## Conversations With...

WLF

FALL 2008

Washington Legal Foundation

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## The Honorable Dick Thornburgh Robert A. Armitage Michael D. Fricklas Brad Smith

## The Issue: The Changing Legal Landscape for Intellectual Property

This edition of Washington Legal Foundation's Conversations With examines the ongoing evolution of intellectual property rights in America's free enterprise system. Former Attorney General of the United States and Pennsylvania Governor Dick Thornburgh leads an informative discussion with Senior Vice President and General Counsel of Eli Lilly and Company, Robert A. Armitage; Executive Vice President, General Counsel, and Secretary of Viacom Inc. Michael D. Fricklas; and Brad Smith, Senior Vice President, General Counsel, Corporate Secretary, Legal & Corporate Affairs for Microsoft. The participants explain why copyrights, patents, trademarks, and other forms of intellectual property merit the same respect under the U.S. Constitution as real property, and what can be done to foster further public respect for IP rights. They also comment on several key issues and debates involving IP rights such as online copyright protection; the patent system in the U.S. and abroad; and efforts to prevent overseas counterfeiting of technology.

Governor Thornburgh: When most people think of property rights, they

think of personal property and the "taking" of it, but in today's economy, property derived from thought, or intellectual property, has become critically important. Each of you certainly understands that, but Bob Armitage, do you think the general public understands?

Robert Armitage: Anyone with children who grew up in the era of downloading copyright-protected content knows the challenges of explaining how it is that something that appears to be free for the taking can nonetheless be protected as the property of its creator. Good children, not to mention some of their good parents, who would never condone and engage in the taking of personal property, will accept, or even participate in, the taking of intellectual property. have an amazing legacy of human creation and innovation, most of which is today freely available because it was once protected as property that could only be used by paying for access to it. Making appreciation of and respect for intellectual property rights as pervasive and intuitive as it is for conventional forms of property protection remains an unfulfilled challenge.

Governor Thornburgh: Mike Fricklas, what arguments are effective in coun-



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Michael Fricklas

tering those who assert that patents, copyrights, and trademarks allow big companies like Viacom to lock up ideas, thus diminishing competition and consumer access to products?

Michael Fricklas: We deal primarily with copyrights, and opponents of copyright deliberately disregard the distinction between "idea" and "expression" that is at the very core of copyright, creating the misimpression that copyright "locks up" culture and ideas. The genius of the law is that it encourages people to make their ideas public, by compensating them when people make copies of the way those ideas are expressed. Artists and journalists are generally eager for the public to take their ideas and use them and make them part of the culture and a part of the intellectual discourse. Copyright compensates artists and journalists and other creators for putting all these ideas into the public domain and encourages people to write and create in new ways. The way it does this is by allowing the creators to protect the way the idea is expressed while putting the ideas themselves in the public. In this way, artists are encouraged to create, while the public benefits.

The beauty of copyright is that, like any other property right, it helps create free markets. Free markets in intellectual property works empower the public — the public decides what content is created by expressing its view as consumers. No one forces someone to watch a movie or listen to a song — if the movie isn't good, we suffer losses.

Every alternative to these free markets is clearly inferior. Some professors have suggested that the government could tax everyone and dole out the funds to creators. Do we really want the political process to decide what investigative journalists get paid, or which movies can poke fun at the president or make the case against global warming? Should Congress decide whether to make an extra movie or put more money into schools or bridges? Another approach would be to depend on private contracts — but that runs the risk that speech would be locked up privately.

Governor Thornburgh: Is there a generational difference in respect for intellectual property rights, that is, do younger consumers have a harder time grasping that a software program or a digitally downloaded song or movie is "property"? Brad Smith, what are your thoughts on that?

**Brad Smith:** I agree with Bob Armitage that children today grow up in a different era — an era when technology has made it easy for copyright-protected content to be downloaded free of charge without the permission of the owner. Current technology presents children with an opportunity and a responsibility that earlier generations did not have. Current generations have a responsibility to use this technology responsibly — including respecting intellectual property rights. Just as importantly, creative industries also have a responsibility to make access to legal content easy and as attractive as the non-legal alternatives. We all have a responsibility to be certain that younger consumers understand the role that intellectual property plays in making it possible to bring them the software program, song, or movie they are downloading and to guide them towards readily available, legitimate sources for those products.

Governor Thornburgh: Mike, your thoughts?

Mr. Fricklas: I do think there are generational issues. First, some kids assume that if it's readily available, then explicitly or implicitly it has been authorized. They actually believe that we have the power to eradicate pirate websites. Scam artists know that they can charge \$10.00 for unlimited access and fool people into thinking they are engaged in legitimate behavior. Finally — people don't want to pay for something that all their peers get free.

This puts the burden on industry to find ways to root out the intermediaries who want to make a profit on pirated material and to work with ISPs, search engines, so-called "user-generated content" sites and college networks to protect the public from all kinds of network pollution: whether malicious viruses and spyware, scams, frauds, undesired pornography, or pirated content.

I think older generations are able to understand that nothing is free for long. Their values are consistent with the general notion that rules are for the public benefit and that sneaking into a movie or listening to a stolen song are both wrong.

Governor Thornburgh: Staying with perceptions of IP rights for a moment, Bob, how do opinions about intellectual property differ between the U.S. and in other areas of the world where your company does business, such as Europe or China?

**Mr. Armitage**: The perceptions are mixed, depending on the form of intellec-

tual property and region of the world. Since you specifically mention China, let me use that as an example to draw what I believe to be a telling comparison. Today, the leadership in Beijing, the world's oldest communist state, articulates the need for China to adopt strong patent laws and enforce meaningful patent rights. They view this as one element of building a strong, 21st century economy. They are looking to IP to help spur additional investment, and to leverage their workforce, which is growing in its scientific and engineering capabilities. Ironically, today in the United States, which historically has had one the most effective patent systems in the world, we are in danger of permanently tarnishing our leadership posture as respecters and protectors of IP. current Congress is examining legislative proposals that could diminish our patent system in profound ways. The worst of the legislative proposals that have emerged would be damaging to the U.S. economy and in the ability of the U.S. to lead the world in technological innovation. The ultimate irony, however, is that it is undeniable that the U.S. patent system does need major reforms, but those reforms should address root-causes of well-understood problems.

In 2004, the National Academies of Science laid out a reform agenda that would produce a more transparent and predictable patent system, with more efficient ways in which to enforce valid patents and challenge questionable ones. Unfortunately, these reforms are being held hostage to an anti-patent agenda. This leads to another contrast between us and a major trading partner. Europe, where needed patent reforms have long been stalled by squabbles among member

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countries of the EC, has put in place reforms that will dramatically reduce the cost of obtaining a patent in Europe.

Governor Thornburgh: Each of your industries faces significant challenges overseas with counterfeiting. A question for each of you: Have you found success working with local government officials in nations where it is most prevalent?

Mr. Fricklas: The first priority in attacking counterfeiting and piracy overseas is to work with the local creative community to help people understand what they can do to prevent piracy in their own countries. The voices of the local movie producers in India and of the Olympic committee in China to protect the legitimate rights of producers and creators are more forceful than any American demands. At the end of the day, regardless of what is in an international treaty, it is the public's view of the legitimacy of these rights as well as law enforcement's willingness to investigate and enforce the law that really matters. As a practical matter, if authorities are against piracy it helps us and helps the local creative community.

Mr. Smith: Yes, we have. Software counterfeiting is a global issue that often involves highly organized manufacturing and distribution operations managed by criminal syndicates. And, the impact of the problem is significant as software counterfeiting takes opportunities away from legitimate businesses that actively contribute to their local economies.

As a result, Microsoft has worked hard to collaborate with government agencies to go straight to the root of the problem, and we are increasingly finding significant support around the world. We draw on the expertise of our global investigative team and forensic and technology experts, and we work with customs organizations and local law enforcement agencies across the world to help track software counterfeiters. A recent example was in July of 2007, when, after years of Microsoft investigation and our collaboration with the FBI and the People's Security Bureau of China, law enforcement authorities announced the largest counterfeiting enforcement action in history. China's Public Security Bureau made a number of arrests and raided premises and storage facilities in the southern Chinese province of Guangdong. We were able to establish forensically that the China-based criminal syndicate had produced counterfeit versions of Microsoft software in fourteen languages, supplied the counterfeits to at least 36 countries and five different continents, and we believe the syndicate was responsible for manufacturing and distributing more than \$2 billion worth of counterfeit Microsoft software.

Mr. Armitage: We have an obligation in our industry to be leaders in addressing counterfeiting problems on a global basis. For us, it is a life-and-death issue for the patients we serve. Sadly, counterfeit medication entering the marketplace inevitably presents health and safety issues to patients. The packaging and pill may look identical to the life-saving medicine, but the content may not include any medicine, may have the wrong dose or the active ingredients contaminated with unsafe impurities. Counterfeit medications are not limited to street corner, back alley, or questionable Internet sites. Increasingly, counterfeit medications are entering legitimate distribution channels throughout the world through sophisticated and globally integrated supply chains. The patient and often the health care provider, who are relying on the safety and efficacy of the medicine, are powerless to recognize the counterfeit. There have been numerous deaths attributable to counterfeit medications, including deaths from medicines purchased over the Internet.

The recognition of this problem has allowed us to set up a global network of both governmental and non-governmental resources to help combat the counterfeiting problem. However, it is a continuing fight. From the vantage point of any organized criminal enterprise, counterfeiting medicines remains a less risky business, with a higher potential for profit, than counterfeiting currency or other goods. Until the dynamic changes with increased penalties and enhanced enforcement, the problem of counterfeit medications is not going away anytime soon.

**Governor Thornburgh:** Brad, have you found a positive reception for your international counterfeiting concerns with U.S. trade and law enforcement officials?

Mr. Smith: Yes, absolutely. We've had strong support from U.S. officials, and they've been quite active in helping spread the word internationally about the harm caused by software piracy and counterfeiting. They and their counterparts in other countries recognize the damage that counterfeiting does in deceiving consumers and destroying legitimate jobs in the economy.

Governor Thornburgh: Staying on the

international front for a moment, Bob, the pharmaceutical industry faces a growing threat from nations invoking "public health emergencies" as a justification to essentially seize patented drug products. Could you address that?

Mr. Armitage: The very best way for the pharmaceutical industry to provide access to needed medicines is to invent a new drug and make more than the billion dollar investment needed to establish its unique value for patients. In the developing world, many of the medicines that would most improve public health and spur the economic growth that can come from a healthy and long-lived population fall into two categories.

In the first category are medicines we call "generic drugs" that are relatively inexpensive and available from many suppliers. These drugs have typically been on the market for more than the 10- to 15-year period that IP protection for innovative medicines typically runs. As an example, these generic drugs represent roughly 70% of all prescriptions filled in the United States today. They can be freely used in any country anyway to meet a huge array of health needs. In the second category are needed medicines that do not yet exist and must be discovered and developed. They are the medicines for endemic local diseases and chronic conditions that cause premature disability death. and Disrespecting IP rights on patented drugs available today destroys any possible incentive for addressing these unmet needs for medicines. The failure to take full advantage of the availability of generic drugs, combined with a disrespect for IP systems that lie at the heart of incentives to tackle unmet medical needs, "We are concerned that some nations may seize on exclusions and interpret them broadly to deny patent protection for computer-implemented inventions."

Brad Smith

is shortsighted policy.

The pharmaceutical industry, which has been offering solutions in the form of new medicines, has been painted as the chief impediment to access to needed medicines. However, making a solution-provider the problem-maker is morally and intellectually dishonest, not to mention unproductive.

Governor Thornburgh: Are you concerned that the protections contained in the World Trade Organization's Trade Related Aspects of Intellectual Property (TRIPs) are slowly being eroded?

Mr. Armitage: Yes. In some countries the transition from little or no IP system to an IP system compliant with TRIPs has been difficult and slow, particularly in the enforcement of new patent laws. example, it is still too difficult to enforce pharmaceutical patents or data exclusivity rights in China, and in India the so-called Section 3(d) has been applied to usurp the patentability of novel compounds. countries like Japan and Korea, who have had modern TRIPs-compliant patent laws for some time, and Jordan, which more recently enacted a TRIPs compliant regime, have demonstrated that a steadfast commitment to intellectual property can stimulate research investment. China and India as well are benefiting from substantial investment directly attributable to IP implementation of patent laws and the expectation that the laws, including data protection, will be enforced. TRIPs through lax enforcement, delayed implementation, or weakening of its provisions will undermine the substantial progress to date. Doing so will also widen the chasm between the "haves" and the "have nots" in the world economy and in the pursuit of innovation.

Governor Thornburgh: Brad, much of Microsoft's technology is protected by patents. Are software products patentable in other nations? In those nations where patents don't provide protection, are other forms of IP rights adequate?

Mr. Smith: There is a general obligation in the TRIPS agreement that WTO Members provide patent protection in all fields of technology. This includes software products. There are some nations such as those that are members of the European Patent Convention — that exclude software "as such" from patent protection, but still provide patent protection for computer-implemented inventions, products and processes, which are implemented using computer software. While we find that to be a generally acceptable approach for patent protection, we are concerned that some nations may seize on exclusions and interpret them broadly to deny patent protection for computer-implemented inventions. That would not only deny that important form of protection to inventors and companies working in this area, it is also contrary to obligations under international law such as found in the TRIPs Agreement and bilateral free trade agreements. It would also run counter to the fact that many technologies that in the past were "hardware"-based are increasingly being replaced by digital alternatives that rely on software.

Finally, it is also important to note that most computer-implemented inventions for which patent protection are sought are not in the software industry as such. Rather, they are in consumer electronics, health care diagnostic equipment, automotive, and a wide range of other industries that use software to introduce functions and inventive capabilities to their products. So this is an issue that is important not only to software companies like Microsoft, but to a wide range of industries and companies.

Governor Thornburgh: Mike, what is your perception of our trading partners' copyright law protections? Also, where are the trouble spots for you among so-called emerging economies?

Mr. Fricklas: We are seeing a very mixed picture around the world. We are very encouraged, for example, that the governments of France and the United Kingdom have announced plans to legislate if the major Internet service providers fail to take effective action against online piracy. On the other hand, some trading partners, notably China, Russia, Spain, and Sweden, either have inadequate legal protections or, more significantly, fail to enforce the laws on their books. For example, I believe that privacy and anti-piracy initiatives can both be accommodated, but all too often piracy is cloaked behind overly expansive views of privacy rights. Recently, Sweden finally took action against the owners of a flagrant and notorious pirate site based there and the Olympics are spurring Chinese efforts to cause user generated content sites to filter for infringing content.

As to developing nations, some argue that somehow copyright "locks up" knowledge. Somewhat in opposition to this is the concomitant idea that their own ancient cultural creations should receive the benefit of intellectual property protection. I think developing nations need to understand that it is in their interest to protect the modern creative works of their own artists in order to support their own cultural community and keep it thriving and that their own economies cannot make a sensible distinction between pirating some content and respecting the rights of the creators of others.

Governor Thornburgh: Bob, how are your and other pharmaceutical companies' patent rights implicated in legislative efforts to permit the importation of drugs that were sold to other countries such as Canada?

Mr. Armitage: Drug importation from Canada or other countries implicates patent rights as well as serious health and safety issues for patients. As I previously noted, we must keep counterfeit medicines out of the legitimate distribution channels so that a patient can receive medicine from their retail or hospital pharmacy with confidence that the drug is safe and effective. Permitting the importation of drugs dramatically increases the risk that counterfeit drugs may penetrate these distribution channels. The exporting country may often lack appropriate regulatory standards or the resources to inspect and monitor all exports, and the U.S. FDA lacks the resources to inspect and monitor foreign manufacturers and importers.

Furthermore, if the drug is patent protected in the United States, legislation that permits the importation of drugs in violation of those patent rights presents serious issues of intellectual property and "Public policy should encourage and support the discovery and development of new cures and treatments. Ill-conceived policies such as legislation to permit importation from other countries could be the death nail to these cures."

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constitutional law. The underlying issue to be solved by importation is price, particularly for those who struggle to afford to buy drugs. There are much better ways to address this underlying issue, including demanding that Canada and other developed countries that can afford fair market prices for medicines not artificially set prices well-below a fair market value with the expectation that the United States market will sustain pharmaceutical innovation for the world. Patients expect the pharmaceutical industry to discover new cures and treatments for debilitating diseases.

Public policy should encourage and support the discovery and development of new cures and treatments. Ill-conceived policies such as legislation to permit importation from other countries could be the death nail to these cures. It would dramatically set back innovation.

Governor Thornburgh: One way IP holders profit from their property, and also use it to advance innovation, is to license it or enter into agreements. Brad, in 2006, Microsoft entered into a ground-breaking agreement with open-source software company SUSE Linux. Could you briefly describe that, and comment on how it is working?

Mr. Smith: You are referencing our historic deal with Novell, signed in November 2006. This agreement was the first significant step in helping build a bridge between open source and proprietary software business models. The agreement has greatly enhanced interoperability between Linux and Windows and gives customers greater flexibility in their IT environments. The deal also includes a patent cooperation agreement, in which

Microsoft and Novell provide patent coverage for each other's customers, giving customers "peace of mind" regarding potential patent issues. We also created joint marketing and sales resources to promote joint solutions. By all measures, the deal has been a success to date as we have seen wonderful crosscollaboration, great receptivity customers and most importantly we have exceeded business goals set for the deal. In addition, this deal laid the groundwork that helped us sign similar deals with Linux vendors Xandros, Linspire, and TurboLinux.

Governor Thornburgh: Also, last year Microsoft committed to business practice changes aimed at expanding interoperability between your software programs and others that might use the Windows platform. How do those changes implicate your and other companies' IP rights?

**Mr. Smith:** What we announced then was a significant move forward and another step in our longstanding interoperability Through our experience and direct customer feedback, we have developed a way, we believe, to strike a balance between open source and proprietary software business models. In an effort to work more collaboratively with the open source world and at the same time meet customer expectations in the area of interoperability, it required a certain level of transparency on our part to create open connections to our highvolume products. So we announced a set of principles and actions that apply to interfaces and communication protocols and APIs [application programming interfaces], and also addresses the actual set of innovative features and functionality inside the products that will enable differentiation to exist among vendors. When it comes to the internal functionality of the software, what customers want is competition. They want product differentiation. They don't want their vendors to offer the same product; they want their vendors to compete with each other. This approach allows both to happen.

What is also unique about this effort, particularly in terms of IP, is all developers that are creating implementations of our specifications in the context of an open source project are covered by a Microsoft patent pledge which provides them patent coverage without the need to sign a contract or pay a royalty. The pledge covers an individual working out of a garage in Seattle the same as it does an employee of a commercial company working as a developer in the context of an open source project. All developers are covered. addition, for anyone making commercial distribution of an implementation of Microsoft specifications in an open source product, we are making available to them a royalty-free, RAND license.

Certainly, some people will always wish we'd gone a step or two further, but I dare say that this is more than any other company in our industry has offered to date, and we do hope this effort will serve as a catalyst for others to follow, as well as improve upon.

Governor Thornburgh: Microsoft also entered into an agreement with Viacom, Disney, and others which involves the participants' approach to potential copyright infringement by Internet companies. Mike, can you tell us about that?

Mr. Fricklas: The User Generated

Content (UGC) Principles represent a historic agreement among a broad group of media and Internet companies including, in addition to those you named, NBC Universal, Fox Entertainment, CBS, MySpace, Veoh Networks and Dailymotion to solve a specific new problem in content creation. I say historic because industries with widely divergent interests recognized the legitimate interests of others and worked together to create a practical solution to the problem of users "sharing" others' copyrighted works using the facilities of "user generated content" sites such as that of Veoh and Dailymotion. Essentially the principles ask sites to use practical techniques to seek out and remove unauthorized copyrighted content while copyright owners agree not to sue the companies that operate these sites and abide by the principles. It's good for industry since much of the legal cloud is removed for sites that employ reasonable efforts to solve the problem. Of course, as you know, Google, the operator of the largest such site, YouTube, has not signed on to the principles and numerous copyright owners, including Viacom, are in litigation with them. We are disappointed in their position. Nonetheless, Google is working on a filtering system and we hope that ultimately they come into compliance with the principles.

**Governor Thornburgh:** Brad, do you anticipate that we will see more agreements similar to this one, which address IP protection proactively among market participants?

**Mr. Smith:** I believe so. When it comes to copyright and the Internet, we are in a very fluid time, where business models, technology, and consumer expectations are all changing rapidly. We believe that copyright

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Michael Fricklas

has a very important role to play in sorting these issues out, and will be a key part in making the Internet a stable platform for creativity. But the dynamic nature of today's environment calls for flexibility in the copyright rules and standards we need to develop, and the way to ensure that flexibility is through a voluntary, industryled agreement like the User-Generated Content Principles, rather than more formal mechanism like legislation. types of voluntary agreements can adapt to change more easily than legislation, and allow for experimentation in new rules or modifications to existing rules. think they encourage cooperation and collaboration among industry participants.

Governor Thornburgh: Bob, it seems that every patent held by a pharmaceutical company is eventually subject to legal challenge. However, when a "branded" company settles litigation with a generic company, the terms are increasingly challenged as anticompetitive. Could you comment on this?

Mr. Armitage: It is a dynamic that is unhealthy for the pharmaceutical industry and over the long-term, patients, who look to and expect the industry to discover and develop new life-saving medicines. Currently, the generic company challenges the patent as early as possible, generally four years in the U.S. The cost, burden, and risk this presents to the pharmaceutical industry as it makes decisions for research and other investment is significant. It creates substantial uncertainty. If you then allege that any settlement of the litigation is anti-competitive, you exacerbate the problem. A company cannot manage the uncertainty by settlement and is forced to go to the expense and risk of

litigating every issue through to a decision by the court.

The policy questions raised by this prolitigation dynamic should also be viewed in context. The investment to discover and develop a new medicine is nearly \$1 billion dollars. The number of new medicines being approved by the U.S. FDA is alarmingly low — less than 30 new chemical entities were approved in 2007. In context, it becomes clear that an industry that invests over \$90 billion dollars in research and development cannot be sustained if the intellectual property protecting the few medicines that are discovered and approved are attacked after four years.

For this reason, Lilly and others in the industry have opened the dialog to extend data package protection to 14 years. The assurance of a 14-year period for data package protection would provide business certainty for investment and extend the period to recoup research and development expenses. The period of exclusivity and product liability tort reform, which is a topic worthy of additional discussion, are two of the pressing needs for legal reform for the pharmaceutical industry.

Governor Thornburgh: To follow that up, do you feel the Hatch-Waxman Act has done a good job in balancing patent protection for innovator companies and generics' ability to develop equivalent products?

**Mr. Armitage:** Yes. That said, its basic framework has been unchanged over almost a quarter of a century. It no longer provides the right balance of exclusivity

protection for innovators. The periods of innovator exclusivity are variable and uncertain. On the generic side, the timing of generic drug entry is unpredictable. It provides misguided incentives to seek generic drug approvals irrationally early in the life of an innovative product so as not to be disadvantaged if another generic company gets the "first filer" status. It provokes early and speculative patent challenges against innovator products. It takes the focus of generic companies away from fulfilling their part of the Hatch-Waxman: providing safe and effective versions of innovator medicines at the lowest possible cost to patients once innovator exclusivity periods have ended. It instead focuses the innovator and the generic company on hugely wasteful patent litigation. being one of the leading biotechnology companies in the world, has been actively involved in the process of developing a similar pathway for approval of follow-on biologics. As Congress moves forward on that pathway, it must define the interface between innovator exclusivity and market entry of follow-on products in a far more rational and far less litigious way.

**Governor Thornburgh:** For such followon biologics, what are the important issues to watch in the debate?

Mr. Armitage: Any legislation that would create a new regulatory pathway to authorize follow-on biologics should protect patient safety and product integrity, respect proprietary information, and contain intellectual property provisions that help ensure the research and development of innovative, life-saving biological products. The first responsibility is to patients. Approval standards, including clinical trials and manufacturing require-

ments, must be sufficiently rigorous for both pioneer and follow-on versions of biologic products to assure that the patient will receive a safe, pure, and potent product.

On the IP front, Lilly has been adamant that a period of data exclusivity of 15-20 years for innovative products would represent the best policy choice for overall patient welfare. Innovators need assurance, before follow-on products take over the market, that the original research investment will be recovered. Typically in our industry today, 7 of every 10 new medicines marketed do not pay back the cost of their development. More importantly, patients have a stake in medicines being the subject of on-going research after they get to market. In what patient populations do they provide the greatest advantages? How do they stack up against medicines? What further indications for use can be established and approved? Most of the research that a pharmaceutical company undertakes on a medicine today comes after it gets new to market. That research typically comes to a halt as the end of exclusivity looms.

With relatively few new medicines coming to market, as safety and comparative value hurdles get ever more demanding, it does not make sense that a 5- or even 10-year period of data exclusivity be all that may stand in the way of the approval of multiple follow-on products. A period of data exclusivity of 14 years or longer also provides the opportunity for a paradigm shift in the relationship between patent protection and data exclusivity provisions. Virtually without exception, significant patent production for new medicines expires at the 14-year mark under Hatch-

"The principles in our lawsuit against YouTube are about squarely placing the responsibility for piracy on those who knowingly facilitate it and profit from it."

Michael Fricklas

-Waxman. Aligning the end of significant patent protection with the expiration of the data exclusivity period should open the door to a highly simplified interface between patents and FDA approval for follow-on products, one largely free from patent litigation defining timing of entry for follow-on products.

Governor Thornburgh: Let's switch gears here for a bit. Mike, the prevailing belief among those who spend substantial time online is reputedly that "content wants to be free on the Internet." How can content providers like Viacom counter that notion?

Mr. Fricklas: I think it's true to a degree that consumers of content want it to be free on the Internet — but it's a very short-term view and not one that should appeal to policy makers. Consumers would like free milk, too, but someone has to feed the cows, milk them and get the milk to market. What consumers may like in the short term is not always in their own best long term interest or the interest of other affected persons, in this case creators.

There has always been theft and there will always be piracy. But we are working hard to generate great alternatives to piracy. For example, we have a website called Colbertnation.com, where users can see all the Stephen Colbert shows for free, can embed links to their favorite clips and can email them to friends or post them in their blogs. The quality of our professionally encoded clips, the easy indexing and search functionality and new and original content make it a superior alternative for consumers to finding random clips in other locations.

Similarly, we are seeing a burgeoning marketplace in paid downloads on iTunes, Amazon's Unbox, cell phones and other online sites. I think the emerging solution is to make content available to online consumers in multiple ways with multiple business models. Some people will be willing to pay out of their own pockets for ad-free content. Others will prefer to accept advertising so that there is no out-of-pocket cost. Of course, it impedes these legitimate business models if we have to compete with free high pirated content, so we also need to continue to address the infringement issues. As a result, we enforce our rights against those who try to profit from our content — the aggregators, linking sites and unprotected "sharing" sites who want to sell advertising themselves.

Governor Thornburgh: About a year ago, Viacom filed a \$1 billion copyright infringement lawsuit against YouTube. Its parent, Google, argues that it is protected by the Digital Millennium Copyright Act (DMCA). Is Google's interpretation of the DMCA accurate?

Mr. Fricklas: The DMCA does not protect those who knowingly profit from infringement. YouTube is a media company that sells advertising against content that in large part is not its own and its growth has been fuelled in significant part by piracy. It appears that YouTube employees were never instructed to remove even the most obvious infringements — such as full copies of recent theatrical motion pictures or television shows. Some of those received hundreds of thousands of views and appeared on the "most popular" lists on the site's home page. Google has raised some interesting questions at the boundaries, but at the core is conduct that simply isn't close to being protected by the DMCA.

**Governor Thornburgh:** Some commentators say that the future of how media is provided online is at stake in your lawsuit. Are the stakes that high?

Mr. Fricklas: I do think the stakes are Piracy undermines the free very high. market in creative content, as well as in software and other intellectual property goods. In free markets, producers create the products consumers want. If levels of piracy are more than minimal, material that consumers want, whether movies or portable music or books or whatever, doesn't get produced or becomes an inadequate target of investment. Ultimately, consumers lose.

The principles in our lawsuit against YouTube are about squarely placing the responsibility for piracy on those who knowingly facilitate it and profit from it. That's the only place it can be to ensure that the costs and benefits are properly measured.

Governor Thornburgh: Are there adequate technological solutions to protecting digital content, such as movies and music, that are provided online? Has "digital rights management" been an effective approach?

Mr. Fricklas: There are effective copyright filtering technologies available in the marketplace and they are improving all of the time. The broad coalition of companies subscribing to the UGC Principles last October expressly recognized that "highly effective" content identification

technologies could significantly advance the goal of eliminating all infringing useruploaded content. Systems such as Audible Magic match the audio track of uploaded content against a reference data base consisting of content provided by copyright owners. The coalition also recognized that content identification technologies were continuing to improve and evolve and that advances in technology would likely address variations in patterns of infringing content and changes in users' online activities. We are seeing now the rapid evolution of content identification technologies which match on the video track or both the video and audio track. Responsible sites, such as ours, already employ these technologies and the law requires that they be By the way, it is the implemented. demand for these technologies that is encouraging our companies and venture capitalists to invest in their improvement.

Digital rights management (DRM) is a very effective approach in the right circumstances. DRM, to work well, should be more or less invisible to the consumer and provide the consumer with rights that match the consumer's expectations. For example, the Apple iPod employs a DRM technology called Fairplay that allows consumers to choose to buy or rent movies — and consumers seem very comfortable with the technology. Poor implementations and mismatches with consumer expectations need to be avoided.

Governor Thornburgh: A suggestion was made recently at a Consumer Electronics Show that some Internet Service Providers (ISP) may start filtering for copyright-infringing materials at the

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Brad Smith

network level. Can this be effective?

Mr. Fricklas: It will eventually become one of the many tools to combat piracy. Network-level detection, using the same types of content identification tools we just discussed, has numerous benefits, including greatly reducing the cost of detecting and deterring. Network-level management may provide a relatively low cost and efficient approach to prevent unauthorized use and destruction of investments in high value programming. It has the potential to help considerably with the problems posed by piracy havens outside the United States. At the same time, these solutions are complex: they need to impose an acceptable burden on the network, need to respect the privacy of users, and need to be fairly imposed so they don't block legitimate traffic or prevent innovation.

Governor Thornburgh: What are your thoughts on this type of filtering, Brad?

Mr. Smith: We don't offer ISP services directly, but clearly our MSN online service provides a great many services to consumers. As a result, we follow these debates very closely, because they are all part of efforts to make copyright effective in the online world, which is very important to us. As for filtering, we are open to evaluating whether it can be an effective tool to help enforce copyright, but the circumstances in each case must be examined carefully. We do think filtering can help in the online video context, thus our participation in the UGC Principles. At the network level, the circumstances are very different, given the much broader scope of materials and activity that are subject to the filtering in that context. We

would need to answer a lot of questions about that context before we could be comfortable supporting filtering at that level.

Governor Thornburgh: Back in 2005, the U.S. Supreme Court stepped into the debate over online copyright infringement with its *MGM v. Grokster* opinion. Mike, has that ruling had an impact on protecting copyrights?

Mr. Fricklas: Yes, the Supreme Court's unanimous and unambiguous condemnation of business models built on infringement has been an important tool enabling content providers to enforce their rights pursue unscrupulous businesspeople who operate sites that are clearly dedicated to, and predominantly used for the dissemination of infringing content. We are seeing many such sites voluntarily discontinue their infringing activity when they receive a demand letter and there are also a number of important litigation successes. At the same time, some courts have been reluctant to follow Grokster, so I imagine there will be further opportunities for the Court to clarify the case. For example, in the CC Bill case in the Ninth Circuit, credit card companies that knowingly provided payment services to infringing websites were found not to be contributory infringers — a decision that seems squarely at odds with the Grokster holding that knowingly facilitating piracy is actionable.

Governor Thornburgh: The Supreme Court's interest in intellectual property has grown substantially over the past three years. Bob, what impact has the Court's most recent patent rulings had on your industry, especially KSR v. Teleflex?

Mr. Armitage: First let me start with what I think is the most important job for the USPTO and the courts: apply all requirements for patent validity rigorously. The patent system cannot operate well if it becomes a forest chocked with underbrush. Having the Supreme Court remind patent owners that the non-obviousness requirement is a principle gatekeeper to preventing trivial subject matter from becoming the subject of patents is in no way harmful to the patent system. The Court's opinion in KSR v. Teleflex appears thus far to have had no significant impact on the pharmaceutical and biotechnology industries. Prior to the opinion in KSR the Federal Circuit had restated a more flexible approach to the so-called "teaching, suggestion, and motivation" test. In this sense, the Supreme Court did not fundamentally change non-obviousness law.

The jurisprudence since KSR from the Federal Circuit and other U.S. Federal Courts have also not reflected a major shift in the analysis of obviousness, although the additional scrutiny of the obviousness standard perhaps has led to patents being held invalid on the ground of obviousness more frequently post-KSR. My major concern with the case is its potential for misuse by critics and activists with an agenda to weaken the patent system. Any perception that the U.S. is systematically "weakening" the patent system with KSR or any other case or reform is detrimental to the implementation of robust IP laws in countries struggling with full implementation of TRIPs. The U.S. should recognize its role as a leader and make sure any changes in law by judicial decision or reform are consistent with the principles of a strong IP system.

**Governor Thornburgh:** What are your thoughts on that Brad? Microsoft had a case in the Supreme Court recently, right?

Mr. Smith: Yes, we've been active in a number of appellate and Supreme Court cases relating to patents. The most notable case in which we were a party was probably AT&T v. Microsoft, which addressed questions of the scope of damages liability under U.S. law for activities outside the country. We also asked the Supreme Court to clarify whether the presumption of validity extends to prior art and evidence that the PTO did not consider during examination. We argued that the strict "clear and convincing" standard is appropriate with respect to prior art considered by the PTO, but that such a high level of deference to the Office's decision was inappropriate with respect to evidence it didn't have the opportunity to consider. We've also been actively filing amicus briefs in most of the significant appellate cases before the Federal Circuit and the Supreme Court.

As for Bob Armitage's overarching points, I tend to agree that KSR hasn't turned patent law upside down. It does appear to have increased the chances of an invalidity ruling based on obviousness, but in a number of the cases in which this has actually occurred, it seemed likely that that defendant could have made a strong invalidity case based on novelty or mounted an effective defense based on inequitable conduct.

I agree with Bob that there's a danger that people who want to weaken intellectual property rights and undermine any "The problems with the patent system such as the backlog of patent applications and the rising cost of procuring and enforcing a patent — are real."

Robert Armitage

effective remedy for infringement will use recent cases, as well as the legislative reform efforts, to create a public perception that the system is broken and that fundamental changes are required to minimize the ability of patent owners to protect core innovations and sustained investment in R&D. In fact, that was precisely the concern that I had when the \$1.5 billion jury verdict against us in the Alcatel-Lucent case related to MP3 audio patents was the subject of a lot of media discussion. In fact, I felt strongly enough about it that I wrote a short editorial a few weeks after the verdict entitled "Two Cheers for Intellectual-Property Law," in which I voiced concerns that people might draw the wrong lessons from the Alcatel-Lucent case and other high-profile dis-The excessive verdict against putes. Microsoft was eventually overturned after the court determined that the jury had ruled incorrectly.

Nonetheless, while I do think that there have been some unfortunate excesses in litigation, these problems are by no means unique to patent suits. There are certainly some improvements that should be made, but a vibrant, robust IP system is essential to investment in innovation and absolutely critical to a nation's long-term economic growth, so we should actively push back on the notion that these imperfections somehow justify weakening IP protection internationally or here in the U.S.

Governor Thornburgh: One final question on which I'd like each of your opinions. For the remainder of this decade, will the flow of public opinion, and the actions of policy makers, be in favor of continued respect for intellectual property rights, or will IP rights yield to

pressure from activists and others who feel they stifle competition?

Mr. Smith: I don't think that this decade will see the resolution of the debate about intellectual property rights. After all, it is a debate that has been going on in one form or another for over three hundred years. One thing that this long debate has made clear is that the IP system will both continue to adapt and continue to survive. The challenge for companies such as Microsoft that make large investments in R&D and rely, therefore, on IP protection, is to make the case to consumers and to policy makers that IP protection is important to long-term success. And that success is not just specific to companies like our own, but extends to the economy as a whole that relies on invention and innovation to improve productivity, bring new products and services to market and, indeed, to create the industries and jobs of the future.

Mr. Armitage: We cannot be guaranteed that the forces advocating IP regimes tuned for innovation-driven progress will overcome the agenda of those who insist on sharing the current wealth at the expense of future prosperity. With education and explication of compelling economic reasons to recognize property-like respect for human creations, the better argument is that IP will grow the economy and create high-value jobs. The important question for the public and policy makers should be how best to reform the patent system to make it stronger. The problems with the patent system — such as the backlog of patent applications and the rising cost of procuring and enforcing a patent — are real. We must not forget the essential role of

the U.S. patent system and that these problems are indicative of greater demand — more patents being filed and issued on increasingly diverse technologies. It is a sign of success not failure of the system. However, the problems also present a compelling need and an opportunity to reform the patent system to make it more transparent, more efficient and stronger.

Mr. Fricklas: IP is always about balance. We are all both users and creators of IP, and have an interest in seeing reasonable parameters on protection and in reducing those areas where innovation is chilled because of uncertainty.

The core case for copyright IP is very strong: the U.S. core copyright industries accounted for an estimated \$819.06 billion or 6.56% of the U.S. gross domestic product (GDP) in 2005. As a society and as an economy we need to protect the enormous costs attendant to the creation of compelling, diverse programming by large organizations and the creative efforts and professional livelihoods of hundreds of thousands of authors, filmmakers, photographers, songwriters and performers.

At the same time, in an industry changing as rapidly as ours, debate is inevitable and close calls abound. I don't think IP is threatened, but I do think we need to meet with our critics and need to continue to make the defense to ensure that the public and policymakers have a balanced and reasonably nuanced perspective. It is enormously important that we get the answers right.

Governor Thornburgh: Gentlemen, thank you for your participation in this

important discusion.

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## THE ISSUE: THE CHANGING LEGAL LANDSCAPE FOR INTELLECTUAL PROPERTY

The Honorable Dick Thornburgh is a former Attorney General of the United States, Governor of Pennsylvania, and Under-Secretary-General of the United Nations. He is currently Of Counsel to the internaional law firm  $K \stackrel{*}{C} L$  Gates LLP, and Chairman of Washington Legal Foundation's Legal Policy Advisory Board. Governor Thornburgh began his public service career as a United States Attorney in Pittsburgh and an Assistant Attorney General in charge of the Criminal Division. As a private attorney, he was appointed in 2002 as Examiner in the WorldCom bankruptcy proceedings, the largest ever filed, to report on wrong-doing and malfeasance that led to the company's downfall. Governor Thornburgh was also chosen in 2004 by CBS to conduct an investigation into the 60 Minutes Wednesday segment on President Bush's service in the Texas Air National Guard.

Robert A. Armitage became Senior Vice President and General Counsel for Eli Lilly and Company in January 2003, and is a member of the company's policy and strategy committee. He joined the company as vice president and general patent counsel, Lilly Research Laboratories, in October 1999. Prior to joining Lilly, Mr. Armitage was chief intellectual property counsel for The Upjohn Company from 1983 to 1993. He also was a partner in the Washington, D.C., office of Vinson & Elkins LLP from 1993 to 1999.

Michael D. Fricklas is Executive Vice President, General Counsel and Secretary to Viacom Inc. He joined Viacom as a Vice President, Deputy General Counsel/Corporate in 1993, became Senior Vice President, Deputy General Counsel in 1994 and became General Counsel in 1998. Mr. Fricklas assumed the additional title of Executive Vice President in May 2000, following the Viacom/CBS merger. As General Counsel, Mr. Fricklas is responsible for Viacom's legal affairs and management of its law department.

**Brad Smith** is Microsoft's Senior Vice President, General Counsel and Corporate Secretary. He leads the company's Department of Legal and Corporate Affairs, which is responsible for all legal work and for government, industry and community affairs activities. Mr. Smith previously worked for five years as Deputy General Counsel for Worldwide Sales, and before joining Microsoft, he was a partner at *Covington & Burling*, having worked in the firm's Washington, D.C. and London offices.