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Keynote Address

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This gathering is an unusual one for me. Normally, I am speaking before groups consisting either of lawyers or government officials. This is the first time I have ever spoken at a conference that is directed at public affairs professionals. However, while the audience may be slightly different, the topic – patents and pharmaceuticals – is one in which I have had a long interest. I have written and spoken about it frequently in the last five and one half years since I left public service as Assistant Secretary of Commerce and Commissioner of Patents and Trademarks in the Clinton Administration.

At the outset I should disclose my prejudice: I am a passionate supporter of intellectual property rights, especially patent rights. My deep respect for the importance of intellectual property rights in modern society goes back to the beginning of my career as a lawyer, when fate landed me my first real legal job, recently discharged from military service in January of 1974. I had the enormous good fortune of being hired as one of a very small number of lawyers on the staff of the Committee on the Judiciary of the United States House of Representatives. That was an exciting time to be working for the Committee. From a public affairs point of view, perhaps the most exciting time in the history of the United States: the commencement of impeachment proceedings against President Richard M. Nixon. While I later would become deeply involved in investigations and the drafting of legislation leading to post-Watergate reforms, during my first day on the job I found myself far from the lights and television cameras of the Committee's hearing room where everyone was focused on the case against President Nixon. In fact, my job had opened up because more senior colleagues were working on impeachment, and I had been enlisted to advise on the Committee's more mundane responsibilities. One of these was legislation regarding patent, trademark and copyright law. So, on my first day on the job I was assigned to work on the patent policy provisions of the Non-Nuclear Energy Research and Development Act of 1974, then working its way through the Congress.

Of course, as staff of the Committee I was an adviser and technician, not a policy maker. My principal client was the Chairman of the Subcommittee on Courts, Civil Liberties and the Administration of Justice, the Honorable Robert W. Kastenmeier of Wisconsin. While it might be hard to tell from the name, Congressman Kastenmeier's subcommittee was, among other things, responsible for all legislation relating to intellectual property law. He was a classic post-WWII liberal Democrat. His concern was with the equitable distribution of wealth in our society, not with the mechanisms by which it is created. He felt very much that private enterprise was quite able to take care of itself without a big assist from Uncle Sam, and that government intervention should be primarily to constrain the prerogatives of wealth rather than to stimulate its creation. And, with regard to intellectual property rights – particularly patents – his views reflected the prevailing sentiment of the time, that patents were inherently monopolies that should be granted sparingly. That view was promoted on the Supreme Court by Justice William O. Douglas and was even embraced by President Nixon's Department of Justice, which was advising us to take a decidedly restrictive view of giving government contractors any exclusive patent rights in new technologies to be developed under the Non Nuclear Energy Act I had been given as my first work assignment. That Act, which was enacted and is still on the books, reflects those anti-monopoly concepts.

Times change, however, political contexts change. And, Chairman Kastenmeier, while a classic mid-century liberal, was also one of the most honest, thoughtful and open-minded public servants I have ever known. He was always able to re-think his position if facts and circumstances changed. After the crises of Vietnam and Watergate the next big crisis my country had to face was that of globalization of the economy and a very noticeable decline in U.S. competitiveness in the face of the rising economic power of Japan and Europe. President Jimmy Carter defined this phenomenon – much to his political detriment—as the "American Malaise." Indeed, it seemed then that America was fast losing its pre-eminent position in the post-WWII world. At the core of this sense of decline was the poor performance of the nation's economy in the face of challenges from Europe, and particularly, Japan. U.S. companies that had dominated the domestic market were losing market share to superior imports from abroad, particularly in the consumer electronics and automobile sectors.

In response to this sense of decline, policy makers in both the public and private sectors began searching for the cause of this problem and solutions to it. Many observed that while both public and private sector investments in technology remained high, these investments were not being translated into competitiveness in the international market place. And, since patent law had for much of American history been an important incentive to development and commercialization of new technologies, there was a re-thinking about the role of patents in society and competitiveness. This led to a distinct shift from the view that patents were dangerous monopolies that should be seen with suspicion to the view that the patent system was not sufficiently strong to support the commercialization of investment in competitive new technologies. So, the pendulum began to shift, and policy makers in both political parties began to support reforms designed to make patents stronger. In the House of Representatives, under the leadership of Chairman Kastenmeier, bills were introduced to: strengthen the patent office through increased funding, add staff and deploy state-of-the art electronic search technology; to consolidate all judicial and administrative appeals in patent cases into a single, specialized court in Washington; to grant title to patents for government funded inventions to universities and small businesses with a mandate to seek commercialization of the inventions, and legislation to

extend the patent term of pharmaceutical inventions to compensate for the delay in ability to market those inventions due to safety and efficacy regulation.

Between 1980 and 1984 new laws were passed in each of these areas. The result was a system of stronger patent rights. Within a few years this new policy began to achieve success and the nation began to spawn a whole new generation of high technology industries and companies characterized by Silicon Valley. Beginning in the Reagan Administration, this new emphasis on strong intellectual property rights was incorporated into the U.S. position in trade negotiations. And, during my tenure as Assistant Secretary of Commerce in the Clinton Administration, that position was successfully embodied in the TRIPS Agreement annexed to the WTO Treaty. Two years later the World Intellectual Property Organization concluded a successful diplomatic conference promulgating new global copyright and neighboring rights treaties for the Internet era. The principles in these two treaties were incorporated in U.S. Law in 1998 in the Digital Millennium Copyright Act (DMCA.)

Six years latter I think that we can now look back and see the WIPO Treaties and the DMCA in the United States as the high water mark for intellectual property rights. Since 1998, the pendulum has been swinging back in the other direction. With respect to Copyrights and the Information Industries this is seen in the explosion of unauthorized file sharing and the growing intellectual and political support for legitimizing file sharing. With regard to patents, we see this in the backlash against the TRIPS Agreement that began with the 1999 WHO ministerial. That ministerial first addressed the role of patents in the AIDS crisis and ended with the September 2003 WTO Council decision giving an expansive interpretation to Article 31 of the TRIPS Agreement.

We are now seeing a full scale assault on the assumptions U.S. policy makers made in the early 1980s about the need for a strong patent system – particularly in the field of pharmaceutical products. Having successfully rolled back the TRIPS Agreement on the eve of the 2003 Cancun ministerial meeting, anti-patent activists are now attempting to directly target one of the most important – and effective – reforms of the U.S. patent system, the Bahy-Dole Act of 1980.

Last year the Economist magazine called the Bayh-Dole Act the most important legislative achievement in the U.S. since World War II. However, in spite of this journalistic accolade, a negative reaction to Bayh-Dole has been building up in intellectual and scholarly circles for several years – as part of the pendulum shift away from strong intellectual property protection. And, this academic criticism has begun to win support among a small, but growing number of Congressmen and Senators. In recent weeks the embers of resentment against Bayh-Dole have burst into a raging fire. In reaction to a decision of Abbott Laboratories to quadruple the price of the AIDS therapy, Norvir, a coalition of activists has petitioned the Director of the U.S. National Institutes of Health (NIH) to exercise march-in rights under the Bayh-Dole Act, reclaim the patent rights to Norvir, and license it to others willing to sell it for less.

According to published reports no more than $3 million in NIH funds went to the development of Norvir while Abbott's investment exceeded $300 million. Yet, the activists are attempting to punish Abbott for the lawful exercise of its patent rights as a result of this alleged small government investment. It is my understanding that Abbott contests the allegation that Norvir is subject to Bayh-Dole march-in rights. However, the Director of the NIH is taking the petition

seriously. Should he decide that Norvir is subject to NIH march-in rights and to exercise these rights, he would be making a decision unprecedented in the 24 year history of the Bayh-Dole Act.

Of course, any decision to exercise march-in rights would be litigated by Abbott, which could undoubtedly delay the implementation of a decision against it. However, the very fact that the activists' petition is being seriously considered by the NIH Director in a Republican Administration, with a record of support for the pharmaceutical industry, is a testament to how quickly and how far the pendulum has swung in the anti-patent direction.

When one looks at the assault on the prerogatives of pharmaceutical patent holders – the Doha Declaration, the pressure to permit importation into the U.S. of price controlled products from Canada, and now the petition to compulsorily license a drug alleged to have been developed, in part, with taxpayer money – it is apparent that pharmaceutical patents are under an unprecedented public relations assault. This assault continues. I believe that we can expect developing countries to increase their efforts to roll back the TRIPS Agreement as the Doha Round of trade negotiations unfolds, and that in the all-important U.S. market, patents as the mechanism by which pharmaceutical companies can control prices will become an increasingly important political issue in an election year.

In the past I have written extensively about the importance of exclusive patent rights as the key to investment in new medical technologies. And, I believe strongly in that supposition. However, I must admit that I find myself among a dwindling number of defenders of the industry and its intellectual property rights.

As this conference is focused on public perceptions of the industry – as opposed to purely legal and technical concerns – we should ask why it is that the research intensive pharmaceutical industry finds its ability to exercise the exclusive rights of its patents under such an intense assault?

I would offer several reasons for the success of the attack on pharmaceutical patents.

First, the industry – and indeed the intellectual property community in general – did very little in the wake of the TRIPS Agreement to help developing countries understand and implement the TRIPS Agreement. The industry provided little technical assistance on its own, and it used virtually none of its significant influence with developed country governments – particularly the United States – to see that public development aid was channeled to such technical assistance. The patent system is viewed in the developing world as something principally benefiting a handful of rich countries. And, and statistics published by the World Intellectual Property Organization (WIPO) show that over 95 % of all patent filings in the world are from nationals of OECD-member countries. This means that there is virtually no constituency for patents in most developing countries, even though research – and invention – takes place in many of these countries.

As an example, I would point to Brazil, a country where my own International Intellectual Property Institute currently has a modest program underway. Brazil has a significant scientific research capability. For example, the State of Sao Paulo dedicates 1% of its tax revenue to a

foundation, FAPESP, that provides grants to academic researchers in the state. These grants have supported significant research efforts in the life sciences, particularly in biotechnology. However, patenting in the health sciences was unknown in Brazil until bilateral U.S-Brazil negotiations resulted in accelerated implementation of the TRIPS Agreement. Consequently, there is little understanding of how to patent, license and otherwise exploit commercially their health-care inventions. This has meant that a constituency in Brazil that understands and supports the patent system has been slow to develop and remains politically weak in the face of domestic interests that favor weak patent protection and favors a policy of the use of generic products as substitution for the importation of more expensive patented pharmaceuticals from abroad.

What was the reaction of the U.S. pharmaceutical industry to this situation in Brazil?

Well, in the wake of the bilateral agreement, the U.S. industry persuaded the United States Trade Representative to bring a WTO enforcement action against Brazil for failure to abolish a vestigial statute permitting compulsory licensing of patents on products not manufactured – or "worked" – in Brazil. While it is true that Brazil's outdated law was technically in violation of its WTO obligations, Brazil was not, in fact, actually enforcing the local working requirement.

While the U.S. ultimately settled with Brazil on the matter, the pharmaceutical industry wasted valuable political capital in Washington and seriously harmed its own image in Brazil by this action, which only empowered the anti-patent forces in Brazil. Today Brazil is a leader in the efforts of developing countries to scale back on the TRIPS Agreement in the current Doha Round of trade negotiations.

The pharmaceutical industry's heavy hand was felt in South Africa when it brought a lawsuit – latter withdrawn – over regulation of the sale of its products in that country. All the South Africa litigation did was to focus attention on the pharmaceutical industry and its patents as the leading impediment to the availability of medicines rather than the archaic policies of South Africa's government which refused to acknowledge the role of the HIV virus as the cause of AIDS.

These are two examples of where the industry's confrontational approach – and over-reliance on trade policy – have promoted a backlash against the patent system around the world.

The irony of the global backlash against the pharmaceutical industry and its use of patent rights is that anti-industry activists have been able to obscure the very important fact that the pharmaceutical industry itself has to date contributed more in-kind and financial assistance to developing countries than any national government.

As I have already noted, the pendulum has not only swung against pharmaceutical patents in the global context, but the free exploitation of exclusive patent rights in the United States has come under much criticism from domestic interests in my country. This is reflected not only in the petition to the NIH to exercise march-in rights in the Norvir case, but also in the growing political pressure in the U.S. to encourage importation of price-controlled pharmaceuticals from Canada.

In the case of the importation of Canadian drugs, the U.S. industry's reaction has been to mount a defense based upon the argument that imports may be unsafe for U.S. patients. I find it interesting that the industry should be relying on the safety defense rather than taking the issue

head on – namely that Canadian price controls are shifting the costs of drug development to U.S. consumers. In fact, developed country governments around the world, particularly in Europe, have effectively used national single-payer systems or outright price controls to reduce costs of drug purchases to national treasuries. This has resulted in the United States – with the possible exception of Japan – being the only major market for pharmaceuticals still operating without any significant government intervention to depress drug prices. And, I think that explains why the industry has failed to call a spade a spade in Canada, or to shift significant lobbying and public relations resources to the inequitable treatment of the patent-based pharmaceutical market outside the United States. Not only is the industry afraid of putting ideas in the heads of U.S. policy makers, but it has spent the lion's share of its PR and lobbying resources trying to make sure that the U.S. market remains one in which the national government does not have significant market power to put downward pressure on prices.

The industry effort to keep the U.S. market as free as possible from downward price pressure is understandable in the face of statistics which show that over 50% of the global industry's profits derive from sales in the United States. The 2003 financial report of Abbott Laboratories – a sponsor of this conference – proves the point. In 2003 Abbott's sales in the U.S. were $11.978 billion versus $7.699 billion elsewhere in the world.

The focus on maintaining profitability in the U.S. market was the main reason for the industry's embrace of the Bush Administration's legislation creating a Medicare drug benefit. While the new legislation will provide as much as $400 million in subsidies for drug purchases by the elderly beginning in 2006, it has been carefully crafted to prevent the government – as is currently the case under the Medicaid program (the drug benefit for the poor) – from having any role in setting the prices that will be paid for medicines. Instead, the heart of the program will be the establishment of hundreds of private companies who will offer insurance-like plans to provide drugs to the elderly. These hundreds of private companies will not have anything like the market power to demand lower prices that would be the case if the government itself were to purchase the drugs.

When you stand back and look at what is happening to the patent-based pharmaceutical industry at large what you see is that the primary investment in legal, public relations and lobbying resources is in the United States and is directed at maintaining the high profitability in that market. Elsewhere in the world the emphasis has been on using a hard-edged U.S. trade negotiation policy to protect patent rights. This trade-negotiation strategy has relied heavily on the U.S. government itself and has involved very little in the way of a significant commitment of resources to build pro-patent constituencies in these countries or to build the intellectual property infrastructure of such countries. This even extends to a lack of industry lobbying in Washington and other major capitals to see that assistance is provided by donor nations and development banks.

Indeed, the industry stood mute in recent years when the U.S. Department of State forced WIPO to cut its PCT fees – and therefore its revenue – with the result that WIPOs development assistance programs have now been cut back. That is all the more distressing when you realize that WIPO's program – at less than $20 million per year – is far and away the largest development assistance program for intellectual property rights in the world. And, that $20 million has to cover the needs of all countries. It is hardly enough money to put a respectable

computer system into one developing country patent office. My own International Intellectual Property Institute is the largest private NGO providing such development assistance in the field of intellectual property rights and its programs last year totaled a little more than $2 million, including in-kind contributions that did not directly flow through IIPI's bank account. By contrast the industry spent $155 million last year on its U.S. trade association, largely to fight the legislative battle on the Medicare drug bill.

I think it is always important to keep in mind that pharmaceutical companies exist – like all public companies – for one fundamental purpose. That is to return maximum investment to shareholders. And, the primary responsibility of CEOs of these companies is to maximize profit. However, within the corporate community I think that there is always tension between strategies that maximize short term profit and those which take a longer view of shareholder interests. The great companies in my view are those which effectively balance short term interests with the long term interests of shareholders. After all the foundation of the capital markets is not day traders, it is pension funds and individuals saving for retirement. Their interests are in a good rate of return five, ten or fifteen years from now as much as in today's closing stock prices.

Given this longer view, I am not sure that the pharmaceutical industry's approach to maintaining the long term value of its patent assets and the ability to exercise the exclusive rights inherent in those patents is a sound one. In short, I believe that the industry has devoted far too little attention too making friends and winning support for the patent system in the developing world and has spent too much attention trying to keep the goose laying golden eggs in the United States. In both cases – in the developing world and in the United States – the industry has found itself relying increasingly smaller political constituencies and relying on hard-ball tactics that have made more enemies than friends. In the United States that is apparent in the current election campaign where the industry's fortunes virtually depend on a victory by President Bush in his campaign for re-election and on maintenance of a Republican majority in Congress. Anyone who has followed the debate has heard candidate Kerry refer to pharmaceutical companies and health maintenance organizations in the same breath as corporate malefactors such as Enron's Ken Lay or MCI's Bernie Evers, both under criminal investigation for alleged misdeeds.

I have spent over 30 years as a Washington lawyer going back and forth from the public to the private sector. And, although I have always been involved in politics I have always had a basic rule when it comes to representing clients – you are non partisan and make your case on the merits. To do otherwise risks exposing your client's interests to the vagaries of politics and to retribution should someone they have offended take power.

Certainly patents are not political. Indeed, many of the most important efforts to strengthen patent rights in the 20th Century were initiated under Democratic Administrations and carried through into Republican Administrations. The Bayh-Dole Act was the product of a Democratic and a Republican Senator, and was supported and signed into law by Democratic President Jimmy Carter, who also proposed creating the U.S. Court of Appeals for the Federal Circuit, which greatly strengthened patent rights. The TRIPS Agreement was conceived in the Administration of President Reagan and made a reality in the Administration of President Clinton. That is the way it should be. However, I am afraid that the industry's focus on preventing taxpayers from benefiting from the government's purchasing power in last year's Medicare bill has made it the subject of warranted partisan attack in the current election

campaign. Should Senator Kerry win the election and/or should one or both houses of the Congress shift party control in the fall, the industry should be prepared for a backlash. It will have to weather the storm.

However, I think that in the longer term there is a better approach that I would recommend to industry CEOs as being in the long term interests of their shareholders. I believe that pharmaceutical company CEOs need to recognize that the days of relying on the U.S. market for over 50% of their profits are coming to an end. You can see this in the fact that even prominent conservative Republicans are supporting legislation permitting the importation of price-controlled drugs from Canada. The industry needs to adjust to a time in which the U.S. Government will have greater market power in the purchase of drugs, with consequent downward pressure on prices. The industry can remain very profitable, however, if the great promise of non-U.S. markets is more effectively pursued. This means that the industry needs to encourage U.S. trade policy to focus more on the market distortions of unfair price controls in places like Europe and Canada that shift development costs unfairly to U.S. consumers. And, it needs to work with rich country governments, development banks and NGOs to see that that patent-based industries take root in developing countries. These new industries – already growing in places like India, Brazil and China offer not only an enlarged constituency for the patent system, but also the possibility of creating new industries that can develop therapies of value to the markets they serve at prices those markets can bear. With domestic support for a strong patent system in these emerging markets they can become a source of increased sales – and profits – as their consumers become wealthier.