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INTRODUCTION

Good morning. I'd first like to thank Richard Levin and Mark Myers for their commitment and effort, not just in chairing this conference, but in organizing the preparatory meetings leading up to it.

I'd also like to thank Steve Merrill for the enormous amount of work he put into organizing the program and for giving the Patent and Trademark Office (PTO) the opportunity to be involved. Not only do I have the pleasure of joining you today, but Kevin Baer of our office will be on one of the panels this afternoon; Justin Hughes from our office participated in the New Haven and Berkeley meetings leading up to today's conference; and just before the holidays, President Alberts, myself, and some of our staff had the chance to get together and talk about some of the issues we'll be discussing today. I'm actually honored to be invited. Never did I think that my lowly B.S. in Chemistry would bring me before such an august body.

Being the kick-off keynoter often means one has the luxury of having first crack at an audience, and the opportunity to frame many of the issues to be discussed. On the other hand, you may often be set up as the straw person against which other speakers get to take pot shots all day. So, it all balances out. We'll see.

What I want to talk a bit about is the relationship -- and perhaps the tension – many perceive between the goals of intellectual property (IP) and the goals of research, both on research and innovation. In many ways, we're here today because of those perceptions.

For example, we've seen concerns expressed that biological research will be disrupted by genomic patents; that the academe will be damaged by the extension of copyright into the digital, networked environment; that the development of the Internet – and its promise for e-commerce, science and civil society – will be retarded by business method patents; and that proposals to protect investment-laden -- but uncopyrightable -- databases will hurt scientific research and commercial innovation.

In short, we're here because of a perception in some quarters that "gears" of the intellectual property system and the research establishment may be grinding against one another -- that the IP system may not be doing as much as it could to increase social utility with minimal transaction costs.

THE RELATIONSHIP BETWEEN THE RESEARCH COMMUNITY AND THE COMMERCE OF INTELLECTUAL PROPERTY

In all of the examples I just mentioned, the concern is that the intellectual property system "locks up" new knowledge and information, in contrast to the goal of science -- to gain new information and disseminate that knowledge with little or no cost.

I believe this simplifies things far too much. Therefore, what I would like to talk about today is the source of the research-IP tension; some specifics on how the patent system is trying to ensure that subject matter expansion and the increasing number of patents do not impose unreasonable costs on society – research and innovation included; and how the research and development communities can help the IP system increase social utility – both for the United States and for emerging economies.

If there has been more of a perceived "collision" recently between the goals of intellectual property and the goals of science and research, there are probably several reasons. One reason is the overall trend in how research and development is funded.

One such trend bringing science and intellectual property closer together has been government-funded research becoming an increasingly smaller relative portion of our country's research budget.

The Clinton-Gore Administration has done a good job fighting for increased funding for agencies like NSF and NIH. In fact, the President's budget for fiscal year 2001 includes a nearly $3 billion increase in spending on science and technology. Still, the overall trend of the past few decades

has been for government to fund less of the total U.S. R&D budget and for the private sector to fund more. In the 1960's, the government and private sector roughly split America's R&D costs; today the private sector funds two-thirds.

In supporting this research, the private sector often looks for financial returns in a way that Uncle Sam doesn't. Of course, the financial returns are very often packaged as – or linked to -- the intellectual property rights the private sector receives. So, the increasing role of private funding in R&D has meant an increasing role for IP.

We've looked at this question as it relates to this public-private duality quite carefully in the fairly recent past. For example, in the 1970's, the government discovered that many of the inventions that resulted from its own funding were not reaching the marketplace because no one would make the additional investment to turn purer research into marketable products. Hence, the Bayh-Dole Act allowed universities, small companies, and non-profits to commercialize the result of federally-funded research.

The results of Bayh-Dole have been very significant. Prior to 1981, fewer than 250 patents were issued to universities each year. A decade later, universities were averaging approximately 1,600 patents a year. Dr. Bernadine Healy, the former Director of NIH, has credited Bayh-Dole with the development of the entire biotechnology sector.

Over $30 billion dollars of economic activity a year -- with 250,000 jobs and over 2,200 new companies -- can be attributed to the commercialization of new technologies from academic institutions. Indeed, Bayh-Dole has worked so well that our Japanese colleagues are now seeking to emulate it in their country.

In addition to the decline in the ratio of government funded research, there is a larger, macroeconomic trend that has brought research communities and intellectual property increasingly into each other's gravitational field. That trend is the increasing importance of the economic value of information and knowledge.

Competitive success in a market economy depends more and more on the information and knowledge held by a company -- from the skills of its employees to the results of the latest research. It is estimated that the largest proportion of our Gross Domestic Product, some six percent, is attributable to IP-related goods and services, as is some six percent of all exports – the largest sector of exports, just ahead of agriculture.

As private actors have come to realize that more of the value in the society rests in information and knowledge, there has been a natural push to convert that value into assets. And one way -- if not the principal way -- that conversion occurs is through intellectual property.

This does not mean that the IP system is "intruding" upon research and science. It does not mean that IP takes "locking up" knowledge as its main goal, in opposition to the knowledge dissemination goals of the arts and sciences. To the contrary, in the patent system, the basic quid pro quo is clear dissemination in exchange for exclusive rights.

That is a point I want to emphasize. A properly calibrated intellectual property system balances within itself the two fundamental principles which seem to animate the intellectual property-science tension.

Information is a public good and, as such, if it already exists, the utility-maximizing distribution principle would be to distribute the information at marginal cost. But the trick is the phrase "if it already exists." The distribution principle is balanced by an information-generating principle: if you do not give people an incentive to produce information, there will be no information to distribute.

As John Barton, one of tomorrow's speakers, has said, the "right price" for transferring information is the marginal cost of such transfer "unless there is a solid economic basis for an exception." And in sectors where the initial investment can be high and the costs of copying are low, such as biotechnology, a solid economic basis does exist – the need to provide "incentives

for research, authorship, and the like." [World Bank's 1998 online think tank "IPRSTEAM:19," submission by John Barton on May 1, 1998.]

Practically every major policy dispute in IP centers around the question of where to draw the balance between these two principles: the best way to generate intellectual property and the best way to distribute it. For that reason, our Constitutionally-based patent and copyright systems are founded upon -- and clearly provide -- incentives for information disclosure and dissemination.

In that regard, let me stress that it is far, far better for a researcher to be working with funding from a company that seeks patented technology than with a company that would try to protect research results as trade secrets.

The patent system not only permits the scientist to publish his results; it also ensures that those results – in the form of the specification of a patent – will be published for all the world to see regardless of whether the researcher ever gets a single article past his reviewers. This disclosure, in turn, permits and facilitates improvements in technology, allowing it to be expanded upon, while building an important database of technological information. This disclosure incentive is the social contract upon which the patent system is premised. In fact, our office has put a great deal of energy into promoting real, widespread disclosure of technology and technological ideas.

The best example of this might be our completion last year of a two-year project to put our databases on the Internet. Now, there are complete, searchable texts of all registered and pending trademarks and all U.S. patents granted since 1976 – and full-page patent images -- drawings and schematics -- to complement the patent text database. All totaled, we have put on the Internet a 2 terabyte database system of some 21 million documents. With some budgeting luck, we can put the rest of our database up next year.

This, I believe, can have an enormous beneficial impact on American research and development. For example, one of our international sister agencies, the European Patent Office, estimates that over $22 billion dollars a year is wasted on research that has been done before.[i] While repeating the same experiments might make for good high school science projects, it's good neither for

business nor for one chance's of tenure. We believe that putting our patent databases on-line will help researchers more quickly understand what avenues they should pursue to achieve real innovation.

Another change in our patent system advancing the cause of disclosure is a provision in the new patent reform bill which became law late last year, which I was pleased the Clinton-Gore administration supported. The new law provides for the publication of patent applications 18 months after the U.S. filing or priority date, unless one opts out by not filing overseas. This "pre-grant publication" will allow American inventors to see an English language translation of the technology that their foreign counterparts are seeking to protect in the U.S. and elsewhere at a much earlier point than today. As a result, it will allow people to better understand the state of the art so that they can improve upon it and make wise R&D investment decisions.

SUBJECT MATTER EXPANSION IN PATENTING

Despite this balancing that occurs between information dissemination and exclusive rights, there is no question that once information exists, intellectual property rights impose costs on people who would use the information. For that reason, concerns have been raised about patent "subject matter expansion" -- that is, the law of patents being applied to emerging technologies or new areas of the economy. Several sessions of this conference deal with that topic, and I would like to address it as well.

One of the principles – or we could say meta-principles – of our 210 year-old patent system is that it is technology-neutral. It aims to apply the same norms to all inventions in different sectors and technologies. Some people are critical of this uniform system – including, perhaps, some people at this conference. But the uniformity and the facileness of the patenting standards of novelty, obviousness, and utility have allowed the patent system to respond to whole new sciences and entire new industries without the need for Congress to constantly retool the law.

This is not to say that each new invention in every new field of technology must be patented; that is the choice of the inventor or the owner. For example, the inventor of the World Wide Web chose not to avail himself of IP protection. Moreover, it does not mean that every patent or copyright will produce license fee obligations on science and research. Many inventors and writers choose to make their protected works available to non-profits for little or no royalties.

But the general rules of the patent system mean that the system evolves based on demand for protection – when researchers, and those funding research, believe that they need protection in order to secure a return on their investment of time, energy, and money.

It's also important to understand the role the Patent and Trademark Office plays in the evolution of the patent system. As an administrative agency charged with the application of the law as it exists today, we take our guidance from Congress and the Courts as to what is patentable and what standards we use for granting those patents. We are receptive to a continued broad view of subject matter eligibility, where appropriate, because twenty years ago the Supreme Court instructed us that "Congress intended statutory subject matter to 'include anything under the sun that is made by the hand of man.'"

Although we are an administrative agency, we recognize that our examiners also serve in a quasi-judicial role, responsible for "judging" the patentability of applications that come before them. Similarly, the Administrative Patent Judges on our Board of Patent Appeals and Interferences (Board) are responsible for handling appeals from the final determinations of examiners and for determining priority of invention in interference procedures.

Since neither the Supreme Court nor the Federal Circuit issue advisory opinions, our examiners sometimes confront new issues and new problems with only the general guidance of existing case law to help them. To help administer this process more uniformly, we have recently been promulgating Examination Guidelines, including written description and utility requirements in areas from software to genomic inventions.

In the hundreds of thousands of patent applications that the PTO handles each year - 270,000 last year -- we inevitably confront new issues in emerging technologies. Whether or not we issue a patent "answers" the new question. However, the final resolution of the matter – sometimes a significant policy issue -- may not occur until after adjudication through the Federal Circuit -- or in the rare situation that the Supreme Court takes a patent case on certiorari or the even rarer case that Congress decides to intervene. With the single exception of thermonuclear devices, however, Congress has never removed a particular subject matter from the scope of the statute.

Let me add that sometimes the new issues are purposefully and carefully framed by the applicant, the examiner, and/or the Board to provide appropriate test cases for the courts. This is one way the PTO promotes the evolution and maturation of intellectual property policy -- by "prompting" decisional law it facilitates the application and interpretation of the federal patent statute. The recent Utility Guidelines relating to the examination of genomic inventions are a good example of this.

By its very nature, this process of legal development is accretive. It is evolutionary -- not revolutionary.

Software and Business Method Patents

Let me take the case of software and business method patents. They are an excellent example of the evolutionary nature of IP policy.

Responding to concerns as to which aspects of software-related inventions should be eligible for patent protection, the PTO issued guidelines, first in 1989 and again in 1996, detailing our position on the proper analysis for computer-related inventions. The first set of guidelines recognized that although algorithms per se are not patentable, practical applications of mathematical algorithms may be. Building on the earlier version, the 1996 guidelines provided a uniform methodology for examining computer-related inventions and included a recognition that business method processes implemented through a software-based system may be patentable subject matter if they have a useful, concrete, and tangible application.

Last year, in ***State Street Bank & Trust Co. v. Signature Financial Group, Inc.***, the Federal Circuit validated our analysis in those guidelines. The Court also rejected the so-called "business method" exception, stating that inventions of this nature may be invalid for other grounds, such as lack of novelty or obviousness – but not because they were improper subject matter under section 101.

As I mentioned, this has been an evolutionary development. In keeping with the statutory charge of section 101, we've been granting software patents for a quarter century (about half the time there have even been programmable digital computers) and what people call "business method" patents for a good 15 years. We've also issued patents on methods of teaching since the 1860's.

Moreover, as many of you know, the PTO is not the only Patent Office providing increased protection for computer-related inventions. Both the European Patent Office and the Japanese Patent Office have recognized that innovative aspects of software-related inventions may be patentable.

To those who are concerned about the ultimate ramifications of the ***State Street*** decision and who criticize our ability to examine business method applications, I can assure you that we are working tirelessly to ensure that our office has the skills and resources we need to handle the growth in business method filings – which doubled between FY1998 and FY1999 (from 1,300 to 2,600).

To handle such a dramatic increase in workload, we obviously need more staff to handle the applications. Therefore, in the last two years, we hired over 500 new examiners in the Technology Center that examines software, computers, and business method applications. Those examiners have an average of four years of practical experience in industry and some fifty percent have advanced degrees. You may also be surprised to know that we have about 450 Ph.D. scientists examining our technologies. In addition to requiring examiners to have a scientific or engineering background, we also are recruiting candidates with business backgrounds.

QUALITY AND WHAT THE PTO IS DOING TO MAKE PRIOR ART AVAILABLE TO EXAMINERS

This all raises another issue: the quality of the work we do. Indeed, the questions formulated for this forum referred to the issue of "poor quality" patents, and you will likely hear from several sharp critics today, armed with usually anecdotal evidence.

I would respectfully note that the only regular, comprehensive study of patent and trademark quality is conducted by the PTO. We have regularly reviewed our quality for years through our Patent and Trademark Quality Review process, measuring against six major quality measures, such as whether the best 102/103 prior art was applied. These reviews are conducted independently of the Patent Office by seasoned, Grade 15, Patent Review Examiners, whose sole job is this review function.

This process has shown a continuing, consistent level of quality, with no apparent deterioration over time. Even though this data is freely available, it is rarely considered by critics.

Now to those who might suggest that this is a case of the "fox in the hen house," let me point out that this process is regularly reviewed by the Commerce Department's Inspector General. Nonetheless, we would certainly welcome any additional third party scrutiny.

We do, however, have a regular measure of quality conducted by that most demanding group of third parties: our customers. Our annual survey of customer satisfaction has shown fairly dramatic increases in customer perception of search quality, rising almost 50% in the last 3 years alone. These results are remarkable, especially given the fairly steady drumbeat of often anecdotally-based criticism to the contrary by those whose own business model might depend on institutionalizing such a belief.

All of this is not to say that search and examination is always perfect and cannot be improved. Quality management, after all, is a process of continuous improvement; but I am very pleased with the improvements we've made in this area.

Our examiners have access to more prior art than at any time in our history. Specifically, our in-house patent database and our commercial database provider provides access to more than 900 databases, including Westlaw, Lexis-Nexis, and Chemical Abstracts. From their desktop computers, patent examiners can also search the full text of over 2.1 million United States patents issued since 1971; images of all U.S. patent documents issued since 1790; English-language translations of 3.5 million Japanese patent abstracts; English-language translations of 2.2 million European patent abstracts; IBM technical bulletins -- a key database in the software area; and over 5,200 non-patent literature journals. And our paper search files and libraries are still in place as well.

Finally, common wisdom to the contrary, Examiners have had a consistent level of search and examining time, time which is adjusted for the complexity of the technology.

Does that mean we should not devote even more time, if possible? Of course not. We should definitely try to devote more time to search and examination, especially for those technologies that are emerging or which are becoming more complex. Like most things, however, it is a question of resources.

It should be noted that the appropriations process over the last few "capped" budgets has resulted in the PTO being denied access to more than $200 million of our patent and trademark fees this year -- about 20% of our total. This is a significant problem for us, and we are hopeful of proposing a permanent fix to this inequity later in this session of Congress.

It should also be noted that our original search and examination is not the end of the quality story. There are additional safeguards available, which are intended to improve our patents still further. Rule 56, for example, requires that each applicant disclose the most material prior art of which the

applicant is aware, under penalty of possible forfeiture of the patent. We are currently discussing additional means to heighten this obligation.

We also have Section 301/Rule 501, which permits any art, even art submitted anonymously, to be placed in the file and used in subsequent litigation. Finally, there is the reexamination system, which now provides for both ex parte and inter partes reexamination in view of unconsidered or newly discovered prior art. Surprisingly, very few avail themselves of either of these options.

The PTO Commissioner may also order reexamination, as I recently did with a Y2K fix patent, when the prior art and broad public concern warrant it. However, when expanding reexamination was recently debated in Congress, certain interests – principally independent inventors and the university research community – opposed it, either fearing abuse or hoping to maintain the fear of expensive and debilitating litigation as a barrier to entry. This resulted in a significant curtailing of the scope of inter partes reexam.

Of course, as new technologies come into the realm of patentable subject matter, we not only need examiners with new skills and training, but also access to additional sources of technological information. That's why last year we held hearings -- in San Francisco and here in Washington – to solicit interested parties on how to expand access to non-patent literature. I am pleased that we have had a number of organizations with access to such information, such as the Securities Industry Association, meet with our examiners on the state of the art and the databases which contain this information.

WHAT THE PRIVATE SECTOR AND THE SCIENCE COMMUNITIES COULD DO TO HELP ON THE PRIOR ART ISSUE

As you can see, the PTO is undertaking a number of initiatives to try to improve the examination of software-related patent applications. Still, there are at least two ways the research community -- both public and private -- could help us in this endeavor.

First, there appears to be a real problem in the software industry with commonly accepted terminology.

One of the basic tenets of the American patent system is that each applicant is allowed to describe his invention in his own words. In case law parlance, "the applicant may be his or her own lexicographer." The PTO then relies on the applicant's disclosure to determine the meaning of terms used in the claims. At the same time, our examination guidelines explain why it is important, particularly for prior art purposes, for applicants to use commonly accepted terminology.

In this area, the software industry and the computer research community as a whole -- ironically, an industry built on languages and focused on standards -- should explore whether, and how, more commonality in the language of patent applications could improve the patenting process.

In addition to this nomenclature issue, there is also a place for industry-wide work in developing a robust, well-organized library of prior art. The 900 databases we now make available to patent examiners are an enormous improvement over the situation ten years ago, but those databases are still incomplete. If a complete, "universal library" of software prior art can be built, the question remains: who should do it and how?

Some people believe that the PTO needs to embark on this effort, but that is a daunting proposition. In other technologies, we rely heavily on private or non-profit databases, like Chemical Abstracts from the American Chemical Society and "Medline" from the National Institutes of Health. So, I would like to ask STEP to consider one definitive research project: to make recommendations on how we could move toward a "universal library" database for software-related inventions. We need your help in exploring what resources we could bring to bear from organizations like the IEEE, NSF, and the private sector, and how we could configure participation and allocate burden in such an effort.

GENOMIC PATENTS

Of course, the computer industry is not alone in its struggle with legal issues. Advances in biotechnology have sparked vigorous and emotional debate regarding the patenting of certain types of biotech inventions. At the heart of the controversy is the issue of patenting inventions concerning life forms and gene fragments that can be critical as research tools.

The patentability standard for biotech inventions that has guided the PTO since 1980 is that a product of nature transformed by humans can be patented if it is new, useful, and non-obvious. Products produced from raw materials, giving these materials new forms, qualities, properties, or combinations, are patentable, provided that they are supported by either a well-established utility or by an asserted utility that is specific, substantial, and credible – for example as a marker for a particular disease or for gene therapy. Under current law, genomic inventions are patentable.

Some fear that patents on gene fragments, such as expressed sequence tags (ESTs) and single nucleotide polymorphisms (SNPs), might retard basic research and that these claims will form an intricate licensing web that will impede their use in developing cures for diseases.

The PTO is cognizant of these concerns, and we continue to take steps to ensure that patent applications in these areas are meticulously scrutinized for an adequate written description, sufficiency of the disclosure, and enabled utilities, in accordance with the standards set forth by our reviewing courts. In fact, commenting on our Revised Utility Examination Guidelines, Dr. Harold Varmus, the outgoing director of NIH, who has been previously critical of these guidelines, recently stated that he was "very pleased with the way [the PTO] has come closer to [NIH's] position about the need to define specific utility."

In discussing genomic patents and access to research tools, it's important to distinguish between patentability and access. While the need for a possible "research tool exemption" – presumably for "pure researchers" – is a valid topic for debate, it should not drive a narrowing of subject matter patentability in order to create such an exemption de facto. There are often more traditional methods of dealing with difficult access issues, such as the Justice Department's anti-

trust guidelines. And if the issue is truly a "research tool exemption," then that is what we should discuss -- mindful, however, that the distinction between pure research and applied research grows fuzzier every year.

Moreover, research tools themselves can be of great commercial value. We must not forget that one university's access issue may be another university's critical licensing revenue.

PLACES AND TOPICS WHERE THE SCIENTIFIC COMMUNITY CAN HELP US IMPROVE AND REFINE THE INTELLECTUAL PROPERTY SYSTEM

Let me turn now to highlight some of the changes that are taking place in our patent system as a result of the recent enactment of landmark patent reform legislation, and areas where the scientific community can help us improve the system even further.

The patent reform bill signed into law by President Clinton last November includes several changes in patent law that are an important step forward for our systems. These include:

- A guarantee of a minimum 17-year patent term for diligent applicants, so that they are not penalized for processing delays and for delays in the prosecution of applications pending more than three years.

- The publication of most patent applications, 18 months after the U.S. filing or priority date, unless the applicant requests otherwise upon filing and states that the invention has not been the subject of an application filed abroad; and.

- The establishment of a limited defense against patent infringement to inventors who developed and used a method of doing business prior to that method being patented by another party.

Of all the bill's substantive provisions, the pre-grant publication of patent applications represent the most significant step toward information disclosure and global harmonization. Still, much more remains to be done.

A truly global patent system will be realized only when the currently divergent requirements -- both substantive and procedural -- for the grant and enforcement of patents converge. The costs associated with maintaining our current duplicative systems cannot be tolerated much longer.

We are currently negotiating a treaty at the World Intellectual Property Organization in Geneva that will address most of the procedural requirements associated with the examination of patent applications and the grant of patents. That treaty is scheduled for conclusion this May.

At the same time, there is much that needs to be done about differing substantive requirements. For example, the U.S. alone grants patents on a first-to-invent basis, whereas the rest of the world grants patents on a first-to-file basis. We also have an important and generous one-year grace period that inures to the benefit of our patent applicants.

Prior attempts to "harmonize" these and other differences were fraught with controversy and met with failure. Now that there has been a cooling-off period, I would like to ask for the support of the scientific community in studying the impact of the changes here, or throughout the world, that would be required to achieve such a global patent system. We need the benefit of your perspective and the rigorous academic analysis of the issues that you could offer.

One of the most obvious areas where the research and scientific community can help us is one that will be touched upon by Thursday's 1:00 PM session: issues about knowledge and technology transfer. What we need is for the American scientific and research community to be involved, including helping researchers and scientists in other countries understand the impact of these proposals. This partnership could greatly aid developing countries, in particular, as they move further forward into global economic development.

CONCLUSION

Let me close by again thanking the National Academies -- and particularly the members of the STEP Board -- for the time and resources they are devoting to study these issues. The impact of intellectual property rights on technological innovation in our economy is clearly of the utmost national and international significance. These issues deserve all of our attention and, speaking on behalf of the Patent and Trademark Office, we are glad to have you involved and look forward to working with you as the study progresses.

Thank you very much.

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[i] European Commission, Green Paper on Public Sector Information in the Information Society, paragraph 34, COM(1998) 585.