See Edmond W. Kitch, "Policy Consideration: The Patent Policy of Developing Countries", 13 UCLA Pac. Basin L.J. 166, 173-75 (1994).

[24] *See* n. 6 at 25.

4.1.1 IP-based Industries and Job Creation

The intellectual property based industry also has a significant effect on job creation. And, not all these jobs are solely high-tech jobs. IP-based industries also support low-skilled workers.[25] U S job losses between 2000 and 2007 makes for disheartening reading, but it is noteworthy that while both IP and non-IP based industries have lost jobs, the figure is much lower for IP-based industries (-674,066) versus non-IP based industries (-1,968,125). Indeed there are sectors within IP-based industries where jobs were actually created even in this period (pharmaceutical/medicine up by 4.4 percent, creating 5,150 new jobs, petroleum/coal up by 1.7 percent).[26]

Table 11: Production Workers, by Industry, 2000-2007

	Average 2000-07	**2000**	**2007**	**Job Creation/ Losses (+/-)**	**% Change in 2000 Level**
All Tradable Industries	**9,464,202**	**11,943,646**	**9,296,953**	**-2,646,693**	**-22.2%**
IP-Intensive	**1,892,765**	**2,975,007**	**2,300,941**	**-674,066**	**-22.7%**
Petroleum, coal products	66,032	67,130	68,272	1,142	1.7
Chemicals	467,248	510,797	463,802	-46,995	-9.2
Basic chemicals	99,037	109,825	96,470	-13,355	-12.2
Resin, synthetic rubber, fibers	64,436	73,715	67,475	-6,240	-8.5
Pharmaceuticals, medicines	116,816	116,816	121,966	5,150	4.4
Computer, electronic products	581,787	853,295	497,895	-355,400	-41.7
Computers, peripheral equipment	46,667	76,543	33,896	-42,647	-55.7
Communications equipment	74,281	128,948	54,654	-73,294	-57.6
Semiconductor	257,440	397,169	222,854	-174,315	-43.9

[25] *See* n.6 at 32.

[26] *See* Table 11, n. 6 at 33.

Navigational, electro-medical	164,802	199,779	158,622	-41,157	-20.6
Transportation equipment	1,171,958	1,351,740	1,081,651	-270,089	-20.0
Motor vehicles, trailers	817,668	954,777	709,272	-245,505	-25.7
Aerospace products	201,450	229,243	211,686	-17,557	-7.7
Miscellaneous medical equipment	187,526	192,045	189,321	-2,724	-1.4
Information software	--	--	--	--	--
Non-IP-Intensive	**7,570,875**	**8,964,137**	**6,996,012**	**-1,968,125**	**-22.0%**
Food, beverage, tobacco	1,205,631	1,239,628	1,196,768	-42,860	-3.5
Textiles, apparel, leather	616,835	949,261	403,025	-546,236	-57.5
Wood products	439,980	486,245	417,471	-68,774	-14.1
Paper, printing	859,610	1,022,056	776,445	-245,611	-24.0
Plastics, rubber products	736,434	857,415	662,001	-195,414	-22.8
Nonmetallic mineral products	373,491	407,057	365,926	-41,131	-10.1
Primary metals	373,072	459,111	344,652	-114,459	-24.9
Fabricated metal products	1,175,523	1,375,118	1,179,280	-195,838	-14.2
Machinery	747,350	914,999	739,449	-175,550	-19.2
Electrical equipment, appliances	335,057	430,902	296,191	-134,711	-31.3
Furniture	441,704	513,666	388,495	-125,171	-24.4
Misc non-medical equipment	266,189	308,679	226,309	-82,370	-26.7

The IP-based industries are also among the most capital intensive (and tend to have high capital expenditure as a percentage of value added)[27].

4.2 Technology Transfer

Much has been made of the importance of technology transfer. While technology transfer may be of value to developing countries or markets without access to high technology products, the kind of technology transfer that is important is the technology transfer between universities to private companies that can exploit

[27] *See* n. 6 at 44, Table 16.

that research in a commercial manner. Other types of forced technology transfer can be very destructive to overall innovation enhancing goals. These act as anti-competitive market distortions and will end consumer welfare in the countries where they are applied.

4.3 Do Strong Patent Regimes Displace Local Firms?

Some developing countries in particular have argued that strong patent regimes only help developed countries because foreign companies displace domestic producers of pharmaceuticals. A good test case is Italy, where the country moved from little or no patent protection to a system of full patent protection. One study shared that local manufacturers actually increased their market share by five per cent in the ten years after this change.[28] However, the characteristics of the local firms changed fundamentally. Thirty percent of the companies that existed in 1978 had disappeared by 1988, but the surviving firms became larger and so overall employment rose by 2.7 percent (at the time that there was a decline in the rest of the industry). This was carried on the back of rapid R&D growth (growth rate was 20 percent annually in real terms). Similar support comes from South Korea and Mexico.

Local capital is particularly sensitive to changes in the patent environment because foreign capital is less constrained to a particular domestic market, whereas local capital is more constrained.

[28] See G. Jori:, "The Impact of Pharmaceutical Patent – The Italian Experience", (cited in Fundacion de Investigaciones Economicas Latinoamerianas (FIEL) in Protection of Intellectual Property Rights. The Case of Pharmaceutical Industry in Argentina, 62 Buenos Aires (FIEL) (1990).

5. What are the Barriers to High Value U.S. Exports and the U.S.: Innovation Advantage? The role of Behind the Border Barriers and ACMDs

5.1 It is our contention that the ability of U.S. firms to realize their true comparative advantage is compromised by the presence of ACMDs in global markets. Far from being on the decline, these ACMDs are actually on the rise. For purposes of our discussion, ACMDs include: (1) governmental restraints that distort markets and lessen competition; and (2) anti-competitive private arrangements that are backed by government actions, have substantial effects on trade outside the jurisdiction that imposes the restrictions, and are not readily susceptible to domestic competition law challenge.

ACMDs that are most pernicious are those that artificially alter the cost-base as between competing firms. Such cost changes will have large and immediate effects on market shares, and therefore on international trade flows. By contrast, some activities carried out entirely within a state, and covered by the state action doctrine have no discernible effects on trade. Any attempt to discipline ACMDs would not reach such activities.

With the growing internationalization of commerce, ACMDs not only diminish domestic consumer welfare – they increasingly may have a harmful effect on foreign enterprises that seek to do business in the country imposing the restraint.

We can now develop a classification or categorization of ACMDs. The first method is to divide ACMDs into a number of broad categories based on the applicable government regulation, practice or laws. It should be noted that this classification is designed to help understand the precise nature of ACMDs. However, ACMDs themselves will be judged by their impact on markets from a consumer welfare standpoint. These include laws and regulations that apply to:

(i) Entry;

(ii) Quantity;

(iii) Standards; and

(iv) Price.

Note that these regulatory interventions may or may not have welfare damaging impacts.

5.1.1 Entry

Many regulations prescribe entry in certain markets. Examples of this are regulations that limit the number of pharmacies in a certain area. Some regulations limit entry for professional service providers by making it difficult for them to move from one geographical area to another. In the services sector, many countries maintain rules that limit entry for financial services, telecom services and energy service providers.

5.1.2 Quantity

There are examples of regulations that place limits on the number of products that can be produced or sold. Examples include agriculture, fisheries, as well as the universal service commitment in postal and telecom services.

5.1.3 Standards

Many regulations provide standards often for seemingly very good reasons. Standards relate to health and safety, environment, labor, approval processes for new drugs, and so on.

5.1.4 Price

Some regulations exist that include a price ceiling or a minimum price. For example, the pharmaceutical industry faces price controls in many jurisdictions, whereas in some industries minimum rate schedules apply.

All of these rules and regulations can damage competition in the market and therefore lessen consumer welfare.

5.2 Classification/categorization based on how ACMDs affect market participants

Another way of looking at regulatory interventions is to analyze them from the perspective of how they affect market participants. We have based this breakdown on the OECD Competition Assessment Toolkit:[29]

[29] The OECD Competition Assessment Toolkit available at http://www.oecd.org/document/48/0,3746,en_2649_37463_42454576_1_1_1_37463,00.html

(v) Rules and regulations that limit the number and range of suppliers;

(vi) Rules and regulations that limit the ability of suppliers to compete;

(vii) Rules and regulations that reduce the incentives of suppliers to compete;

(viii) Rules and regulations that limit the choices and information available to consumers;

(ix) Rules and Regulations that apply to State-Owned Enterprises.

5.2.1 Rules and Regulations that limit the number and range of suppliers

Regulations in this space include the grant of exclusive rights for a company to supply a service or product, license requirements, limitations on public procurement opportunities, geographic limitations on the ability of firms to supply goods or services, invest capital or supply labor, reservations on the government to perform a certain service or supply a certain good or perform a service. By limiting the number of competitors through government intervention, this can lessen competition in the market and have a negative impact on consumer welfare.

Regulations on entry are the most common source of complaints from both foreign and domestic firms. These can take the form of direct bans as one would find, for example in retail store bans, or airline agreements. Then there are a host of constraints that apply indirect restrictions. These indirect restrictions include quality standards, certification rules, and capital adequacy requirements for banking services, administrative or bureaucratic barriers. The OECD Competition Assessment Toolkit (Volume 2)[30] contains a helpful series of examples of what constitutes these types of barriers to entry. In some cases, governments grant exclusive rights to certain suppliers. In some cases the bid process requires an exclusivity period without which no firm would invest in the particular opportunity. How the bid is constructed can determine its anti-competitive effect. It may be that a particular exclusivity period is longer

[30] OECD Competition Assessment Toolkit, 2011, Volume 2: Competition Assessment Guidance

than necessary to attract investment, and this has a harmful effect on competition (an example of this is the Jamaican telecommunications privatization which granted exclusive rights for a twenty-five year period, and which led to substantial anti-competitive effects). In these cases, the dynamic efficiencies associated with economies of scale, and sunk costs of investment are important arguments that would be considered in any competition analysis.

Entry barriers are not limited to national entry barriers. In some cases, internal (state or province level) regulations limit entry, and these limitations affect both foreign and domestic firms. Such restrictions also impede competition. While some countries have constitutional limitations on such laws (the U.S.'s Inter-State Commerce Clause for example), many such as China do not. Local protection that applies between states or provinces is a major issue in particular for emerging markets, especially China. Empirical data suggests that this is on the rise, and indeed increases as the overall economy becomes more open.[31]

5.2.2 Rules and Regulations that Limit the Ability of Suppliers to Compete

These regulations can take the form of anything that limits the intensity with which firms compete. For example, regulations limiting advertising can chill inter-firm competition. Some countries have restrictions on direct to consumer advertising that limit consumer information about products and services and could lock in consumer preferences based on imperfect information. This particularly affects new foreign market entrants. Similarly, some regulations can raise the costs of certain firms with respect to other firms. These can be achieved by setting very high standards for some products that happen to favor a national champion or a particularly favored domestic firm. Rules on content and unduly restrictive standards can also have the effect of limiting variety and choice and also have welfare damaging effects.

[31] See *The Razor's Edge: Distortions and Incremental Reform in the People's Republic of China,* Vol. CXV (4), Quarterly Journal of Economics, Nov. 2000.

5.2.3 Rules and Regulations that Reduce the Incentives of Suppliers to Compete

There are many regulatory structures that are imposed on markets that might lead to cartel formation or otherwise take away the incentive for firms to compete. This is particularly a risk where a government exempts a certain group of companies (e.g. state owned companies) from the national competition laws, or where the costs of switching to a different company are increased to the point where firms know that whatever they do, consumers are unlikely to switch.

5.2.4 Rules and Regulations that Limit the Choice and Information Available to Consumers

There are many rules and regulations that limit choice and information available to consumers. Some of these relate to the advertising restrictions referred to above. Some relate to systems of self-regulation and co-regulation, where the regulatory burden falls to market participants themselves through voluntary systems of regulation.

5.2.5 Rules and Regulations that Apply to State Owned Enterprises

One of the most significant problems in global economic policy is the global competition between private and state owned enterprises (SOEs). In order to gain welfare enhancing outcomes, SOEs and private firms must compete subject to the same commercial disciplines and regulatory structures. Presently, governments frequently skew their domestic regulatory environments to give their SOEs an unfair advantage in the global market. This negatively impacts both foreign firms, domestic, non-state-owned firms, and global markets where those SOEs are active. Many of these regulations give privileged licensing terms to SOEs, grant them access to preferential loans and financing opportunities, and provide free or low cost inputs such as water, energy and raw materials. SOEs are sometimes also exempted from national competition laws. This enables them to act in ways that are anti-competitive, and distort global markets without fearing any domestic penalty, while benefiting from variants of the foreign sovereign immunity defense in foreign markets. These exemptions, when applied to SOEs acting in a commercial (as opposed to a political capacity) can be very destructive of competition and substantially lessen consumer welfare.

One test that has found favor, at least with respect to state trading enterprises[32] is the notion that SOEs must be subject to "commercial considerations." Even though the precise meaning of commercial considerations as interpreted by WTO panels and appellate bodies today is troubling, attempts have been made to clarify the precise meaning of commercial considerations. The Australian government has made some progress in this area, under the guise of competitive neutrality. In summary, the Australian government's objectives (which are partially enshrined in the OECD's competitive neutrality guidance)[33] are listed below. (It is important to note that initially the Australian government sought to apply these domestically.)

(1) Universal application of competition rules;

(2) Competitive neutrality between government and private business activity; and

(3) Reforms to public-sector monopolies and price oversight arrangements

The key was to ensure that governments should not use their legislative or fiscal powers to advantage their own businesses over the private sector. Examples of government benefits include "exemptions from various taxes, access to borrowings at concessional interest rates, exemptions from complying with regulatory arrangements imposed on private sector competition and other benefits associated with not having to achieve a commercial rate of return on assets."[34]

It was deemed important in order for competitive neutrality to be maintained for the corporate structure of state-owned companies to be transparent in the same way that a private company's corporate structure is transparent.

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[32] State trading enterprises are governed by GATT Article XVII.

[33] Capobianco, A and H. Christiansen (2011),"Competitive Neutrality and State-Owned Enterprises: Challenge and Policy Options" OECD Corporate Governance Working Papers, No.1, OECD Publishing. http://dx.doi.org/10.1787/5kg9xfgjdhg6-en

[34] Commonwealth Competition Neutrality Policy Statement, June 1996

When a government agency undertakes significant business activity, agencies should pay all applicable taxes or tax equivalents and debt guarantee charges.

In Australia, the productivity commission can investigate allegations of violations of competitive neutrality by government businesses. In doing this, it will assess, inter alia, whether the regulatory arrangements which distort competition between the government business and its private sector competitors. In making its assessment, it will consider a number of factors including:

- Whether the business activity in question has a substantial degree of market power.
- Whether the pricing behavior of the government business has had the effect of eliminating or substantially damaging a competitor, preventing entry or preventing or diluting competitive conduct.
- Whether it would be cost-effective to apply competitive neutrality principles to the activity.

The OECD's Corporate Governance Papers[35] have analyzed the question of competitive neutrality and State-Owned Enterprises, and these papers draw heavily from the Australian experience. The OECD also draws on the European experience. In particular, Article 106, of the Treaty on European Union (TEU) deals with distortions between government and private entities. European state aid rules limit the ability of government to give money to its SOE-sector (or indeed to any undertaking where the aid distorts competition).

The OECD corporate governance papers contain a useful catalogue of anti-competitive practices.

(i) Predatory activity by SOEs (in Europe the test does not require recouping of lost profit because the SOE is a revenue rather than a profit maximizer);

[35] See generally, Matthew Rennie and Fiona Lindsay, OECD Corporate Governance Working Paper No. 4, "Competitive Neutrality and State-Owned Enterprises in Australia," Aug. 2011.

(ii) Raising rivals' costs and raising barriers to entry (by not giving access to essential inputs or infrastructure, or obtaining selective grandfather clauses with regard to new regulations);

(iii) Cross-subsidization; where the SOE uses its monopoly position in a particular market to cross-subsidize into a related competitive market to knock out rivals; and

(iv) Imposing an inefficient technology on a given sector, because the use of such technology harms it less then its use harms its private rivals. It can also artificially lower its costs in this way to give it more flexibility to act in a predatory manner.

5.3 Legislative and Administrative ACMDs

5.3.1 Legislative ACMDs

5.3.1.1 Tax Distortions

In addition to some of the ACMDs highlighted above, governments also provide benefits to preferred companies through certain manipulation of the tax rules in a variety of ways. While some of these tax distortions will violate Article III.2 of the GATT because they are discriminatory, many of these tax distortions will not violate GATT's national treatment rule.

5.3.1.2 Monopoly rights

In many cases, governments entrust SOEs with exclusive or monopoly rights. This can be seen through examples of single desk agricultural marketing arrangements that exist in countries such as Australia, New Zealand and Canada.

5.3.2 Administrative ACMDs

There are a number of actions by regulatory agencies that distort markets in anti-competitive ways. In many countries, most legislative change is secured by administrative decision-making. These can emanate from almost any regulatory body. We highlight some non-exhaustive examples below:

(x) Environmental Agency decisions. Environmental agencies can issue decisions about particular products and services that limit competition. Often such regulatory decisions may be overly broad, or there may be other ways of achieving the regulatory goal that are less market distortive;

(xi) Actions by domestic competition agencies. Simply because it is the competition agency that is taking a particular action does not mean that the action is automatically pro-competitive. In fact, in many cases, actions by competition agencies can distort markets and achieve the opposite of the goals they are intended to pursue.[36] Indeed actions by domestic competition agencies are particularly pernicious since they are more difficult to attack (as the agency's mandate is to preserve and protect competition);

(xii) Decisions by Labor Boards. In many countries, Labor Boards can make decisions over where companies locate investments. Sometimes these decisions can act to keep a supplier out of the market, thereby impacting competition;

(xiii) Decisions by regulatory bodies on standards regarding product content or characteristics. This includes local content rules for media, or safety regulations for the automotive sectors;

(xiv) Exemptions from building permit regulations or from zoning regulations;

(xv) Preferences in public procurement, often through policy statements.

5.4 Tax Policy Favoring National Champions and Local Firms

Many countries use their tax policy to favor certain domestic companies that are national champions. They can do this with a combination of tax breaks and incentives that are only available to particular preferred national champions, or

[36] Chapter 3, Shanker Singham, A General Theory of Trade and Competition; Trade Liberalization and Competitive Markets (CMP Publishing, 2007).

by specific tax discrimination where lower tax rates are applied to domestic firms.

5.5 Technical Barriers to Trade

Many of the regulations that impact U.S. exports relate to labeling. These regulations are particularly pervasive in the case of the pharmaceutical industry, and when they are not based on sound science, or when they are highly restrictive they can be serious barriers to trade.

Many of these regulations are globally divergent and contribute to difficulty for U.S. exports. We advocate that regulatory divergence should be addressed in the following manner:

(i) Regulatory impact assessments (RIAs) that focus on the welfare impact (in an economic sense) of proposed new regulations. In addition to the business compliance costs, sound RIAs would look at consumer welfare impacts of new regulations, including the impact of the regulation on productive and allocative efficiency; The impact of new regulations on the market should be analyzed separately from any alleged benefits so that these costs can be made explicit and better regulatory decision making can be effected;

(ii) Ensuring a role for relevant shareholder agencies to have a seat at the regulatory promulgation process table;

(iii) Ensuring RIAs fully take into account impact on trade; and

(iv) Ensuring new regulation promulgation processes fully take into account all the available alternatives as well as ensuring selection of the least distortive regulation possible, consistent with regulatory goals.

5.6 Government Procurement

Government procurement rules are also used to artificially skew the market, by favoring domestic producers. In extreme cases, government procurement can also be used to effect trade restrictions based on where intellectual property is localized (such as China's Indigenous Innovation policies). These policies are designed to facilitate technology transfer, and damage the innovation ecosystem by forcing companies to localize intellectual property in places which are not

their first choice. These policies also operate just like Trade-Related Investment Measures (TRIMs), and are significant impediments to investment flows.

Anti-Competitive Market Distortions

5.6.1 Price Controls

This includes government policies and regulations that lead to welfare damaging outcomes. One example of this is the plethora of price control regulations in many OECD and other countries. Price controls artificially lower the revenue stream which products can command in these markets, and are a government-imposed distortion.

Price controls, such as exist in many countries in the pharmaceutical sector, are a radical departure from a competitive market. Governments use their monopsony power to negotiate prices with the suppliers that do not reflect actual market prices. These low prices directly and negatively impact R&D budgets of suppliers (See ITA Study).[37] These non-market prices lead to inefficiencies that ultimately harm the innovation ecosystem, because they impact the incentives to enhance productive efficiency and eat into potential R&D revenue streams.

There are a number of other barriers that the ITA study looked at, including;

- Restrictive formularies
- Health guidelines
- Health budgets
- Obstacles to marketing and promotion

The ITA study referred to above, highlights the benefits to consumer welfare from deregulating prices, and therefore implicitly notes the damage to consumer welfare caused by price controls.

[37] See ITA Study, Pharmaceutical Prices in OECD Countries; Implications for U.S. Consumers, Pricing, Research & Development, and Innovation. (December, 2006)

5.6.2 Distribution Restraints which Imperil the Ability of U.S. Firms to have Market Contestability

Many countries maintain distribution laws, or laws that impact the distribution sector which diminish competition at the distribution level. By limiting competition, these laws often lead to higher prices and less choice for consumers. They often operate by imposing substantial termination indemnities on firms if they make the decision to terminate their local distributors. These termination indemnities are set at very high levels and tend to change the relationship between the distributor and the supplier shifting power into the hands of the distributor.

Distortions at the distribution level are very significant. If the distribution sector is not competitive, then any openings for U.S. exporters secured through market access concessions will be thwarted by anti-competitive distribution restraints. The gains of increased market access for exporters will be vitiated by distributors or middle men simply taking all the "rents" or benefits of tariff liberalization, in effect pocketing any liberalization gains for themselves.

Examples of distribution restraints include those laws that give great protection to local distributors and make it very difficult for them to be terminated by their foreign suppliers, except on payment of substantial termination indemnities. These distribution restrictions are classic ACMDs, because they artificially lower the level of competition in the distribution sector. This harms domestic consumers of products. The welfare losses flow from the fact that distributor relationships are locked in for much longer periods than would be the case if the distribution restrictions are not present. These laws prevent switching from distributor to distributor and thus restrain inter-brand competition by limiting the effectiveness of a particular and specific distribution channel. Vertical restraints imposed by governments are generally acknowledged to be anti-competitive.[38] The restraint operates in the same way as a dealer cartel which allocated specific suppliers to specific dealers would operate. In countries which maintain these restrictions, one often sees much higher dealer profit margins than would otherwise be realizable.

[38] See Shanker A. Singham, A General Theory of Trade and Competition (CMP Publishing, 2007) at 507.

This particularly affects small markets where there may be fewer distributors to start with. In markets where the distributor market is concentrated then these effects will be even more pronounced. If barriers to entry are high, then the anti-competitive impact will also be high.

5.6.3 Regulatory System for Approval of New Medicines

The regulatory system for the approval of new medicines can be cumbersome, non-transparent and in some cases would constitute anti-competitive market distortions especially where such systems artificially increase the costs of foreign pharmaceutical firms. In many countries the regulatory approval process is used as a trade barrier.

5.6.4 Lack of Proper Enforcement of Competition Law

Merely having a competition agency does not necessarily mean that a country is properly enforcing competition law according to best practice. Many competition laws are enforced by domestic competition agencies in ways that actually harm the process of competition. They do this when they lose focus on their mandate which is to protect competition in the market, as opposed to specific competitors. Competition agencies can lose focus in a number of ways, highlighted below.

5.6.4.1 Unduly Interventionist Approach to Competition Enforcement

Competition agencies may pursue policies that tend to fragment markets for the sake of having fragmented markets. These agencies tend also to follow the notion that "big is bad" and therefore seek to discipline larger market participants simply because of their size. This policy bias translates into attacking larger firms through a number of discrete means. The first involves the increased use of remedies to deal with unilateral conduct. Competition agencies can set very low levels of market share as a prima facie indicator of market power (i.e. power over price) – in some cases market shares as low as thirty five per cent have been used by new competition agencies to indicate market power. Some competition agencies take the position that once market power is established, firms should be highly restricted in what they can do going forward. For example,

these firms may find that their property is regarded as an essential facility, and they are required to license it on terms favorable to potential licensees. They may find that any activities they contemplate as private parties carry significant antitrust risk because they have been designated as monopolists, or firms with market power. This can include pricing decisions, agreements with customers, discounts, rebates or any other legitimate competitive business strategies. This type of practice can seriously impact the legitimate business operations of large firms, put them at a competitive disadvantage and ultimately damage the very process of competition that the competition agencies are mandated to protect.

5.6.4.2 The Threat of Compulsory Licensing

The threat of compulsory licensing is a significant barrier to pharmaceutical exports. Business models where products sold are high value intellectual property rely on the fact that that intellectual property will be protected in markets where the property is sold. In particular, if a patent-owner believes that the patent is at risk of compulsory licensing, or that it will be forced to license the patent on terms unfavorable to the patent-owner, then this will be a significant disincentive to actually investing in the necessary research and development to actually produce the product.

Many countries, including Brazil and Thailand, have used this threat to damage property rights owners, and extract favorable licensing terms from them. In order for the threat to be effective, it is necessary for the competition agency to hold that the patent in some way constitutes an essential facility, and that the failure of the patent holder to issue a license basically constituted an anti-competitive practice. This is based on the erroneous notion that the patent confers a monopoly over a relevant product market. However, whether a patent does indeed confer a monopoly depends on whether that market in which the monopoly is alleged is

in fact the product market. In many disease treatments, the patented product is but one of several ways in which such treatments exist. All of these several alternatives together act as a constraint on the patented products' price which takes away the patent's ability to confer power over price on the patent holder.

However, if the competition agency assumes such power over price simply by virtue of the patent, it may then restrict the patent holders' conduct in a number of ways:

(i) Duty to deal with rivals. The patent holder may be forced to deal with rivals. It may be forced to license patents or technology on terms favorable to the licensee and unfavorable to it.

(ii) Pricing decisions. A patent holders' pricing flexibility might be challenged, specifically when rebates, discounts or marketing initiatives may be challenged as violating the competition laws even though the same decisions would not be problematic if carried out by firms without market power.

Although competition is often cited as the reason for the compulsory license (to correct the market failure allegedly caused by the patent), in fact the compulsory license as a remedy for antitrust violations has long been regarded as a poor policy choice. The U.S. Supreme Court has noted that "Compulsory Licensing is a rarity in our patent system…"[39] The cases where it has been used are a relatively small group of cases where the intellectual property has been wrongfully acquired or pooled and cross-licensed with competitors and only if one of

[39] Dawson Chem. Co. v Rohm v. Haas Co., 448, U.S. 176, 215 (1980)

these acts is accompanied by other predatory conduct.[40]

The major problem with compulsory licensing as a remedy is that 1) it is administratively difficult to supervise, and 2) it entails a transfer of wealth between the patent owner and its rival with little demonstrable benefit for consumers. It is a marginally better remedy in the case of patent misuse. However, even here, the federal circuit of the U.S. has interpreted the patent misuse doctrine narrowly. The doctrine itself is a court made doctrine intended to prevent the patent holder from extending the power of the patent beyond the grant defined by the relevant patent statute. If the competition agency has deemed the patent holder to be a monopolist without analysis, this effects what they can do with their property (the patent in this case). Similarly an overly broad patent misuse doctrine coupled with a non-economic approach to competition enforcement can lead to severe erosion of the patent right.

Compulsory licensing has been addressed in WTO cases, notably the Canada – Patent Protection for Pharmaceutical Products, WT/DS114/R (2000), but only to the extent that the panel upheld the notion that compulsory licensing laws which only applied to pharmaceutical products were discriminatory under Article 30, TRIPS.

5.6.4.3 Compulsory Licensing as a Remedy for Refusals to Deal

The general position has been that the compulsory licensing doctrine has only been used in the case of refusals to deal where the patent has been wrongfully acquired or pooled or cross-licensed with competitors, and only if one of these acts is accompanied by some predatory conduct.[41] Under Data

[40] See James B. Koback, Jr., Antitrust Treatment of Refusals to License Intellectual Property, 566 PLI/Pat 517, 533.

[41] S. Pac Communications Co. v. AT&T Co., 740 F.2d 908 (Cir. 1984)

Gen. Corp v. Grumman Sys. Support Corp, 36 F.3d 1147 (1st Cir. 1994), there is a rebuttable presumption that a monopolists desire to exclude others from its protected work is a presumptively valid legal business justification for any immediate harm to consumers. The actual position is well expressed in Lithograph Corp v. Intel Corp, 195 F.3d 1346, 1358 (9th Cir. 1999) where the federal circuit stated that:

> [the] courts have well understood that the essential facility theory is not an invitation to demand access to the property or privilege of another on pain of antitrust penalties and compulsion; thus the courts have required anti-competitive action by a monopolist that is intended to eliminate competition in the down stream market.

The TRIPS agreement was the WTO's attempt to express this position. The TRIPS agreement recognized the damaging effect of compulsory licensing on economic development. To that end, TRIPs Article 31 contained certain provisions that had to be complied with in order for compulsory licensing to be found. These included the notion that minimum requirements such as the license not being exclusive, it should be predominately for domestic market use, and requiring proper compensation could be dispensed with in the case of anti-competitive actions by patentees (see Article 31, TRIPs).

This, of course, begs the question of what precisely constitutes anti-competitive practices. In evaluating this, the EU made a significant contribution to the state of knowledge on the subject with their submission to the WTO Trade and Competition Group (as then constituted in 1998).[42]

[42] EU Submission on the Relationship Between the Trade Related Aspects of Intellectual Property Rights v. Competition Policy, and Between Investment and Competition Policy, WT/WGTCP/W/99 (15 September 1998).

The core rationale for their [IPR] protection is that they tend to create a dynamic efficiency that is pro-competitive and outweighs any short term allocative efficiency gains that might exist in the absence of such protection…[43] The EU notes that the exclusive right given to the patentee will, in and of itself, not give rise to an abuse of market power. This depends on the availability and market share of substitutable products. Grounds for anti-competitive abuse of a monopoly right are:

1. If competitors grant licenses to each other for the purposes of dividing up markets, then there may be a market division problem. But transfers in and of themselves do not present a problem. Competition problems only arise if the transfer is the subject, the means, or the consequence, of an anti-competitive arrangement.

2. The patentee may not try and impose a fixed margin on licensees. If he does so, that may constitute a competitive problem.
3. The exclusive right conferred by the patent is not in and of itself sufficient to determine the existence of a dominant position. The price of goods is not necessarily an abuse of dominant position. Indeed the EU submission states that "only in exceptional circumstances, should abnormally high prices be considered as an abuse in themselves."[44]

4. Refusal to grant a license, even for a reasonable royalty, does not in itself constitute an abuse of a dominant position. There are additional requirements, such as where the patentee is not

[43] *Id.*

[44] *Id.*

working the patent itself, withholding important technical information from the public against the public's interests, engaging in unfair sales prices, or engaging in discriminatory sales practices (e.g. unfairly refusing to supply certain parts of the market.)[45]

These principles have been summarized by the statement:

> "Allowing competition policy to trump intellectual property rights is, in all but the most egregious of cases, an extraordinary result."[46]

The essential facilities doctrine and its variants are, in fact, more appropriate for regulated industries such as telecommunications, or transportation. This is because it is often the regulatory framework that gives a particular entity an "essential facility" not its own business merits. Having one's intellectual property recognized through the patent system does not mean that relevant industry is itself regulated.

6. Policy Prescriptions

So how then do we deal with these issues? We lay out some policy prescriptions that we believe will be helpful in solving the problems laid about above.

(i) Negotiation of a multilateral agreement, such as a WTO plurilateral agreement or some other agreement with like-minded countries (countries that accept competition on the merits as an organizing economic principle).

(ii) Facilitate more trade ministry (country X) – competition agency (country Y) dialogues. These dialogues would bring export interests for adversely affected markets into alignment with consumer welfare interests in the distorting country which will more likely lead to a solution of these problems.

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[45] *Id.*

[46] Robert P Taylor, Intellectual Property as "Essential Facility" ABA/PLI (20-21 July 2000).

(iii) The domestic regulatory process needs to better conduct cost-benefit analysis using a welfare metric to measure cost (as market impact). Competition agencies should have a seat at the table in arguing for pro-competition regulatory reform based on consumer enforcement. This is in line with the OECD's Regulatory Toolkit and Competition Assessment.

(iv) Countries will need to have access to self-help remedies (subject to the agreement in (i)). These remedies would allow countries to tarifficate the market distortion, subject to demonstration of welfare impact, causation and harm. This gives the distorter an incentive to eliminate its distortions.

All of this requires, at least, two things. The first is a reorganization of the U.S. government around the idea of global supply chain competition and the second is the development of an economically robust metric to measure distortions. If these are advanced, and the policy prescriptions set forth in this paper followed, we believe that this will constitute the grounds for a systematic reduction of ACMDs and the liberation of trillions of dollars of wealth into the global and U.S. economies.

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