FRANKLIN PIERCE LAW CENTER'S SEVENTH BIENNIAL INTELLECTUAL PROPERTY SYSTEM MAJOR PROBLEMS CONFERENCE

DIGITAL TECHNOLOGY AND COPYRIGHT: A THREAT OR A PROMISE?

I. INTRODUCTION

A. *Conference Background*

On November 14, 1998, Franklin Pierce Law Center (FPLC), in cooperation with the Kenneth J. Germeshausen Center for the Law of Innovation and Entrepreneurship and the PTC Research Foundation, both of which are headquartered at FPLC, held its Seventh Biennial Intellectual Property System Major Problems Conference. While noteworthy for a broadening in scope over previous conferences — from "patent system major problems" to "intellectual property system major problems" — the seventh biennial conference continues a tradition of scholarship and discussion begun in 1987 by former FPLC professor Homer O. Blair.

The discussions in Professor Blair's inaugural major problems conference focussed on such varied topics as new forms of patents, litigation cost reduction measures, and first-to-file versus first-to-invent systems.[1]

The 1989 conference was devoted primarily to patent trial simplification and dispute resolution.[2]

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[1] *Franklin Pierce Law Center's First Biennial Patent System Major Problems Conference*, 28 IDEA 61 (1987) and 28 IDEA 117 (1987).

[2] *Franklin Pierce Law Center's Second Biennial Patent System Major Problems Conference*, 30 IDEA 107 (1989).

The 1991 conference took up the issue of patent-law harmonization, with a particular focus on secret prior art, prior user rights 35 U.S.C. § 104, and publication of pending applications.[3]

The principal topics for the 1993 conference included abolition of jury trials in patent cases, a new specialized patent court in England, prior user rights, and the U.S. Patent and Trademark Office as an independent government corporation.[4]

The 1995 conference covered patent costs, the future of the U.S. Patent and Trademark Office, and prior user rights.[5]

The most recent prior conference, in 1997, discussed medical procedures patents, software protection and the Doctrine of Equivalents, and featured remarks by the Deputy Assistant Commissioner of Patents.[6]

B. *Conference Design*

As in previous years, the 1998 conference was designed to bring together a significant number of invited scholars, industry representatives, practicing attorneys, and government officials for a roundtable discussion. The conference was designed to encourage in-depth discussion and exchanges among the attendees, without formal, prepared presentations other than the prefatory comments offered by the moderators to introduce new topics.

The conference's principal objective was to have knowledgeable and influential participants explore the conference's principal topics with each other, with an eye toward enabling each participant to leave at the end of the day with a better understanding of the viewpoints of others, and, ideally, with knowledge of some newly discovered — or perhaps newly created — common ground.

The theme of the 1998 conference was "Digital Technology and Copyright: A Threat or a Promise?" In the letter that invited participants to attend the conference, the following five issues were identified as the principal subject matter of the conference:

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3 *Franklin Pierce Law Center's Third Biennial Patent System Major Problems Conference*, 32 IDEA 7 (1991).

4 *Franklin Pierce Law Center's Fourth Biennial Patent System Major Problems Conference*, 34 IDEA 67 (1994).

5 *Franklin Pierce Law Center's Fifth Biennial Patent System Major Problems Conference*, 36 IDEA 345 (1996).

6 *Franklin Pierce Law Center's Sixth Biennial Patent System Major Problems Conference*, 37 IDEA 623 (1997).

1. The capabilities of digital technology. What can digital technology really do? Now and in the near future, what threat does it actually pose for owners and users? (We intend to have engineers with relevant experience present to serve as continuing "guides" on this subject.)

2. The implementation of technological protection. What is the history to date, and what are the pros and cons, of various implementation approaches, e.g., industry-negotiated versus government-imposed?

3. Technological protection and public policy. What are the merits and disadvantages of proposed anti-circumvention and copyright information management approaches? What is the potential significance of technological protection and remedies in the context of copyright licensing?

4. Digital technology and copyright liability. What is the copyright significance of temporary copying, the proper role and responsibility of Internet service providers and the relationship of technological protection to the foregoing?

5. Alternatives to technological protection. If technological protection is limited, inherently or by law, to what extent, if any, should copyright owners receive alternative forms of protection, such as compulsory license fees, equipment levies and the like?

In addition to being asked to consider the issues outlined above, participants were provided with the following documents, to facilitate their preparation for the conference:

1. WIPO Copyright Treaty.

2. WIPO Performances and Phonograms Treaty.

3. Conference Report on H.R. 2281, the Digital Millennium Copyright Act ("DMCA").[7]

[7] H.R. REP. 105-796.

4. Proposal for a European Parliament and Council Directive on the harmonization of certain aspects of copyright and related rights in the Information Society.

The conference was organized by Karl Jorda, Silke von Lewinski, and Jeremy Williams, and was chaired by William Keefauver.

II. PARTICIPANTS

Fritz Attaway	Senior Vice President, Washington General Counsel, Motion Picture Association of America.
Jon Baumgarten	Partner, Proskauer, Rose LLP, Washington, D.C.
June Besek	Director of Intellectual Property, Reuters America, formerly a partner with Schwab, Goldberg, Price & Dannay, New York, New York.
Chris Blank	Professor, Franklin Pierce Law Center.
Rochelle Blaustein	Intellectual property attorney, Roberts, Brownell & Abokhair, LLC, Vienna, Virginia; Adjunct Professor, George Mason University Law School; formerly Assistant Professor of Clinical Law, Franklin Pierce Law Center.
Gerry Brill	Director of Intellectual Property and Corporate Patent Counsel, Macrovision Corporation, Sunnyvale, California.
Jon Cavicchi	Intellectual Property Librarian and Clinical Professor of Law, Franklin Pierce Law Center.
Manuel Desantes	Professor of Law, University of Halicante, Spain; National expert for the Legal Service of the European Commission.
Mihály Ficsor	Assistant Director General, World Intellectual Property Organization, responsible for copyright and related rights.
Tom Field	Professor, Franklin Pierce Law Center.

Bryan Harris	Director, Patent, Trademark and Copyright Research Foundation; Member of the Board of Trustees and Adjunct Professor, Franklin Pierce Law Center; formerly, head of intellectual property for the European Commission.
Karl Jorda	David Rines Professor of Intellectual Property Law and Industrial Innovation, Franklin Pierce Law Center; Director, Kenneth J. Germeshausen Center for the Law of Innovation and Entrepreneurship.
William Keefauver	Patent attorney, consultant in intellectual property for clients such as Bell Laboratories and AT&T; Member, Board of Trustees, Franklin Pierce Law Center.
Silke von Lewinski	Head, Department for international law and particular problems of developing countries, Max-Planck institute for foreign and international patent, copyright and competition law, Munich, Germany; legal advisor to the European Commission; Adjunct Professor, Franklin Pierce Law Center.
Len Mackey	Consultant, Harkavy, Mitchell, Stewart & Lovesky, Sarasota, Florida; formerly, general patent counsel for ITT Corporation.
Dean Marks	Senior Intellectual Property Counsel, Time Warner.
Sam Masuyama	Advisor to GEIDANKYO (Japan Council of Performers' organizations), a nonprofit organization representing fifty-nine organizations of Japanese professional performing artists.
Michael Meurer	Professor, University at Buffalo Law School; Visiting Professor, Boston University Law School.
Bill Murphy	Professor, Franklin Pierce Law Center.

Christopher Murray	Head, Entertainment, Media, and Intellectual Property Department, O'Melveny & Myers, LLP, Los Angeles, California.
Ralph Oman	Of counsel, Dechert Price & Rhodes, Washington, D.C.; Adjunct Professor of copyright, George Washington University Law School.
Matt Oppenheim	Associate Counsel, Civil Litigation, Recording Industry Association of America.
Shira Perlmutter	Associate Register for Policy and International Affairs, United States Copyright Office.
Marybeth Peters	Register of Copyrights, Library of Congress, United States Copyright Office.
Frank Politano	Trademark and copyright counsel, AT&T; Adjunct Professor, Seton Hall University School of Law, Newark, New Jersey.
Sarah Redfield	Professor, Franklin Pierce Law Center.
Susan Richey	Professor, Franklin Pierce Law Center.
Katherine Sand	General Secretary, International Federation of Actors, London, England.
Glen Secor	President, Yankee Book Peddler (a seller of books and bibliographic services to libraries); Adjunct Professor, Franklin Pierce Law Center.
Gordon Smith	President, AUS Consultants, Moorestown New Jersey; Adjunct Professor, Franklin Pierce Law Center.
Bernard Sorkin	Senior Intellectual Property Counsel, Time Warner.
Bill Strong	Copyright attorney, Kotin, Crabtree & Strong, Boston, Massachusetts; former Adjunct Professor, Franklin Pierce Law Center.

William Tanenbaum	Partner, Intellectual Property Department, Rogers & Wells, New York, New York; Past President, Computer Law Association.
David Thibideau	Patent attorney, Hamilton, Brook, Smith & Reynolds, Lexington, Massachusetts; Adjunct Professor, Franklin Pierce Law Center.
Robert Viles	Current President and former Dean, Franklin Pierce Law Center.
Sallie Weaver	Executive Administrator, Screen Actors Guild.
Jeremy Williams	Deputy General Counsel, Warner Brothers; Adjunct Professor, Franklin Pierce Law Center.

III. WELCOME

MR. KEEFAUVER:

I think it's time that we begin to gather in discussion formation. Good morning everybody. My name is Bill Keefauver and my role here today is to act as master of ceremonies, and my first pleasant duty is to introduce to you Bob Viles, President of Franklin Pierce Law Center, and for many years before that, the Dean of this institution.

MR. VILES:

Let me informally welcome you to Franklin Pierce Law Center. We are grateful to Silke von Lewinski and Jeremy Williams for organizing this conference. Speaking as an academic administrator, it is always wonderful to see such productivity from adjunct faculty members! We are particularly grateful for their bringing to the conference so many people who are new to the Law Center. You may have noticed over the main entrance to this building a banner celebrating the twenty-fifth anniversary of Franklin Pierce Law Center. Indeed, it was twenty-five years ago when we held our first international intellectual property conference. It was organized by Robert Rines, the principal founder of the Law Center, and it concerned the intellectual property law then evolving in the European Community. Today's international intellectual property conference is on a different subject, of course, because we continue to strive to be on the front lines of intellectual property development. Your being here today certainly helps us to do that, and I thank you for coming.

I would also like to mention that the cost of this conference has been defrayed to a considerable extent by Shell Oil. The grant was facilitated by a graduate of ours who came to FPLC with previous training as a chemical engineer and who used his FPLC education to get a job in the Shell intellectual property department as a patent lawyer. In talking with him recently, I learned that he now spends half his time on computer issues and has recently given a paper on a topic closely related to the subject of today's conference. His experience testifies to the Law Center's own expansion from a strict patent-law orientation twenty-five years ago into the full breadth of today's information-based intellectual property law. Now let me return the microphone to Bill Keefauver.

MR. KEEFAUVER:

Thank you very much Bob. My justification for holding the important office of Chair of this conference is that I'm a trustee of this institution. Now let me briefly outline and remind you of the format that we will follow here today. Our discussions are being transcribed electronically. Later, they will be recorded on paper and, obviously — as those of you familiar with litigation already know — those transcriptions will come out as most transcripts do, relatively unintelligible. They will then be forwarded to each and every one of you to edit, revise, extend or even cancel your remarks if you care to.[8] So you may feel free to say what you want today, and you will have an opportunity to delete anything you do say if you later think it's inappropriate, or you just don't want to be associated with it. You will have an opportunity to edit. Your remarks are under your control, and I want to emphasize that. Let me also point out to the discussants at this conference that arrayed around the room in various corners are students and other interested persons who are here to listen to the discussion, and we certainly welcome them as well.

This is not the first major problems conference held here at Franklin Pierce but, as Bob said, it's the first one on copyright law. In my view, the copyright law has been stressed more by new technologies than other areas of intellectual property law, although each has had to undergo a certain amount of modification. But, in my time at least, it's become obvious, beginning with CONTU in the 1960s and 1970s, that the copyright law is ever more a work in progress and unlikely are we to ever get it entirely right.

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[8] In addition to this "self-editing" by conference participants, the transcript has been given a light edit by the staff of IDEA, undertaken simply to comb out the conventions of oral communication and replace them with those of written communication, for the benefit of our readers.

As Bob said, we are indeed fortunate to have Jeremy and Silke, two copyright experts, willing and able and energetic enough to put this conference together and to lead our discussion today. On behalf of my fellow trustees, I too want to thank Jeremy and Silke for their considerable efforts in managing that part of the program today. I also want to acknowledge the great assistance and help of Karl Jorda and his very capable assistant, Carol Ruh, in handling the administrative details of the conference. Now I want to give Karl an opportunity to make some housekeeping announcements.

MR. JORDA:

Thank you very much. Very briefly, good morning and welcome to everybody. Just one quick point. We have at the table, outside in the lobby, Franklin Pierce literature, not to say propaganda. Help yourselves, pick up anything you want to. And if you don't already know the answer, see whether you can use that material so solve this riddle: how is it possible for Franklin Pierce, the smallest independent law school in the country, only twenty-five years old, without any institutional support or endowment, and out in the country (when most of the approximately 180 American law schools are in metropolitan areas), how is it possible for Franklin Pierce to be number one in intellectual property education and training? So help yourself to the literature.

MR. KEEFAUVER:

Thank you Karl. As Karl indicated, we will have a coffee break somewhere in the middle of the morning so you'll have an opportunity to stretch and get coffee or other liquid refreshments as are available. Now, in accordance with the tradition of these prior conferences, we are going to introduce ourselves, going as quickly as we can around the table, so that we each have a brief idea of who the others are and where we come from.

[For biographical information on conference participants, see *supra*, Part II.]

MR. KEEFAUVER:

Thank you very much. Sarah Redfield's presence here reminds me to point out something that is obvious to some of us, but maybe not to all of you. Despite our reputation in intellectual property law, Franklin Pierce is a complete law school, and we have some very innovative programs in other areas, like the program in education law that Sarah has put together. If we had more time we could talk about those programs and areas of law, but we don't have the time for that. So, once again, it's a pleasure to have such a diverse group here.

We should also remind ourselves occasionally that there are other interested parties who are not here for one reason or another. Perhaps foremost among these absent interested parties is the public, and we will hope that from time to time the interests of the public in the matters which we are discussing will be brought forward. And now, without any further ado, I will turn the proceedings over to our co-moderators, Silke von Lewinski and Jeremy Williams.

MR. WILLIAMS:

Thank you Bill and welcome everybody. First of all, we passed out an informal discussion outline to those of you who were at dinner last night [reproduced below]:

Digital Technology and Copyright

1. Introductory remarks

2. Technical measures/Anti-circumvention
   - A. The digital threat: What is the extent of the threat to copyright protection?
   - B. The digital response to the threat: technical measures
     1. Is the DMCA a "copyright grab"? Will copyright owners "lock up their works" and create a "publisher-dominated toll road"?
     2. Does the DMCA encourage or support that?
     3. How will the marketplace affect that?
     4. What will be the nature and the role of licensing in the digital world?
     5. What is the role of fair use in a world of digital licensing?
   - C. The EU proposal
     1. What is the status, and what are the outstanding controversies?
     2. What is the European reaction to the DMCA?
     3. What is the U.S. reaction to the European proposal?
   - D. Implementation of technical measures: mandated versus negotiated

3. Liability on the Internet
   - A. What does the DMCA actually do?
     1. The OSP viewpoint: What must an OSP do, and what does it actually get?

2. The content-owner viewpoint: What must it do to ensure protection? Did content owners gain or lose?
3. The user viewpoint: How are users affected? How is communication on the Internet affected as a whole?

B. The EU e-commerce proposal and OSP issues
1. What is the status, and what are the key issues?

C. Jurisdiction and choice of law in the online context

4. Other issues

A. Alternatives to technical protection
1. What is the role of statutory licensing and levies?
2. What is the role of education and voluntary compliance?

B. Copyright and world trade law: Is trade the growing and future source of copyright law?
1. What is the role of the WTO in the digital context?
2. What are the areas of future compliance controversy?

This is intended to be an informal outline that gives a general idea of the flow of our discussion today but, obviously, there's no obligation to stick strictly to the outline and we hope that people will raise their own issues as we go through it.

IV. THREATS & OPPORTUNITIES; OWNERS & USERS

MR. WILLIAMS:

Digital Technology as a Threat to Copyright Owners. The inspiration for the subject of this conference was an observation that some of us were discussing here some months ago, and which I think many in the room have made, which is that when digital technology hit the world and started to become a harbinger of our future, many copyright owners, content owners such as my employer, and commentators looking at digital technology from the point view of copyright owners, regarded this new technology as the greatest threat yet to copyright protection. We started to see commentary about the end of copyright and the impossibility of enforcing copyright protection. But as people got a little more used to digital technology, there started to be a noticeable shift, at least among many commentators, who began to look at digital technology as a source of great promise for content owners and as a great threat to content users.

The New Legislation and Threats to Content Users. In the course of this process, we had the introduction in this country of the *White Paper*, followed by the 1996 WIPO Copyright Treaty, leading just a few weeks ago to the passage of the Digital Millennium Copyright Act ("DMCA").[9] There have been a lot of congratulations passed among many people in the copyright field about this whole process from the *White Paper* to the WIPO Treaties to the DMCA. As we know in Europe, the European Union is working on WIPO implementation and has a proposal with some similarities to the DMCA. Other people, of course, have been more cynical about these legislative developments.

The Copyright Grab. I want to begin our proceedings by reading just a few words from an article called *The Copyright Grab*,[10] which I'm sure many people in the room have read, by Professor Samuelson, who was invited but is unable to attend our conference today in person. In view of her absence, I thought it important for her to be here in spirit. To bring her spirit into the room, I want to read a few words from her article, to kick off our discussion. Referring to the *White Paper* in January of 1996, Professor Samuelson wrote:

> If legislation recommended in [the United States government's] white paper "Intellectual Property and National Information Infrastructure" is enacted, your traditional user rights to browse, share, or make private non commercial copies of copyrighted works will be rescinded. Not only that, your online service provider will be forced to snoop through your files, ready to cut you off and turn you in if it finds any unlicensed material there. The white paper regards digital technology as so threatening to the future of the publishing industry that the public must be stripped of all rights copyright law has long recognized — including the rights of privacy.[11]

She went on to say:

> Some publishers, however, want to control not only all public and commercial uses of their works, but all private uses as well. They assert that this would better fulfill the constitutional purpose of copyright, because the greater financial return to them, the greater will be their incentive to make works available to the public . . . . [T]hese publishers fear digital technology far more than videotape machines. Ever since they began to realize that digital technologies could "free" information dissemination, the established copyright industry has been shaking in its boots. Now a group of major motion picture producers, sound recording companies and print publishers have figured out a way to turn the threat of digital technology into an opportunity. Under this plan, they would retain all of their rights under existing law and quietly attain a host of new ones.[12]

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9 Pub. L. No. 105-304, 112 Stat. 2860 (1998).

10 Pamela Samuelson, *The Copyright Grab*, WIRED, Jan. 1996, at 134.

11 *Id.*

12 *Id.*

One of the things that I want to do to begin our discussion is to ask the question "Is that what's happened?" Have we had a "copyright grab" by what Professor Samuelson refers to as publishers, meaning content owners in the larger sense? Obviously there are a lot of aspects of that discussion, and many people here will have different views and different ways of approaching it. But I thought it would be a good theme now that we have passed our copyright changes here in the United States, and similar changes are being considered in Europe. Did Professor Samuelson's copyright grab actually take place, and even if that is what's happened, is that a bad thing?

Is the Digital Threat Any Different from Previous Threats? One of the cynical aspects of the view that I just read is the idea that the threat wasn't so great to start with and, therefore, the attack on the threat through digital technology is really a promise as far as content owners are concerned. We've had threats before from the printing press to the photocopy machine to the Betamax machine to the simple audio cassette recorder and, in each case, content owners claimed the sky was about to fall and it did not. There was a degree of piracy, but industries thrived. I'd like to start the discussion by asking whether there is anything about the digital threat that is all that different from the various threats that have come before? Does the digital threat require a response of the kind that we expect technology to offer, or does the technology go well beyond the threat and offer something in the nature of a promise to content owners? I invite the start of discussion on those topics.

MR. SORKIN:

I'd like to answer the question very briefly by saying yes, there is a threat. But in order to do that I'd like to go back to your first two propositions in which you saw a shift in the approach to it all. It seems to me that there are, in these developments, two strains with tension between them existing simultaneously.

Digital Opportunities. First, there are the great opportunities offered by digitization to content owners and to society at large, great opportunities for new markets, great opportunities for new ways of dealing with and distributing content, great opportunities for educational activities such as distance learning. These are huge opportunities that should be taken advantage of. That's the silver lining.

Unlimited Reproduction, Mass Distribution, and Content Modification. In my view there is also a cloud around that silver lining, and it's a very significant cloud. It is true that threats were posed by the printing press, the video machine, and other new devices and technologies. What we face now is something that is quantitatively so different as to import a real qualitative difference, in at least three particular areas. The first of

these areas is the ability of digital technology to reproduce unlimited numbers of copies, copy after copy from copy after copy, without any degradation of quality at all. The second is the ability of digital technology to, for lack of a better word, "distribute" content via the Internet in the flash of an eye all over the world, if not all over the universe someday. Obviously, this capacity for "flash-distribution" entails the very real possibility of distribution to jurisdictions in which copyright protection is non-existent or very inadequate. The third area of concern is the ease with which the content of digital works can be modified. This applies to all manner of digital works, including audio-visual works, musical works, and textual works. I think about this susceptibility to modification in terms of a long-held personal fantasy: I would like to be Rick in *Casablanca*. Well, now I can be. But my ability, through digital technology, to be Rick in *Casablanca* poses at least two problems: 1) a copyright problem from the point of view of the owners of *Casablanca*, and 2) a major problem for Ingrid Bergman when she finds herself playing romantic scenes opposite me.

A Stark Choice: Copyright Protection or Fair Use. The three problems I have described are so great that there have to be significant protections enacted, I believe, and protections which are perceived, in some quarters, as raising the kind of "counter-problems" to which you have referred. It may well be that technology will resolve these problems but, in my view, until such time as technology does so, we may be faced with a very stark choice: a choice between a world without copyright protection and a world without the fair use and the other public domain advantages that currently exist. If we have to make that choice, then we will have to decide where are we better off. As we decide whether we are better off in a world without copyright, we will also have to consider — from the perspective of the infrastructure manufacturers and the hardware manufacturers — whether there is any point in manufacturing and developing an information superhighway on which there will be no cars.

MR. MEURER:

Different Impacts on Different Industries. I think we need to keep track of the impact of technology across different industries. Some industries will see greater problems with regard to piracy. But some industries are going to see a great benefit from enhanced marketing through digital technology and the ability to introduce micro payments or the ability to measure intensity of use of copyrighted material. This is going to mean that some media industries are going to practice price discrimination like the airlines do so skillfully, and those industries are going to see greater profit opportunities. I'm not talking about digital

encryption. I'm not talking about technical means of combating piracy. I'm saying that, apart from the issue of piracy, we should realize that digital technology offers a lot of profit opportunities. In the past we have seen publishers like West(law) and Lexis shift from selling books that sat on library shelves to delivering data through phone lines or the Internet, a big advance in technology that allowed them to profit greatly, and it has nothing to do with piracy.

MR. MARKS:

Threats Become Opportunities. I want to follow up on what Michael said because, in the past, with the traditional content industries — and speaking in particular for the film industry — new technology was traditionally regarded as a threat. When the video cassette recorder was introduced, the film industry got together and brought the famous, or infamous, *Betamax*[13] case thinking that these VCRs were going to destroy the economic basis of film distribution, particularly theatrical exhibition and profitable television distribution. What actually happened was just the opposite. With the introduction of video cassette recorders came the advent of pre-recorded video cassettes. This has become one of the most profitable channels of distribution for the film industry. I would like to think, at least at our company, that there has been some wisdom gained from this past experience to the point that we now regard the new technologies as offering the sorts of opportunities that you're describing. We are embracing things like digital video disks, and we are looking into electronic delivery, both of our music content and our film content. Content providers are getting smarter about these things. We want to be able to harness the technology in a way that will lead to greater distribution, hopefully wider distribution, and even lower prices while avoiding the real threats of piracy that I think are still there.

MR. BAUMGARTEN:

Threats and Opportunities are Connected. I just want to comment that the threat that Bernie mentioned and the promise that Michael mentioned are not separate things. They are different sides of the same coin. Price differentiation is a perfect example today in many areas of professional or scientific publishing, database publishing and the like. It's not uncommon to make works available to the for-profit community at a price greater than the price at which that those same works are made available to the library or educational community. You can't do that if the first to acquire such a work in the educational

[13] Sony Corp. of America v. Universal City Studios, Inc. 464 U.S. 417, 220 U.S.P.Q. (BNA) 665 (1984) [referred to herein as *Betamax*, or *Sony Betamax*].

community turns around and redistributes it for nothing to the for-profit communities. So even the promise of micro payments or the promise of additional price differentiation depends upon the security of the infrastructure against unauthorized copying and distribution that Bernie mentioned.

MS. BESEK:

Users' Privileges, Not Users' Rights. I want to respond to Professor Samuelson's phrase "users' rights." I know she's very fond of that phrase, but I have a problem with it. Users have *privileges* under the copyright law, but the idea of users' *rights*, at least as Professor Samuelson uses the phrase, is troublesome. One problem with new technology is that the easier it is to copy, for example by photocopying or by computer, the stronger the perception of entitlement to copy becomes. Some copying is not prosecuted *not* because it's not actionable, but because copyright owners simply can't go after everybody out there. A lot of infringing activities typically go unchallenged, but that doesn't mean that these acts are legal or that the copier has any entitlement to do these things. What has happened, unfortunately, is that some of the activity that probably should be deemed infringing has started to be perceived by certain groups as an entitlement. They believe, for example, that a copyright owner is taking something away from them if that owner now has the ability to track usage. I understand that digital technology will bring with it a greater ability to track usage. There is a danger that copyright owners will overreach, but there's also a "danger" that they will simply be able to better track uses that aren't appropriate anyway.

MS. VON LEWINSKI:

How Much Digital Distribution in the Future? I would like to follow up on something that has been said by Dean and others. Speaking about the threat or the promises of new technologies, the answer also depends, of course, on how much future business will be in the electronic area. So I would like to know of anyone in the group who might dare to have a guess for the future: how much of the business of distributing printed works or audio-visual or musical works, for example, will be done exclusively over the Internet? Will there be a total replacement of the so-called analog or traditional exploitation of works? What percentage will represent electronic distribution?

MR. FICSOR:

Early Views on the Impact of Digital Technology. If we speak about the threat side of this, we also should consider what kind of views

appeared in the first stage of discussions about the impact of digital technology, views suggesting that copyright was dead or that copyright would have one remaining duty, to die and be laid to rest six feet under. That was the first stage of discussions, and then there was a reaction to that, the argument that nothing should be changed, that everything could remain the same as it used to be. The latter view came, mainly, from some authors' societies. Then when we went to the Diplomatic Conference, we were in the very fortunate stage of synthesis, and there was agreement that, yes, some changes are needed but the changes should not be fundamental.

Reactions to the Diplomatic Conference. If you refer to Pamela Samuelson, then you should also refer to another article she published, not before the Diplomatic Conference, but in the March 1997 issue of *Wired*.[14] Professor Samuelson's article, *Big Media Beaten Back*, appeared side-by-side with an article by John Browning.[15] The title of Browning's article, *Africa 1, Hollywood 0*, seems to capture the spirit of both articles. Both authors were very happy about the outcome of the Diplomatic Conference. The problem was that the basis for their happiness was not quite appropriate. They alleged in these articles that Hollywood lost, since it had made some proposals that were not accepted, including a proposal that temporary, transient copies should be recognized as copies, or, in other words, that the concept of reproduction should extend to such temporary copies. According to Samuelson and Browning, this proposal was rejected. But this was not the case at all; just the opposite was true. Some happiness was also expressed by some experts about the agreed-upon statement on certain exceptions or limitations adopted at the conference. According to that statement, the exceptions that exist now may be extended to the digital environment. This was interpreted to mean that if libraries now have particular rights, then they should be able to continue to exercise these rights without any change. The claim was, more or less, that putting a copy into a xerox machine is the same as posting a copy on the Internet. I do not have to explain the difference.

"Threat or Promise?" Is the Wrong Question. I think that the question of whether digital technology is a threat or promise, and whether owners of rights have won, or users have won, or either of them has lost, reflects a wrong approach. I think it's absolutely wrong to put the question in such an antagonistic way, because the interest of owners of rights is not just to be protected *against* the use of their works. Rights owners need to be protected *during* the use of their works, but they don't have an interest in excluding people from using those works. In the end,

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[14] Pamela Samuelson, *Big Media Beaten Back*, WIRED, Mar. 1997, at 61.

[15] John Browning, *Africa 1, Hollywood 0*, WIRED, Mar. 1997, at 61.

this is a kind of offer and demand question, and therefore the pricing business you have mentioned is very important. Pricing may be quite different if all users or the majority of users are covered; in such a case, prices may go down.

Fair Use. As far as the question of fair use is concerned, technological measures for protection represent what Charles Clark referred to in his famous saying "The answer to the machine is in the machine." Now this answer in the machine may create some new problems, but those problems may also be solved through the machine. So it's possible that the answer to the problems raised by the answer in the machine may also be in the machine; that is, all these issues may also be addressed through the same technology.

MR. SECOR:

Academic and Scientific Publishing. I just want to comment on a couple of things that have been said. First, in answer to your question, Silke, about how much will be digital, I work primarily between academic and scientific technical medical publishers and the academic community, and I'm reasonably confident in saying that almost all of it will be digital. Even what's printed will be digital in that it will exist as a digital file somewhere. A lot of that material will be printed on demand, so we'll have a little bit different distribution model than we've had in the past. When I look at academic publishing and academic use, and particularly in the journal field, what strikes me is that we need to consider the legal realties along with the economic and business realities.

Economic Disfunction in Journal Publishing. I would agree with an earlier observation that many infringing or potentially infringing uses are not being pursued by those whose works are being infringed. The question is why are these infringers not pursued? Well they're not pursued because it's either not economically or politically feasible or because it's not economically necessary. In our community right now we have what I would call a very dysfunctional economic system, especially in regard to journal publishing where subscription prices have just gone up and up. As we think about whether digitization is a threat a promise, we have to think in the context of the existing system. Currently, in academic publishing and with academic use, the cost burden is not reasonably shared among users of the content. Also, authors are generally not compensated directly though they're compensated indirectly by tenure or by professional status. There are a lot of people who are looking at digitization and online communication as an opportunity to remedy what is a somewhat dysfunctional system in terms of the economics of and the access to information.

MS. PERLMUTTER:

Assumptions Underlying the Idea of a Copyright Grab. I'd like to throw a couple of thoughts on the table. First, I want to respond to the idea that there's some kind of a "copyright grab" at work in this legislation or in the treaties. That way of thinking is based on a number of assumptions which are not necessarily true.

The first is the assumption that whenever a new right is added, that necessarily expands the scope of copyright protection. Obviously in some sense it does. But such an addition of rights may entail nothing more than changing the definition of copyright protection in response to a change in technology and markets so that copyright simply continues to cover a similar type of exploitation.

Second, there is often an assumption that this is all a zero-sum game, that one party wins and the other party loses. Those of us around this table probably all agree that the beauty and promise of the Internet is the ability for everyone to win, for more material to be made available to users at lower prices, and for copyright owners to be able to make a greater profit. This point is important to keep in mind, and often gets left out of the discussion.

Third, turning to the catch-phrases of the debate, I've been reading less about the copyright grab and more about the dangers of a pay-per-view world. "Pay-per-view world" is a phrase we heard a lot in Washington during the final days of negotiation that led to the DMCA. This phrase, too, masks a number of hidden assumptions. It's not obvious that what people are calling a pay-per-view world is necessarily a bad thing for users. It could be that a pay-per-view world would result in more material being available more cheaply than is the case today. This is at least a reasonable possibility. So it's always very important to think about the assumptions that underlie some of these buzz words.

Historical Roots of "Copy"right. That relates to my second point. We all suffer a bit from too much rigidity of thought. We're too firmly shaped by the system that is currently in place, and it's difficult to think beyond the current model. We think of copyright as a bundle of rights — the reproduction right, the distribution right, and the performance right — and the reason for thinking that way is historical. In the beginning, when people copied manuscripts by hand, we had a "copy"right, which gradually evolved over time to encompass newer technologies. The key idea behind all of these rights is giving copyright owners the ability to meaningfully exploit their works. That's what we should focus on.

Historical Roots of Infringement Defenses. On the other side, people are accustomed to various defenses to claims infringement, the "first sale doctrine," and "fair use." These are very important defenses.

They were developed as responses to existing conditions, which in the case of fair use often included market failure, as Wendy Gordon and other academics have pointed out. Those conditions may be changing, and so we may come to need other kinds of defenses. We can't just look at it as a mathematical equation, with a certain number of rights balanced by a certain number of defenses, although some people are falling into that trap. We're obviously in a time of tremendous evolution. It's exciting, but it's also difficult for people to shift their modes of thinking.

Anti-Circumvention and New Rights for Copyright Owners. Finally, I just want to say that of all the debates I've heard about the DMCA, one of the most interesting questions is whether the anti-circumvention provision provide in essence a new exclusive right to copyright owners to control access. In the past, of course, copyright owners had the *privilege* to control access. They could always do it, they were capable of doing it, but there was no legal right they could enforce against those who got unauthorized access without exercising the rights in § 106 of the Copyright Act. I think that's a fascinating question.

MR. ATTAWAY:

In the spirit of piling on, I'd like to continue the criticism of Professor Samuelson.

MR. WILLIAMS:

We need a few defenders.

MR. ATTAWAY:

No New Rights. Which makes piling on all that much more fun. I don't think that we have created any new rights at all with the legislation that was passed this year. About ten years ago, Congress passed a cable television package which included a prohibition on the theft of cable television services as well as a prohibition on the marketing of devices that would enable that kind of theft.[16] I didn't hear a peep from Professor Samuelson. It sounded perfectly reasonable. All that happened this year was that the concept of protection against theft was expanded in two respects. It was expanded to cover all distribution systems, including the Internet, and it protected conditional access, which seems perfectly appropriate to me. It's no new copyright. And secondly, it allowed copyright owners not only to create an electronic envelope and protect the security of that envelope, but it also allowed them to make the envelope transparent, allowing people to see what was inside but denying them the ability to make copies. Again, I don't see

[16] Satellite Home Viewer Act, Pub. L. No. 100-667, 102 Stat. 3949 (1988).

any new right. This legislation just secured the ability of copyright owners to use technology to protect their rights.

Fair Use: Technical Abilities Versus Legal Rights. June made the comment that technology expands and contracts the *ability* to exercise fair use which I think is definitely true. But technology doesn't expand or contract the *right* of fair use. In the audio-visual field, before the advent of the VCR, I think fair use of audio-visual material was much more narrow than it is today. The VCR expanded the exercise. It didn't expand the right of fair use; it just expanded the ability to exercise it. Now digital technology may contract the ability to exercise fair use in certain cases, but it doesn't narrow the right.

MR. TANENBAUM:

The New World of the Internet. In response to what Silke has said, I'd like to offer my opinion that all the hype about how the Internet is going to change the world is, in all probability, an understatement. There will be a significant change. I have two global points to add to the discussion. The first is based on the fact that I do a lot of work with software patents and with copyright. Some of the distinctions in writing these patent applications are between information and how that's different from data and how that's different from knowledge. That will have an impact on how we consider authorship on the copyright side of the fence. My second point is that with respect to convergence (which, parenthetically, happens at lawyers' desks before it happens in the real world because lawyers are the ones who have to think through what happens when they write contracts) I think we're going to see a more porous distinction between what content is and what technology is, and this will be particularly true of the Internet.

MR. KEEFAUVER:

Creative Marketing as Protection Against Piracy. I have a comment largely from the user side. I grew up and was quite active in the early days of computer software, and we initially didn't know what to do with it. We could sell it, and we had price tags of $100,000, $150,000. We could license it, but we didn't know how to protect it against piracy. And to make my remarks somewhat shorter, the ultimate solution to protect against piracy was creative marketing. The way we kept piracy largely under control — but of course did not completely eliminate it — was through creative marketing, pricing our software at a level that customers were willing to pay because they got something extra, usually support. Obviously, you can go to a friend and copy their disk, but then you don't get the support. In our efforts to control piracy, which

technology will ever increase the capability for doing, marketing will have to play a major role.

MR. STRONG:

I'm just going to be devil's advocate here for a moment, and I hope you won't think I'm a devil appearing pro se. I have been disturbed by the process which gave rise to the DMCA and I'm disturbed by the product.

The DMCA: Legislation by Treaty. The process, I think, was flawed in that instead of having what should have been a vigorous and prolonged public debate in this country among the interested groups, including the users' groups, there was — and I mean no disrespect to our friends at WIPO — a sort of "legislation by treaty," or even legislation by preemptive treaty. There was a successful attempt to persuade the international community that a treaty should be enacted which would require all signatories to enact enabling legislation to conform to certain norms. And having accomplished a treaty, the treaty was then presented to the U.S. Congress as something of a *fait accompli*, which put Congress in the position of either thumbing its nose at the international community or going along without, frankly, very much debate. There were some people who leaped into the process at the last moment, and I think they had some beneficial effects on the outcome of the bill.

A New System Based on No Data. I'm also disturbed about the content of bill. One of the things that it seems to do is to calcify a system before we have any data about what the real problems are and how those problems can be addressed. It's a very elaborate system. It has not been tested in any country, but there it is on the books. I'm disturbed by the fact that there are no penalties for content owners who abuse the system. Consider the following example. Suppose someone comes out with a digitized version of a work that has never appeared in digital form before. They encrypt it, even though it's in the public domain. People will be scared because there will be a copyright notice on it, and the thing is encrypted. The average user will not know whether that is something they can freely get at or not. In the print world, there was always the problem of people putting copyright notices on things they had no business putting notices on. But, there was a more even balance of ignorance between the two sides. Here the balance seems to have shifted to the people who are putting this stuff out. Those are some of my misgivings.

MR. FIELD:

Encryption Cannot Deplete the Public Domain. Bill Strong has raised an issue I find very intriguing. I have heard others, too, speak of

encryption's taking material out of the public domain but I don't see how that can happen. If one firm digitizes, say, the Bible, that doesn't prevent another firm from doing the same thing. If firms can compete in all ways short of sweat-of-the-brow free riding, the public should have digital access to material that might not otherwise be available as well as have it at the lowest possible price

MR. STRONG:

Copyright Notice and User Fears. That was only an example of the kinds of things that I'm concerned about. If someone has come out with a digitized version of something and places a copyright notice on it, the user is going to be faced, if he's the first to try and use that material, with a real risk. Admittedly, as you say, people can come out with competing products in due course. But that initial investment in digitizing — which can be substantial — is going to be protected by a sort of in terrorem effect based on having the copyright notice plus the user's fear that he or she would be violating the anti-circumvention provision. It is also not clear to me whether there is protection for people who make anti-circumvention devices that get around encryption of material that is not copyrighted. I just don't know how I would advise someone who might want to go into the anti-encryption business and sell a product designed to decrypt public domain material.

MR. FIELD:

I think they have at least two years — until the Copyright Office passes some regulations.

MR. ATTAWAY:

The Five-Year DMCA Process. Bill, I've got to take violent exception to the suggestion that there has not been a process. There has been a process, and that process has consumed the last five years of my life. Long before the treaty and the diplomatic conference adopting the treaty, the President convened a National Information Infrastructure ("NII") Advisory Committee that held meetings around the country. I don't know exactly how many there were, but there were scores of them. Public meetings. The Patent and Trademark Office held hearings and provided opportunities for public comment over the course of two or three years. The implementing legislation that was initially introduced was about three pages long. As a result of the legislative process, during which every conceivable issue was debated and analyzed and compromised, a three-page bill grew to about one hundred pages. The process was lengthy and comprehensive. There was certainly no lack of process.

MS. PERLMUTTER:

Congress and the Treaties. I just want to add word or two about the treaties. First of all, while anti-circumvention is a new concept, the treaty language on anti-circumvention was generally agreed to by the interested U.S. parties on all sides of the issue in Geneva in 1996. Second, as someone who works for the U.S. Congress, let me tell you that no treaty is a *fait accompli* in their eyes. But these particular treaties happen to be very popular and, in fact, there was no opposition to the treaties themselves. The question was always what the implementing legislation would say. The implementing legislation did take almost two years of unbelievably intensive work to finalize with much debate in different committees and subcommittees in both the House and the Senate. The way the treaties and the implementing legislation have evolved has been a very intensive and open process.

MS. PETERS:

The Treaties in Congress. I just want to add, with respect to the process, that I agree with what Shira said. The treaty language is very broad with total flexibility as to how to implement it. The debate was very well financed on both sides. The Digital Future Coalition was quite active, and if you look at the end result, effective. There are eight exemptions concerning circumvention for the purpose of gaining access to a work. I don't know how this will play out. I agree it's very difficult, complicated legislation. Hopefully, we have potential solutions that work. But no legislation is carved in stone, and it always can be revised.

The Scope of Public Debate. Title II of the DCMA, the online service provider ("OSP") liability provision, is very complicated; the parties sat down and worked out the legislative language. The Copyright Office had preferred a broad-principle approach rather than an approach that addressed specific activities. There wasn't a real public debate on the agreed-upon language. On the other hand, the language in Title I, the WIPO treaties implementation provisions, was very widely debated. The Copyright Office, which is located in a library, was concerned with the preservation of fair use, the exemptions, and the public domain; we wondered how the system would work. But there was a need to encourage electronic commerce now. We believed that the law could be revised if it was overbroad in its ultimate effect.

MR. MURRAY:

The Fear of Total Content Encryption. To give the devil his, or in this case her, due, before Professor Samuelson is tried and convicted in absentia before the end of the conference today, I think it's important to focus on what the Digital Future Coalition, the Electronic Frontiers

Foundation — the entire constituency that Professor Samuelson speaks to — is afraid of. What they all fear, in its most extreme terms, is a brave new world in which all content, all information, will be encrypted in digital containers and will be available only those who are willing to pay for access. And so, at its extreme, the right to read at the public library, the first sale doctrine, the fair use doctrine, ultimately even the public domain, all go away. The fundamental reason why I disagree with Professor Samuelson, in terms of the enactment of this legislation, is that we're discussing a risk, a brave new world, and we don't know if that new world is actually going to come into being. We live in a democracy, and if ultimately there is an evolution, as a matter of fundamental economics, to a world in which those who sell the widgets choose to sell far fewer at a much higher price to maximize their revenues, then we can enact legislation that will further amend the Copyright Act. In other words, I think the risk of having the anti-circumvention legislation, in its current form, is a risk worth taking. But the calcification that was referred to is something I think we need to be concerned about.

MR. SECOR:

Problems in the Process: Giving Professor Samuelson Her Due. I want to echo that, and I think that when we talk about the process we should give Professor Samuelson and others their due. This was a process that was not begun in the best of ways. It was a process that was begun with a *White Paper* in which many people felt that society's rights, the rights of the non-copyright owners, were not adequately reflected in the specific proposals and in the rhetoric. And just look at the evolution. Read from the *Copyright Grab*, which was written in response to the *White Paper*. What got enacted was not what was proposed in the *White Paper*, and part of that is reflective of some of those opinions that were put forth on the other side.

MR. FICSOR:

Representation of American Interests. There was opposition to some parts of the draft treaties which, in the end, were not adopted. I would say that, of course, certain draft provisions were not always justified, but what was ultimately adopted seemed to be acceptable to everybody. Actually, there was such lobbying during the three weeks in December of 1996 that I think it would have been impossible to have neglected any interest. And then the U.S. delegation actually was, in effect, a kind of Congress; there were so many members of the delegation, all interest groups were represented.

Public Domain Works. Now I would like to address the question of what would happen to works that are in the public domain. We have

to differentiate between two things. First, it is true that access to public domain works, from the copyright viewpoint, is free. But, even so, this "free" public domain work cannot be made available without some effort in the area of production. If you go into a bookshop, you cannot get a copy of, let us say, a compilation of all the dramas of Shakespeare free of charge, because the publisher had to invest in typesetting, printing, binding, and do forth. So as far as users' rights to use public domain works are concerned, we may still differentiate between the availability of rights for everybody who would like to publish such works and the availability of copies for everybody who would like to read these works. As far as the availability of rights is concerned, of course it's very clear that anybody may post on the Internet any non-protected material. There's no problem with that.

UNESCO Public Domain Program. There's a very interesting UNESCO program that focuses on this issue. Some UNESCO experts attacked the two treaties. We had some meetings, and we told them this: if you truly care about this, why do you not do something. In fact, UNESCO is undertaking a very ambitious program to put public domain works on the Internet free of charge. Such a program could also be undertaken at national levels. The Library of Congress, for example, may do that. So I think that the problem actually is not so serious if you consider this: why would a person pay to use something that he or she could use elsewhere, for free?

MS. SAND:

The Status of Neighboring Rights Holders. As I look down today's agenda I find myself wondering — as I often do at meetings such as this one — "Oh God, when am I going to say something?" As usual, I fit into the "Me too, we're here as well" category of rights holders. But when you're faced with the twin monoliths of copyright owners and users of copyrighted works, we performers or neighboring rights holders feel like mere pebbles in comparison; we tend to run along behind, trying desperately to get in on the act. I thought that since this is a general session, I'd say one thing and pick up on something that Shira said about shifting ways of thinking, because I think in our field there is a quantitative shift that's worth noting.

The Protection of Underlying Rights. Performers and neighboring rights holders are pretty far down the food chain. What's more, we're often characterized as copyright grabbers, trying to cash in on everything that's happening right now and to get something new. If any group has had a tradition of viewing rights as a way of stopping things from happening, it's us. But our rights holders, the people we work with, now are starting to change their attitude to rights. And I think it's not only

them. One thing that's been interesting to me is the way that the copyright community generally has embraced, or at least started to understand, the need for the underlying rights also to be protected. That doesn't actually threaten the whole. One of the illustrations of that is, of course, the new process at WIPO which includes not only the copyright treaty but also the performance and phonograms treaty and the ongoing treaty discussions. All of these are very encouraging and very positive.

Neighboring Rights Holders' Views of the Threats. If you want to characterize the way that neighboring rights holders are looking at the threats, or the challenges, I think you could do it in two ways. First, there is some sense of awe and wonder at their own ability not only to see their work used, and used in all sorts of new ways, but also to affect their own work and to make work in a new way. However, there is also fear and trepidation that as their work is used more, it will lose value, and will generate less interest in the future. This is why I think that waiting to see how the market develops and how technology develops is not necessarily the best approach. I think that the legislation has to anticipate and facilitate the technological changes and, to some extent, has to second-guess those technological changes. We have to encourage governments of all kinds to establish sets of protections and to figure out ways of making those protections meaningful, not only for the rights holders but also the neighboring rights holders. And, of course, these protections should take into account the interests of users as well.

MR. STRONG:

Public Participation in the Debate over the DMCA. That's a very interesting comment, and I understand the argument that legislation should be ahead of the curve on this because if it's not, then wild things are going to escape from the zoo and can never be put back in their cages. That may be true. I guess that, rather inarticulately, I was really getting at — and Fritz I was in no way suggesting that you'd wasted five years of your life — I was really getting at the fact that this is a piece of legislation which, perhaps unusually in this field, affects the lives of individuals, or will affect the lives of individuals, as the Internet becomes a presence in everybody's house and as its interactive capabilities are further exploited. What goes on in copyright is going to be a part of people's daily lives, even more than it is now. I'm just concerned that the public, as a whole, was not really involved in this debate. There were certain people who purported to speak for the interests of users, and perhaps they did. It's not clear to me how great their constituency was or how great it was perceived to be. I would have preferred to have more evolution of the technology and more evidence as to how the technology

is truly affecting people's rights before we embarked on very complicated piece of legislation, and that's what I was driving at.

MR. MARKS:

I want to respond to a couple of questions and comments that have been made.

How Much Digital Business? First Silke's question from way back when. At Time Warner, there has been a lot of debate about how much of our business is going to move to digital electronic and how much is going to remain analog. At an internal conference I recently attended, someone from Time, Inc. got up to say that he really thought that even magazine delivery was going to move increasingly towards digitization and electronic delivery. Of course, the chorus came back saying "How then am I going to read my *Time* magazine on the train into the office?" There is still a tremendous amount of debate and wonderment, I think, within companies as to how much exploitation will remain analog and how much will move to digital.

Beyond the Promotional Model of Digital Exploitation. One of the biggest concerns and challenges on the digital exploitation front, especially electronically through the Internet, is that so far the model has largely been a promotional model. For example, our site Pathfinder or CNN or Warner Brothers Online is free. Users access the web site for free, and the material that's made available, at least electronically on that site, is free. We have record company sites where clips from our sound recordings are made available for free. The company realizes that that is not the proper model for economically exploiting the work as a whole, and so the question is how do you move from this promotional model of electronic delivery to a more commercial one? I think that's the big challenge that people are wrestling with. Our music companies, in particular, have significant expenses related to inventory, distribution and delivery, and they see the prospect of electronic delivery as offering tremendous cost savings. But it's got to be done in a way that is secure enough to earn an economic return.

Texaco *and the CCC.* Responding to Glen's remark about the dysfunctional model of academic and journal publishing, I was wondering what your reaction was to the *Texaco*[17] case, because it seems to me that that case was a major wake-up call for lots of companies and users of academic journals. As a result of that case, the Copyright Clearance Center ("CCC") really came into being. We at Time Warner pay a fairly hefty annual fee to be a licensee of the Copyright Clearance Center. It

[17] American Geophysical Union v. Texaco, 60 F.3d 913, 35 U.S.P.Q.2d (BNA) 1513 (2d Cir. 1994).

seems to me, in fact, that there was an interaction between law and evolving markets and technology that created real hope of a viable solution for both authors and publishers of academic presses through something like the CCC.

Paying for Digitizing Public Domain Works. Finally I want to respond to one of Bill's remarks. He said "Well, you know the problem I may have with digitizing a public domain work is that it costs money." That's exactly the point, it does cost money. So if you want digitized versions of public domain works to be available, I don't see how you can get there without guaranteeing some sort of return on the investment made by those who expend the resources to digitize the works.

MR. SECOR:

***Waiting for an Academic* Texaco.** The *Texaco* case could also be known as the CCC Employment Security Act of 1994. *Texaco* addressed commercial photocopying. Many of us were waiting for the academic version of the *Texaco* case, one that would take up academic photocopying of journal articles. Such litigation seems unlikely to happen because we've moved a bit away from a photocopy and fax model of copying. What CCC collects, particularly through the blanket licenses, and then passes on to the copyright owners is helpful, but that's not a big part of the revenue stream of any scientific or academic publisher.

Texaco *for the Digital Age.* On the academic side, most academic content, including all significant academic and scientific journal content, is available electronically. Many publishers are tying a subscription to the online edition, or a site license to the online edition, to a print subscription in order to protect the print revenue base. When the print revenue base goes away, which it will, then comes the question, "Alright now, how do we make the digital economic model stand on its own two feet?" We don't have the answer today, but we do have a lot of debate.

Inter-Library Loan and Digital Materials. I want to go back to something that Shira said about it being a mistake to think in terms of a strict mathematical formula in which the existence of a right over here automatically means that another right or privilege must exist over there. Inter-library loan of digital materials sounds to many like an oxymoron. How can you have an inter-library loan of digital materials? And, finally, some people are starting to realize that inter-library loan may not be the right concept here. We're talking instead about resource sharing in a situation where resource sharing without some sort of revenue sharing is problematic.

MR. OPPENHEIM:

I want to follow up on some things Dean said and harken back to what June had said early-on about how the public is viewing the evolution of the Internet.

Content Protection by Lawsuit. At the Recording Industry Association, we've brought a series of lawsuits against individuals and an internet service provider who put recordings up on the Internet and made them available to the general public — the Netizen community — to download. In the first series of lawsuits we ended up, as many people know, settling without people really paying any money. Since then we've had a campaign. We send out cease and desist letters, on a daily basis, whenever we locate these sites — and there are thousands of them available with tens of thousands of recordings.

Public Perceptions of Copyright. In our second set of lawsuits, we went to these folks and we heard some very interesting reactions which really should guide us. One reaction was: "Hey what are you doing? I thought that unless I got a cease and desist letter, I could do this and that I was allowed to make these recordings available for free until you told me to stop." Another reaction we got was: "Oh, I'm promoting your music. I'm out there trying to tell the world hey, come buy this, this is great stuff." The third response was: "You would never have caught me unless I let you." In light of these responses, I agree with Dean that there is a perception in the Netizen community that everything on the Internet is promotional, that everything is free, and that it's acceptable to take and to use any such material freely. What we need to be doing is creating encryption systems and protected systems to change the public's perception.

MR. KEEFAUVER:

Ladies and gentlemen, the brain cells have obviously been working very well. I would now like to give you an opportunity to exercise some of your other cells, so let's take a ten-minute break.

[The conferees break for ten minutes.]

MR. KEEFAUVER:

Let's take our seats and resume our discussion. Before we return to substantive matters, we've got some introductions to make, since we have been joined by three newcomers who didn't have an opportunity to introduce themselves earlier.

[For biographical information on Jon Cavicchi, Katherine Sand, and Sallie Weaver, see *supra* Part II.]

Thank you very much. Now Jeremy and Silke, please resume.

V. TECHNICAL MEASURES AND ANTI-CIRCUMVENTION

MR. WILLIAMS:

I know that some people have continuing comments to make on issues that we were discussing before the break, and I don't mean to cut them off, so remember those thoughts, and continue to add them. I also want to put on the table a few other issues, to be sure that we cover them in connection with our second major topic, Technical Measures and Anti-Circumvention. Please comment on the following issues in any order that occurs to you.

The Nature of the Technical Measures. One issue is that we've been assuming in this discussion that the technical measures we're talking about will work, and consequently, we've not had much discussion about these technologies themselves. I know that there are some people in the room who are able — without getting into too much engineering detail — to enlighten the rest of us on just what direction some of these technical measures are going in, what their nature is, and how effective they're likely to be. I'd like to elicit some comments on that question.

Operation of the DMCA. Secondly, in light of what we learn about these technical measures, how will a bill like the DMCA actually work in terms of technical measures? For example, there are a number of exceptions to the anti-circumvention provisions in the DMCA. But as I read them, I'm not entirely sure how I would advise a client about how these exceptions work. Just to give one concrete example, there is a provision called, affectionately by some, the "Library Shopping Exception." This exception allows libraries to circumvent technological protection in order to temporarily view works and decide whether they want to purchase them. It's not clear to me, however, that the Act allows for any legal means by which libraries could acquire a tool with which to do that shopping. I may be wrong, but it's an example of the kind of nuts-and-bolts that I think the courts are going to have to start to deal with. So I would be interested in eliciting some comments on how the provisions actually work, including the general question of how the DMCA changes, and to what extent it changes, whatever rule we believe was promulgated in the *Sony Betamax* case, and how one would advise a client on that issue. So this question goes somewhat beyond the nuts-and-bolts of the DMCA.

"No-Mandate" Implementation of Technological Protection. Another question in that general area — and I've asked Dean Marks to

talk a little about this — is how, in the real world, are some of these provisions going to be negotiated or enacted? As we know, one of the big issues in the bill was the issue of whether there should be mandates requiring hardware devices to recognize, for example, information on software that would trigger copy-protection mechanisms. We have a no-mandate principle generally in the bill. That leaves the question how do industries go about implementing technological protection? I think the leading example in the real world right now has been the ongoing development in the DVD area. I'd like to elicit some discussion about how that has gone, what some of the problems have been, what that may mean for the future in a no-mandate world, and whether anybody people thinks that the no-mandate world doesn't work and should be replaced by a world with mandates.

Non-U.S. Perspectives. Finally, under this general topic, I would like to ask our guests from outside the United States to comment on some of these issues from a non-U.S. perspective. For example, in the European Union, what are some of the outstanding issues in their proposal, and to what extent do they differ from what we've discussed here? In that regard, one thing Silke and I have talked about is the question of private copying which, from my perspective, has been a subject of much more debate outside the United States than inside the United States. And to harken back to technological protection, if technological protection is effective, what is the actual practical significance of the legal debate on private copying? Those are a few issues I'd like us to explore — without cutting off any of our previous discussion.

MR. BRILL:

Macrovision's Technological Protection Invention. As I mentioned earlier, I represent Macrovision Corporation. Since some of you here may not be aware of what Macrovision is or has been, I'll provide a little background that ties into the circumvention area in general. Shortly after the *Sony Betamax* decision in 1984, the Chairman of Macrovision, John Ryan, invented a circumvention technological measure which has been used in the analog video world. I don't mean to do a commercial, but this invention has been placed on well over 2.5 billion videocassettes around the world, so I guess you might call it successful.

Protecting the Protection Measure. For any of you patent people who might be interested, part of our success has been due to Mr. Ryan's having patented not just his initial invention, but also various ways to defeat his invention, which was useful to us because the initial invention was pretty easy to get around, from a technological point of view. Over

the years we have had to depend on the patent laws to discouraging people from making black boxes, as we call them.

Public Attitudes Toward Copying. I've been with the company for five years, and I've been involved in several of these situations. One of the things that's been quite remarkable occurred in a case that we settled recently. A very well-known attorney — I won't name him, but he was representing the other side — he said, with a perfectly straight face and his client at his side, "Well, under the *Sony Betamax* case, our client's customers have a perfect right to copy a copy-protected videocassette." Obviously, we differed in our opinion on that.

Analog to DVD. My company's copy-protection technique is an analog technique that has been very successful. It is probably the most-used copy-protection technique in the movie industry. I am counting on Dean and others who represent the movie industry to correct me if I get off the track at all on any of these things — but as I understand it, when DVD came along, a lot of the movie industry was supporting the Macrovision system because VHS-to-VHS copies were not a good idea from their point of view. A VHS copy, as we all know, is not the best when made from a VHS. But when DVD was coming about, there was a major concern that a DVD-to-VHS copy — which is the copy a home viewer would get — would be the same thing they could go down to Blockbuster and rent or buy. So there was a major concern about the problems of DVD. I know Dean earlier made the comment that over the years the movie industry has typically gotten concerned about new technological developments that have turned out to be very profitable, despite their initial concerns, but even so, there was a concern about DVD. As a result, over the last several years, a copy-protection working group has developed, along with the DVD forum and so forth. To make a long story short, the consumer electronics industry, the computer industry and the rights holder industry/community developed the idea of putting the analog copy-protection system into a DVD player. We all know that's necessary because while analog is going to go away, it's going to take awhile. There's a large base of product out there. So we start with the analog technique. And now, of course, there's a big move to use similar technologies — similar in a sense that they are technological protection measures — in the digital world.

Digital Technological Protection Measures. I am familiar with some of the things that are being done to prevent digital copying. There are other things, such as watermarks, that others at the table might be able talk about. There is a system being used now for CD-ROM that is starting to be a possibility for games on CD-ROM. There are a number of these techniques under development that will probably be implemented in

the next months and years to put technological protection measures of one form or another on digital media to discourage people from copying.

Technological Protection as Copyright Law. I feel, having been somewhat involved in the legislation, that the technological protection measure is there. Somebody's paying to implement technological protection measures, and the technological protection portions of the bill are there to say it's illegal to remove these protective measures. If you have removed them, then I think the Copyright Act is what comes into effect, as we know the DMCA as a copyright law, even though a number of people have said that the DMCA is really not copyright law, but is more of a technological enforcement law. That's a summary of where I think the technology has been, where it's going, and why we're here.

MR. SECOR:

The Technologies. Real briefly, just to mention some of the technologies that I see in the text environment, there's secured access, passworded access, secured containers, something like the Cryptolope, there's the actual encryption and metering of the content itself, watermarking, which is now becoming available for text as well as for video and still images and audio, and then online permissions and licensing systems. There's also a lot of work going on in the field of rights metadata, or ultimately what populates that copyright management information that's referred to in the bill, and issues like the Digital Object Identifier ("DOI"). I wish Carol Risher from the AAP were here to talk to us. Beyond the individual technologies themselves, we're seeing increasingly the integration of these different types of technologies, both protection technologies and electronic commerce technologies. The primary example of that in the text arena right now is probably Intertrust, which has combined secured container encryption, metering, watermarking, and has now also announced that they're going to have some sort of an online permissions and licensing facility. My company is looking to do much the same thing with our various technology partners.

Persistent Regenerative Secured Containers. I want to throw a hypothetical out on the floor to take something that you were talking about, Bill, a step further. You were talking about the encryption of a public domain work. One of the technologies being developed by a company called Softlock could be described as a persistent and regenerative secured container. When you get the key to that container, your key applies only to a specific environment, which can be anyplace from a specific machine all the way up to an IP address. If I bought the key, I can get access to the file that's in the container. I can even send you the file. Say I e-mailed the file to you Jeremy. The container will regenerate itself. So it doesn't prevent me from sending you the file, but when the

file appears in your e-mail it will have that container around it again. I was at a library conference last week and we talked about this specific technology in trying to figure out how it might work in a library or academic setting, even let's say within a campus: how does stuff get moved around and how do we keep track of what sort of access has been purchased? And from an academic standpoint, either from the perspective of the institution or the individual, how do you keep from paying what might be a two- or three- or four-dollar charge every time you have to enter into one of the key transactions? Most of this technology has not yet been brought to bear, but it's sitting there, and it's waiting. I don't know what comes first here, the chicken or the egg. Now that we have the statute, does the technology get applied, or does the technology get applied first, and then we find out how the statute works?

MR. WILLIAMS:

Pay-Per-Use. Glen, based on what you said and Jerry, leaving aside the issue of right or wrong, good or bad, do you have any doubt that the kind of marking-up, metering, and pay-per-use that Professor Samuelson fears in the article is coming technologically?

MR. SECOR:

For valuable content, no, I have no doubt that it's coming.

MR. MACKEY:

Control and Commerce. My comment is far broader. It seems to me that there is technology available to effect all of the controls that are envisaged in this bill, and even more. The real issue is a commercial one: "What controls are commercially practical?" I'll give you a contemporary example. If I find a book title at Amazon.com, I really don't know what's in the book. But if I go to Barnes & Noble and browse and decide what I want to buy, I can then go back to Amazon.com if I prefer their price. Amazon.com doesn't provide me enough information to make my purchasing decision. Further, as you maneuver around the Internet, you may come to an interesting screen and then find that you can't go any further unless you pay up, but you don't know what you're paying for. Perhaps you don't pay, and a sale is lost. So there's a commercial issue of how much control to impose. I'm not sure that this forum can really speak to this issue, but it is very real. If you've got all the controls in the world, then you must ask how many do you wish to use, and how do you want to use them?

MR. FIELD:

Counter-Productive Controls. I'm reminded of copy protection for disks. Because I use a Macintosh, I rarely face that, but I recall users complaining that early copy-protection schemes harmed drive mechanisms. This gave a few people more than ample justification to defeat such protection measures and to pass on pirated works after doing so.

I'm also reminded of passwords. I loathe these. One password won't do; every web site seems to have its own formula for composition, minimum length, and so forth. So, when I go to a site that asks me to pick a password, I leave. I'm sure I'm not alone.

Self-help schemes that lose track of consumer preferences will fail. Even if the NET Act discourages self-righteous hackers, one must nevertheless consider the effects of any scheme on consumer goodwill and, ultimately, on sales.

MR. POLITANO:

The "Culture" of Circumvention. I am not a technological expert, but my experts tell me, at least in my company, that what Len envisions, and others envision, will indeed happen. We will be able to put into place measures that will protect various levels of viewing or copying or performing. However, as sure as that is going to happen there will also be ways to circumvent. Whether those techniques for circumvention are legal or illegal, they will become prolific very quickly among a community of users composed of people on the Internet who revel in circumventing technological protection measures. This is a very real problem even though there may be statutory protection, and even though that protection may seemingly be adequate. The question remains: how do you handle a form of protection that has never been tried in a medium such as this one, which encourages (or at least inspires) encryption and disencryption. I just recently saw again the movie *Fahrenheit 451*, which is about a society in which it was illegal to own a book. People owned books, and they read books, and they went into forests and memorized books. People were able to circumvent even though circumvention was illegal and carried a very high penalty. I think the notion that June alluded to a little earlier, a community of users who believe that they have an absolute, God-given, constitutional right to copy is something that no legislation could successfully address.

MR. OPPENHEIM:

Circumventing CDR Machines. Responding first to the point most recently made, there are a lot of circumventions going on already, some of them less technological than others. Chris and I were talking during the break about the new stand-alone CDR machines which are

supposed to be compliant with the Audio Home Recording Act.[18] You're supposed to purchase blank CDRs, royalties from the sale of which are to paid over to the Copyright Office which then distributes the money. As everybody who is in this arena knows, you don't have to pay $8.00 for these expensive blank audio disks if you don't want to. You put the expensive one in, close the door, then you physically open the door, pull out the expensive disk, and replace it with the cheap $1.00 computer CDR, and *voilà*, you've now circumvented the technological protection and the AHR measure. These techniques exist, they're going to exist, and we're going to have to keep changing the protection technologies and improving them in order to keep ahead of circumvention techniques.

Protected Environments for Music Content. Glen, in the music area, the issue that you've raised has been addressed. You can go online and hear little snippets of songs, samples if you will, that are available to help you decide whether or not you want to actually purchase a CD. I suspect that that's where the technology will go. What's very important to remember here is that a lot of new technologies are being developed, and, especially in the recording industry, we're in the forefront because, for bandwidth reasons, our content may be at more risk than other content. While we're seeing all kinds of new technologies being developed to address the need to protect content, it's very important to us to protect the environment until those technologies are put in place. There are companies out there, A2B, Liquid Audio, Real Networks, those types of companies, that are trying to create protected environments for content. All of these companies are in line with us in saying that our work is for nothing if an MP3 community, for instance, makes all the content available for free on the Internet. We can talk all we want about great new technology measures. They really won't serve us if the pirates get to dominate the market first.

MR. BAUMGARTEN:

Book Sampling at Amazon.com. The sampling technique that you mentioned is also available on Amazon.com with chapters of books. More and more e-commerce is recognizing that the consumer has to be given an opportunity to try the merchandise. But whenever these discussions of technology occur, we always tend to be simultaneously under-impressed and over-impressed.

Circumvention Isn't That Easy. We are under-impressed because we talk about how easy it is to circumvent technology. But in the real world there's a huge difference between the ability of a graduate student at Berkeley to break a technology within two to six weeks and the ability

[18] Pub. L. No. 102-563, 106 Stat. 4237 (1992) (codified at 17 U.S.C. §§ 1001-1010).

for that compromise of the technology to be widely disseminated and implemented by consumers. So sometimes technology is pretty good.

Technology Alone Isn't Enough. We tend to be over-impressed because we think that technology alone can do it, and it can't. Take all the hype about encryption. Encryption is a great technology for controlling access. But if you're worried about copying by your customers, encryption is totally useless because when your customer gets your product, they have to decrypt it or they can't enjoy it. And that point, when it's decrypted, is when the copying occurs. That's as true in the academic publishing community with respect to professionals and academics as it is in the record and video community with respect to consumers. So encryption is great up to a point.

DVD. The real secret to DVD — and it's not that much of a secret — is that although the DVD disks are encrypted, the copy protection doesn't really come from the encryption except when you're worried about somebody just taking a disk and duplicating it. Real copy protection comes, instead, from the conditions imposed by license on the decryption of the disk by the makers of the DVD players and drives. The analog outputs of those devices have to have Jerry's technology under current licensing forms, and there can't be any digital outputs until there's a secured digital technology. So encryption is sort of a tool there, but it's not the means of protection.

Watermarks. The same thing can be said of watermarks. First of all, we talk about watermarks as if it were one thing, but there are watermarks for licensing facilitation like the Digital Object Identifier, and then there are watermarks to stop copying. But a watermark designed to stop copying doesn't do you any good at all unless machines are obligated to look for the watermark and respond to the watermark by not copying, which means you need legal support which gets us right back to the meaning and significance of the no-mandate clause of the anti-circumvention provisions of the recent amendments, or other provisions of the new legislation which require responses to Jerry's technology. So we need both, we need the law and the technology, and we're not going to do very well with one and not the other.

MR. MARKS:

Inter-Industry Understanding and Agreement. I want to follow up on what Jon has said, as I think there's a third leg to it. You need the technology, you need the law, and you need inter-industry understanding and agreement. Without that third leg, you really can't go very far, at least in my view.

DVD. That's been the DVD experience. I want to relate a little bit about DVD because Jon's hit the high points of it. In fact, Jon and

Fritz were both involved in this area before I was, so when I misspeak, please correct me. Originally, as DVD was being developed, the film industry sat down with the consumer electronics industry to figure out a way to protect these digital video disks from being subject to unlimited copying. A system was worked out that involved copy control flags, and an entire legislative initiative was developed called the Digital Video Recording Act to ensure that playback machines responded to these copy control flags and did not allow for unlimited copying.

The Computer Industry Response. That was all progressing and then the computer industry came along and said, "What is this? This is unacceptable to us. We are not going to have a government mandate tell us how to build our computers to respond to particular copy control flags." The computer industry has as a nearly religious principle that if data is available in the clear, and coming into their machines, then they are not going to build their machines to filter through all of that various data, be it text or video or audio, to look for a particular flag and respond accordingly. So we had to go back to the drawing board and start from scratch.

A Three-Industry Solution. What developed, and what the three industries could agree upon, is that if the work is encrypted, then a computer has to do something; it has to decrypt the work it in order for the data to be useable. The computer may take the encrypted data and freely pass it along, in encrypted form. But to make it accessible to the end user, the machine has to do something; it has to decrypt. In such circumstances, the computer industry was willing to say, "Fine, if you're encrypting your works, and we want our machines to read them, then we're willing to sit at the table and talk to you about what conditions we must follow when we decrypt that data." And that's how the whole DVD copy-protection structure and technology for both consumer electronics players and DVD-ROM players and computers were developed. The industries sat down and came up with the seven copyright protection principles which govern how that's been implemented. I don't want to take people's time in going through those principles, but if anyone's interested in seeing them, we can distribute them or talk about them later.

MR. WILLIAMS:

Is the motivation going to be there for other kinds of content? I mean in the DVD situation you had industries, all of which saw some pot of gold at the end of the rainbow, right?

MR. MARKS:

Yes.

MR. WILLIAMS:

Electronics companies saw a nice new piece of hardware to sell, and movie studios saw a new way to re-package their content, and so forth.

MR. MARKS:

And the computer industry saw the possibility of trying to have computers function like home entertainment systems.

MR. WILLIAMS:

How does that apply to less commercial content? Is it going to be a different situation or the same? What about in the academic publishing world?

MR. BAUMGARTEN:

Academic Publishing. I would guess that it's going to be the same, judging by what the record industry is doing. I think it's going to have to be the same. Movies and records are now pretty much ahead of the curve. But no industry can view a world with the ubiquitous computer and not have to figure out a way to come to understandings with the Congress and with the computer community about how their machines are going to act. I think the day has passed when manufacturers of devices could just say, "we are not responsible," or, "we rely on *Betamax*." Congress has recognized that those days are over. The private sector recognizes that the content industries and the manufacturing industries will have to cooperate. The literary community, using "literary" in the copyright sense, is probably more focused now on the Digital Object Identifier and licensing mechanisms than it is on copy protection as such, largely because in many ways they want to facilitate copying. You don't sell a book to a high school or a college and expect no copying to go on. If you make that book copy-proof, whether it's a textbook or an electronic book, nobody's going to adopt it for use in their courses. I mean, there's a certain amount of copying that has to be tolerated. Ultimately, the three-legged model that Dean described — involving technology, legislation, and industry cooperation — will be broadly followed.

MR. MURRAY:

A Fourth Leg: Public Ethics and Morality. I want to suggest that in addition to the three legs that have been mentioned, technology, law and inter-industry agreements on standards, there is, in the real world, a fourth leg: the sense of ethics and morality of the general public-at-large and how they feel about whether it is right or wrong to copy. It's a fair

assumption that the eternal arms race between safecrackers and locksmiths is never going to be won by one side or the other. So long as the general public believes that private copying for non-commercial use is not wrong in the digital environment, it is simply a given that we will see the immediate uploading and free downloading of best-selling novels, music, and — once the bandwidth is there — theatrical motion pictures by millions of people. I would ask this group how we change (or do we, in fact, need to change) the attitudes of the general public about this subject? Without a widespread sense among the general public that it's wrong to copy, technology, the law, and inter-industry agreement will not solve the problem of copying.

MR. SECOR:

Academic Content Distribution, Incentives to Digitize. I want to address your question, Jeremy, about academic content distribution. With academic distribution, when we look at things like the ability to aggregate content, the ability to link content through hypertext and other means, and then what that means to someone who's doing research or scholarship, there's obviously a tremendous amount of incentive to digitize. Most publishers view this with a great deal of trepidation. If it had been possible for most of those companies and organizations to have stuck to the print model, they would have been very happy to do so. It's the rest of us. Everybody else down in the distribution chain has a lot of incentive to see the content digitized and available online.

MS. WEAVER:

Selling Copyright to the Public. My comments go directly to the question of how one affects the perception of the public-at-large with respect to the protection of copyright. I think it's actually very simple. The copyright owners have already begun to recognize that one needs to reach back to the essential foundation of copyright which is to protect the creators, to protect those individuals who bring their essence to the works they create. This does not mean that copyright owners shouldn't also be a part of that mix, but in order to sell the very concept of copyright to the public, it is tremendously important to be able to point to those people who bring their gifts to their work. In the recent Act, there are some very specific amendments which are aimed toward protecting the creators. As we begin to expand those aspects of our Copyright Act, you will see less and less finger-pointing, and you will hear less and less name-calling, singling out Microsoft and Time Warner — who I know will forgive me — as evil empires. The fact is that there are many creators who benefit from copyright protection. As we who know about copyright begin to point to those creators who are protected, it will

become harder for consumers to say, "Oh, I'm just going to copy this because there is no real person who will by harmed by my copying," which is, of course, not true. There are human beings who pay their rents just like you and me who are affected by your copying. That's the message that will sell copyright to the public.

MR. FICSOR:

Education for Lawmakers. I would like to underscore that in addition to Dean's three elements, some kind of education is also needed. Unfortunately, not only does the public need to be educated, but so too do lawmakers require education. There is some belief that private copying is a God-given privilege, and, that if it is restricted, then we have somehow extended copyright protection to a field in which it is not justified. It's very important to know that the existing situation, on the basis of the Berne Convention, on the basis of the TRIPs Agreement, on the basis of the WIPO Copyright Treaty, does not permit unrestricted copying. As well, in the case of private copying, the three conditions identified in Article 9(2) of Berne, in Article 13 of TRIPs, and Article 10 of the WIPO Copyright Treaty must be met for any particular use to be free. I don't have to explain this to you, of course, but it should be explained to legislators that, in the case of online availability of works on the Internet, offering works for home copying is a normal exploitation of the works.

Different Prices for Different Uses. It is also important to note that the differentiation between the right to reproduction, the right to communication to the public, the right of distribution, and so on, will not be so important, because there will be a virtual negotiation on the basis of, let's say, a software envelope, and the user will decide how to use the work. The price will at one level if the user would like just to listen to the music, or watch an audio-visual work or study a database, and the price will be different (presumably higher) if the user would like to make a copy. And, actually, making a copy may not be so important if something is available at a time freely chosen by the user. But still, of course, copies will be made, and, of course, allowing a copy to be made is a very significant thing, because when the copy is available, then you may go back to the analog world and then everything may be started again.

So I do agree with the need for education but, unfortunately, the addressee is not only the public but also legislators.

MS. BESEK:

Copyright Education for Young People. I just want to speak to the education point because I think it's a very good one. Education has to start quite young, and trying to develop a program is really a responsi-

bility of copyright owners and authors as well as educators. I have a daughter who is in the fifth grade, and she comes home every semester with a very detailed report card that discusses her progress in the computer area. They've had computers in her school for many years. The report's got about twenty-five categories, including keyboarding, research and other things. One of the categories is something like "knowledge and awareness of copyright." Every semester the copyright category says "not applicable, we haven't covered this yet." I'm interested to know when they are going to cover this. I think it's important that they do. I've offered to come in to school to help out in this area, but my daughter's been understandably reluctant to take me up on my offer. But I do think that it's an important issue. We have re-educated society on things like recycling, for example. We have not been universally successful, but we have changed the minds and altered the perceptions of many people.

Adult Attitudes Toward Copying. About five years ago there was a great little piece in the *New York Times*. It was one of those anecdotal "around town" articles. A reporter had visited a school that was doing a lot of computer education. The teacher was very proud that one of the things she had taught her students was respect for copyright. The reporter asked a series of questions, and the students gave the right answers: "Oh no, this is copyright protected, we shouldn't copy." And then the reporter started asking some questions that weren't scripted. "So do you copy movies at home?" The kids raised their hands and said, "Oh yeah, we do that all the time. We rent movies, we copy them. Dad says it's our constitutional right to do that." I remember that quote because I was so amused by it. Education is important on all scores; we have to keep that in mind. It is the responsibility of all of us to try to make it work.

MR. DESANTES:

Benefiting the Consumer. Were Mr. Guttenberg alive today, he could tell us a couple of things from his own experience in the sixteenth century. The first one could be the following: if copyright were to be protected in those days in the same way as we understand it today, I'm pretty sure that Guttenberg would remark that the solutions being offered for the new problems were merely provisional, because they are being suggested by the monks writing the manuscripts, not by the printers. In fact, technology and law are no more than tools, while the solutions should be for the benefit of the consumers. I do believe that there are still those today who are thinking along the same lines as the monks in the time of Guttenberg. But let me go back briefly to Jeremy's questions.

A Worldwide Perspective. To the first question, that is to say, the exceptions, Guttenberg would urge us to adopt a worldwide perspective. The problem is that the international environment is too vague as to what these expectations are. For instance, Article 10 of the WIPO Convention just says that "Contracting Parties may, in their national legislation, have to provide for . . . ." Further on it refers, in somewhat nebulous wording, to "a normal exploitation of the work [that does] not unreasonably prejudice the legitimate interests of the author." What does this mean? One thing it does mean is that we don't have an international solution regarding the important question of exceptions.

Different Cultural Understandings. The second point Jeremy put on the table was how these contracts are to be negotiated. We have to take into account that the way every state understands the scope of the will of the parties is very different. More specifically, the will of the parties is viewed one way in the United States and another way in Europe. We Europeans currently are obliged to apply American law as the provider of the service when dealing with copyright contracts with American enterprises. This is so because of the Rome Convention and the law applicable to contractual obligations. Our point of departure is the protection of the consumer, not that of encryption or protection of industries.

To conclude, if we in Europe are obligated to set up mandatory rules applied regardless of the applicable law of the contract, this may be because Americans and Europeans did not sit down together and think through real global solutions.

MR. MEURER:

Circumventing Circumvention. I want to follow up on one of the comments that Jon Baumgarten has made. When we've been talking about technical measures, so far most of the discussion has been about copyrighted material that's going to reach a mass market, the consumer market. And we've been talking about technical measures that can create a fence that bars access, or maybe a gateway. Jon brought up some things I'd like to hear more about: the role of technology with regard to the identification of copyrighted material, along with the identification of ownership, and how that would be relevant to enforcement, especially when we shift from looking at consumers to looking at institutions. It is possible that "cracking technology" may circumvent limits to access or limits on reproduction, but will it also be possible to easily strip out identification information or strip out microcode that would phone home? I've heard about software that will call back to its creator when an unauthorized copy has been made, or something like that. What I'm

generally wondering about is the feasibility of circumventing copyright management systems.

MR. ATTAWAY:

Incentivizing Legitimate Copies. I'm far from an engineer, but I can tell you that, at least in my opinion, there is no technology that will prevent access, and preventing access shouldn't be our goal. We are looking for something that makes it modestly inconvenient to make copies or to break into a conditional access system, in order to give us incentive to put product out in these new markets. But anyone in the industry who's at all realistic knows that the best we can do is to make illicit copying inconvenient. We can't stop it and, therefore, we are going to price our product at a level where there's more incentive to go ahead and get a legitimate copy than to break into the system. And that will vary with different kinds of products and different kinds of technical protection systems, but no system is going to prevent access completely.

MR. MEURER:

Protection for Expensive Application Software. I understand and appreciate your point, but I'm thinking about something like expensive application software where more costly enforcement measures might be worthwhile. We're not going to bring lawsuits against consumers who make a few copies to share with friends. But if you're looking at a business that's gotten some expensive application software and has made copies and is sharing that software throughout the firm, it might be worthwhile to go after a target like that. That's why I want to shift attention away from the consumer context. Perhaps technical measures are a significant factor in promoting enforcement activities with regard to expensive digital products.

MR. SECOR:

Facilitating Compliance and Education. Let's turn that around and talk about facilitating compliance activities. Let's make it easy for people to do the right thing as opposed to trying to make it impossible to do the wrong thing. The technology affords us an opportunity to educate on the fly. We can let people know about rights information and copyright ownership information — beginning with the fact that a work is copyrighted and including the name of the copyright owner and the terms under which the owner is making the work available. With that kind of information, (potential) users can make informed decisions as to what transactions they will or will not enter into.

Academic Fair Use. I want to take one step back and talk about the state of academic fair use. Is fair use the law as it's construed, which

includes different constructions by different people, or is fair use defined by the reality of current practice which does or does not comply with the law depending upon how you can construe it? I'm not sure how far we're going to be able to go in that context until we make a policy decision about what, exactly, academic fair use is and isn't.

MR. TANENBAUM:

Company-Wide Licensing of Functional Works. I think Michael has raised an excellent point because in my practice I see a lot of focus on functional works as opposed to entertainment- or content-oriented works. As you say, the issue will be whether there is going to be a technological solution. If you're an employee in a company and you vaguely know that you're not supposed to copy software and that your company has an enterprise-wide license to use an application product or some database, you do not necessarily know enough to know whether you're infringing the copyright when you try to send an e-mail transmission containing the copyrighted material to your colleague in the London office. This is because you don't really know what the enterprise is, and you don't know whether the computer license that your company set up allows you to do that or not. So in this area, I don't think that educating individual consumers is the answer. There is going to have to be some technological component to that kind of company-wide licensing, which I think is different than the kind of education that June was talking about. I mean people in a company, and companies themselves, generally want to obey the law as long as the price is reasonable. What's within or without the scope of a license in international companies is not information that's available to most employees.

MR. SECOR:

But we can make it available through the technology.

MR. TANENBAUM:

Yes.

MR. SECOR:

That's my point.

MR. TANENBAUM:

That's my point as well, that a strictly educational solution is not enough. The software's going to have to phone home. We're going to see some intersection here, I think, with the outcome of the *Microsoft* case, where people are going to want e-mail to be like *Mission Impossible*, self-destructing after it's been read.

MR. SORKIN:

Education. I'd like linger for a moment on the issue of education. I agree, for the most part, with everything that's been said. I believe that education is extremely important, even though I'm not quite as optimistic as some of you are, because in my experience people of intelligence, education and sophistication don't really appreciate that intangible goods are just as worthy of protection as tangible goods are. That's a serious problem that we have to meet. I would add one perspective to what Sallie suggested about an educational program. It's not just the neighboring rights owners, the actors, performers and writers who benefit from copyright protection. There are truck drivers and carpenters and clerks and retail salespeople and even lawyers — which may not be particularly appealing — but there are many, many communities who rely on copyright protection. We all have seen the figures showing the place that copyright plays in the U.S. Gross National Product and balance of payments.

Academic Fair Use. I also want to respond to a question raised earlier about academic fair use and where it stands and what its boundaries are. As others have suggested, the answer is very murky. But there has been success in one area, the area of multimedia production for educational uses, in which a committee struggled long and hard for many months to create guidelines which were acceptable to much of the academic community as well as to the copyright owning community.

MR. SECOR:

But those guidelines aren't binding.

MR. SORKIN:

I'm sorry?

MR. SECOR:

Those guidelines are not law.

MR. SORKIN:

No, they're not law, but they're guidelines, and they've been accepted. I don't know that they have to be made law. They provide exactly what the academic community wanted, namely a sense of certainty and safety with respect to what they do.

Digital Works and the Public Domain. I would like to raise a question which, to some degree, I am ashamed of raising because I don't always like to reveal my technological incapability. And on top of that, I have no capacity for and even less desire to be Pam Samuelson, but I'm

going to take a shot at it. She's got a very poor advocate in this area. Accepting what has been said about access and assuming that there is no technology that could defeat technological anti-circumvention measures, I've got to wonder what happens to works that are — and for this purpose we'll assume that there are no longer any analog works, no paper, none of the carriers with which we've been accustomed to all our lives, we're in a totally digital universe — what happens when a digital work, be it audio-visual, record or text, protected by all of these anti-circumvention devices, goes into the public domain? How does society have the benefit of that? I can make up an answer to that one, but I think it gets more difficult when you get to the issue of fair use. How does one who wants to exercise the fair-use privilege exercise it? That's an honest, ignorance-based question.

MR. WILLIAMS:

Well I was going to ask, when you were talking about the multimedia compromise and thinking about the classroom guidelines and things like that, how do those get implemented safely, from a legal point of view, with a lot of encryption and copy protection?

MS. PETERS:

The Classroom Guidelines. I was just going to add that the Copyright Office has always supported guidelines. With the CCUMC guidelines, we got a request to put them up on our Website. I said "sure." This seemed to have an effect roughly equivalent to a declaration of World War III. Educators came out and said "don't do it." Libraries came out and said "don't do it." I found it distressing that so much controversy was generated by posting on the Copyright Office Website an agreement that so many people had worked so hard to achieve and that so many people said "yes" to, and that's posted on so many other Websites. There's a lot of disagreement over what's fair and what isn't. We're nowhere near agreement on what fair use is in a digital environment.

Fair Use and the Public Domain. This office has a study on distance education through digital technologies that's due in to Congress in the Spring of 1999. In that report, we're supposed to look at whether or not further exemptions are needed. This is an important and difficult question. I agree with what Bernie said. When you encrypt a work and if, in fact, it's not available in any unencrypted form, and it then goes into the public domain, how will it be made accessible to the public? For a librarian, the question is: how does fair use work today? I think this is an extremely difficult issue which is why the effective date of the legislation concerning circumvention and access was put off for two years. During

that time, the Librarian of Congress is to decide whether or not there are any categories of works that are not appropriately available to users. I don't think it's an easy issue, and I don't think we have the answers.

MR. KEEFAUVER:

No Perpetual Anti-Circumvention Device. I could give you what is very possibly a cynical answer to that question, having had a mini-career in cryptography starting in World War II, and having worked with some high-tech cryptographic people. We've extended the copyright term so long I cannot believe that any anti-circumvention device will still be anti-circumventing when that copyright expires. So I think it's a non-problem.

MS. PETERS:

Information Stored in Obsolete Formats. But what do you do with the copy that is locked up? I mean, how do you get access? It's problem for all libraries today. There are new formats tied to specific machines and technologies. How will information stored in obsolete formats be made available in the future?

MS. PERLMUTTER:

Anti-Circumvention. On the issue of locking up public domain works, it is worth mentioning that the anti-circumvention provision in the statute only applies to copyrighted works. That doesn't mean public domain works still won't be locked up, but at least it would not be illegal to circumvent the controls. Apart from that, it seems to me that these are cautionary questions for copyright owners. Because to the extent that systems are built that work wonderfully but don't build in any ability to gain access to public domain works, or don't build in appropriate fair-use type concepts, there is a substantial likelihood that we will be back in Congress looking at ways to repeal parts of this law or to significantly restrict what copyright owners can do online. So the big question is how responsibly systems can be built so that there isn't a need for government interference, and so that the marketplace will continue to function and give some room for fair use and other exceptions that have been developed in the public interest over the past number of years.

Education. I would also like to say a few things about education. For five or six years now I have been going to meetings and conferences where everyone agrees that education is absolutely critical. Some here will remember the work of the Administration's NII Advisory Council, which didn't get nearly as much attention as the Working Group that produced the *White Paper*. Much of the focus of the Advisory Council was on education. A document was developed that tried to make

copyright law intelligible to the layperson, to teachers, to people who work in community centers, and to parents. Scenarios were written that examined whether one legally could do certain things that might typically be done in a library, school or community center, in order to give guidance as to what this body of law meant. It is a useful document, but not much attention has been paid to it. Education is very difficult in this area for three main reasons.

One reason is the problem that I think both Sallie and Bernie were alluding to, that the average person identifies him- or herself as a user rather than as an author or owner of copyright, and identifies copyright owners as being anonymous big businesses. That's going to continue being a problem until people start seeing that there are individuals on both sides.

The second reason is the time-frame problem. Everyone understands his or her own immediate interest in using existing works — the stuff is out there and you want to use it. The more long-term benefits of a copyright system are much more difficult to see. You could tell people, in the abstract, "In the future there will be more works made available if we have adequate copyright protection," but such a proposition sounds very theoretical in the here and the now and the heat of the moment.

Third, the law in this area is complex. We're facing a daunting task, because copyright law was complicated to begin with, and now we have this huge bill that adds tremendous new complexity. It has always been difficult to explain fair use, but just try to explain online service provider liability or the treatment of Macrovision to the average person on the street.

Special Rules for Non-Profit Educational Institutions. June's story showed that some progress has been made, because at least copyright education was identified as a goal, but obviously the progress that has been made is not enough. I also want to point out that in one section of the bill, in the part that deals with OSP liability and that contains special rules for non-profit educational institutions, there is a statutory obligation for a non-profit educational institution to provide users with informational materials describing and promoting compliance with copyright law in order to get the benefit of the special rules. So there is some reference to copyright education in the legislation. Now that the legislation has passed and everyone can turn their attention to other things such as the clearly important projects of developing rights management systems and technological measures, I hope that people also start doing something about education rather than just continuing to talk about how important it is.

MR. FICSOR:

Anti-Circumvention Exceptions Based on Categories of Works. I'd like to address quite a nasty question to Marybeth and Shira. I am currently into my fourth or fifth reading of the DMCA, and now I understand much better what I don't understand and why. I'd like to congratulate Marybeth and Shira, and at the same time offer my condolences to them because I see that they have received a number of interesting tasks in this law, but, in the case of some of the provisions, I can see that their jobs will not be very easy. One of the provisions I'd like to refer to is the exception to the prohibition of circumvention. It's very interesting, because it seems to be based on *categories of works*. But in general, exceptions are not so simple as that. In the case of exceptions you have to take into account, at the international level and also at a national level, not only the category of work but also who carries out a certain act, for what purposes and so on. So I don't know how you will start working.

MS. PETERS:

Strong Interest in Exceptions. I would just add that people have already come to our door, and our answer has been, "This isn't for two years," and, "We've got other immediate tasks that need attention." Somebody came up to me and said, "I want to tell you that 'scientific works' should be exempted." There's also a question about what kind of evidence the parties have to gather and what kind of proceeding is required. It's a determination "on the record." We haven't really come to grips with that, but I agree it is an extremely daunting task where the stakes are very high. It's not something that we sought. This provision arose from a referral of this bill out of the traditional jurisdiction of the Judiciary Committee to the Commerce Committee of the House which is concerned about consumer issues. This was crafted at the behest of the Digital Future Coalition and others. I don't know that anybody who advocated this language thought about how it would be implemented; they believed it was a good way to try to address the concern that everybody identified.

MS. PERLMUTTER:

This is part of the pattern that we've been seeing: when there are tough issues that are insoluble politically, the answer is to let the agency do it, and then we can review their results. Those very broad phrases like "class of works" and "adverse impact on lawful uses" are vague for a reason, because no one could agree on how to make them more specific. And you're absolutely right, it's going to be difficult to figure out what it means.

MR. FIELD:

In administrative process, which I teach here at FPLC, I was just discussing how Congress lobs various hot potatoes to agencies. It seems to be the Copyright Office's turn to catch some. The problem is compounded if issues must be resolved by on-the-record rulemaking. That means a formal, trial-type process — the kind most infamously represented when the FDA generated a 7,700-page transcript to resolve a dispute over whether peanut butter should contain 87.5 or 90 percent peanuts.

Although the copyright amendments suggest that Congress had such "formal" rule making in mind, the legislative history refers to a far less cumbersome procedure. Given a manifest desire for haste, perhaps the courts will allow the Copyright Office to use that. If not, I wish it a lot of luck in making much progress within two years.

MS. BLAUSTEIN:

Expiration of Copyright on Encrypted Works. I'd like to harken back to the not-so-hypothetical that Bernie Sorkin started discussing. What happens when a copyrighted work is encrypted in digital form and the copyright on that work expires? Like Glen Secor, I wish that Carol Risher were here today because part of her DOI suggestion involves an industry-regulated central clearinghouse that would include a data bank for keeping terms and conditions, authors' names — but not the names of copyright owners, because they could easily change over time — and some indication of a contact person for each author in order to facilitate payment for whatever rights should be compensated for. Along with that system it would be entirely possible to include, in an escrow-type form, some work that could be put in the public domain automatically, upon termination of the copyright. Someone could, under such a system, go to the clearinghouse that was holding the DOI information and obtain an expired work.

MS. WEAVER:

Education. I want to note quickly that the Artists' Rights Foundation, which is a wonderful organization in Los Angeles, is doing some work on education in the motion picture area, educating children about the value of the art of motion pictures and just who it takes to make a motion picture. As Bernie rightfully points out, there are many people who benefit from the production of a motion picture. That's just one particular arena in which there is some very important progress being made.

Compensation for Rights Holders. Also, I don't want to lose sight of how rights holders, or those who no longer hold rights, get compensated for their works. I'm very interested to hear about how copyright owners are making sure that payment gets made to those parties who are supposed to be paid in the event that a work is used. I think performers, and artists generally, share a community of interest, as it were, with writers and authors and academics and all those parties who create works in the context of an employment relationship or otherwise. I'm very interested see to whether the industry is progressing toward developing a device that automatically and simultaneously detects use and directs compensation to the copyright owner. We are interested, frankly, in being a part of such an information stream because it's critical for us to get compensation at the time of use rather than seeking it long thereafter.

MR. HARRIS:

Intellectual Property as Property in Europe. This is a fairly short contribution. I only want to say that Bernard's first point, when he spoke just recently, raised the question of educating people to the fact that intangible property is just as much property as other property. You will be delighted to know that, in the directive on copyright in the information society which the European Commission has recently proposed, there comes the startling phrase, "Whereas intellectual property has therefore been recognized as an integral part of property." Now that actually was recognized by the Court of Justice of the European communities about twenty or thirty years ago, but it is good to have it in the directive. If, at the appropriate point in our discussion, you would like an answer to Silke's question about how the copying question was finally resolved by the European Commission in Brussels, then at that time I could offer a comment.

MR. KEEFAUVER:

I think this is a good time to take a break. First let me remind those of you who are staying over and who would like to have some access to food this evening, to put your names on the sign-up sheet. Secondly, we're going to give you an opportunity to get a breath of New Hampshire air.

MR. FICSOR:

It's gloomy and cold outside.

MR. KEEFAUVER:

We just canceled that opportunity. You're on your own for fresh New Hampshire air which has gotten a little raw, so we will break for lunch and I say we return in about an hour.

[The conference breaks for lunch.]

VI. PRIVATE COPYING, LEVY SYSTEMS AND COMPENSATION

MR. WILLIAMS:

We want to continue this afternoon by starting out with the European perspective on the issues we've been discussing. And, Bryan, I begin by taking you up on your offer to make some remarks. I particularly hope that you will respond to some comments that were made before lunch having to do with individuals making private copies. We were talking about how to teach the public-at-large that private copying is a violation of copyright and a bad thing. There's been a much more explicit discussion of private copying in Europe, so I would like to hear comments generally on the European proposal in the areas that we've been talking about, and on private copying in particular.

MR. HARRIS:

The first speaker after lunch always has a heavy burden upon him, or rather his listeners do, so I shall try and be as light as possible about this. In fact, it's quite an entertaining story in its way.

Blank Tape Levy. Some twenty years ago, a very misguided head of the Intellectual Property Division in the European Commission proposed that there should be a levy on blank recording tapes. From that innocent and misguided proposal — misguided for reasons I'll explain in a moment — the European Commission has been beset with problems ever since. The proposal was misguided because it was rolled up with a suggestion which fell outside the bailiwick of the head of the Intellectual Property Division, namely that to discourage copying by means of reprography there should be a special levy on reprographic paper, which in those days was a special paper. That was a characteristic example of legislating when the technology is just about to change. I know Katherine said this morning that legislators must look ahead a bit. I agree, but at the time when this proposal was made, there was no reprographic paper other than that special paper. And so the Commission was lumbered with a couple of tentative suggestions, and the one about the tapes was, so to speak, tainted by the one about reprographic paper. The suggestion for some such levy continued and was given a bit of an impetus when the

United States introduced legislation on the subject. But there was one important difference between the American legislation and its European counterpart: the percentages of levy on blank recording tapes in the United States are relatively low, but the proposals in Europe were that they should be relatively high. Indeed, one or two Member States of the European union had actually gone so far as to impose levies of about fifty percent of the purchase price.

Response to the Danish Levy. Denmark had rate even higher than fifty percent, and that tended to create a situation — not surprisingly — in which people who lived in southern Denmark went across the border into Germany to buy their tapes — and other things of course. The fact is that this proposal, to somehow to curb unlawful private copying by means of a levy, whatever its merits — and I have to say that Dean and I were on opposite sides of the table later on but this does not alter the facts of the case which I'm sure he would agree with — this gave the Commission enormous difficulties when it came to legislating on this issue. Perhaps the biggest single difficulty was that the Commission could not persuade the United Kingdom to go along. There was just no question of it in the United Kingdom. It would have been a political loser. This, by the way, raises the issue of educating the public, which Christopher already raised and which we might discuss in more detail later on. There is a lot to be said on that in the context of the Internet.

Abandoning the Levy. To bring this long story to a close, the tape manufacturers agreed in the end that they could accept some sort of levy legislation. The Commission agreed that there could be legislation. The recording interests agreed that there should be legislation. Then there was a complete change in the Commission and they decided, after several attempts at a directive, to abandon the approach of issuing a direct instruction to Member States to introduce a levy.

The General Directive on Copyright in the Information Society. So what was put in place? The Commission decided to take a lateral view of the problem and came up with a general directive, which I referred to before lunch, on certain aspects of copyright and related rights in the information society. In other words, they angled it toward the digital problems. Recital 26 of the Preamble to the Directive says: — I shall leave out the word "whereas" which is quite unnecessary legally — "Member States should be allowed to provide for an exception to the reproduction right for certain types of reproduction of audio, visual and audio-visual material for private use. This may include the introduction or continuation of remuneration schemes to compensate for the prejudice to right holders." What that means is that the Member States which already have levy systems in force can keep them and those which do not may stay as they are.

Differences from Country to Country. This leads on to the next statement: "Differences between those remuneration schemes" — and that, of course, includes Member States without any remuneration schemes at all — "affect the functioning of the Internal Market." Of course they do. I have given you quite briefly the instance of the Danes who go over the German border and stock up on all sorts of things, not just tapes. Motor cars, for example, are subject to a very heavy rate of value added tax in Denmark. So a Dane will go into Germany, buy a Mercedes and fill it up with tapes and other goods.

Digital Private Copying: Wait and See. The Preamble to the Directive goes onto say: "those differences, with respect to analogue private reproduction, should not have a significant impact on the development of the Information Society." However, "digital private copying is not yet widespread and its economic impact is still not fully known; therefore, it appears justifiable to refrain from further harmonization of such exceptions at this stage. The Commission will closely follow market developments in digital private copying and will consult interested parties, with a view to taking appropriate action." As a civil servant I could not have written that better. There we stand.

MR. WILLIAMS:

Further comments on that? Katherine?

MS. SAND:

I always hate it when people talk about European Community legislation and how it's arrived at. It's incomprehensible to Europeans, let alone to anybody else. But I think it takes us back, in a sense, to the discussion of education. I found it very interesting to hear U.S. interested parties talking about educating right holders. We don't really have those conversations in Europe as much.

Education as a Worldwide Exercise. A fourth element of the educational process that parties here should think about is that education is a worldwide exercise because the major users of U.S. copyrights and material are Europeans, and other people, and will be non-U.S. citizens in the future. Those people have different expectations and different sets of legal traditions, as has been well illustrated. Professor Desantes has explained very well, and I've reiterated, that the approaches of various governments are based on different sets of entitlements and different concepts of what's in the public interest.

Private Copying Still Debated in Europe. What might be useful for you to know is that the debate on private copying has not gone away just because the European Commission would like it to. Even in the context of the directive, there's a whole raft of amendments by the

European Parliament dealing with permitted exceptions and how they should be treated. Some of these amendments concern the question of private copying. I don't really have anything to add, and I certainly don't have a solution. What I do have is a confession which is that many years ago, in a previous life, before I ever knew anything about copyright, I used to work for the organization in the UK that opposed private copying schemes. So I'm especially interested to know the views of the U.S. copyright industries and legislators with regard to these various private copying schemes, including digital, that will arrive, as well as what approach you would take to levies and remuneration right systems which are proposed in many of these amendments.

Performers are Ambivalent. From the point of view of the performers I represent, there's considerable ambivalence on this issue. In many countries, performers derive considerable sums of money from these levies. We could talk about the actual ethics of that, and how those sums of money are calculated and subsequently distributed, but they are an important tool. In many cases, European performers feel that on any other basis, for example on the basis of exclusive rights, they would not derive any remuneration at all. They wouldn't ever receive any compensation for the copying of their work. So I'm interested to know how people around the table view that development in Europe.

MR. POLITANO:

Technology Replacing Levies. One of the benefits of the technology that we've been talking about today is that it will make levy schemes unnecessary. At the very best, these levy schemes were an acknowledgment that copying was taking place and that it ought to be compensated in some way. Because there was no other way of collecting and paying proper compensation, some people thought it better to provide a kind of rough justice by collecting levies on blank tapes or machines and somehow redistributing the money among the class of copyright owners whose works were being copied. The justice is extremely rough, and there's a lot of leakage into the hands of the people who administer the royalty pool. The great thing about this digital technology is that it's going to make direct payment schemes possible. When a product is used or copied, that specific use will trigger a mechanism for payment for that use and to the specific copyright owner whose work is being used. In the future, I think these levy schemes will probably become no more than an excuse used by those who want to perpetuate the idea of free private copying and by those who have an economic interest in maintaining the complicated distribution system which results in good compensation for those who are involved in the distribution but

does not always provide such good compensation for those who own the works and who are supposed to be compensated.

MR. FICSOR:

I do agree that now there's a new situation here. But of course, we have to refer again to the three-step test, and I think that is very important.

Exceptions for Special Cases. Article 9(2) of Berne provides in the first condition that exceptions are only possible in special cases. A statement that private copying in the online context is a special case may be questioned with very good reasons, because in the case of Internet online transmissions, it is just a normal, general situation that there is a public source which is publicly available and the use is private. So it would not be a special case if private copying were recognized as free, without any use limitation, and certainly it must not be.

No Conflict with Normal Exploitation. If we go to the second condition — namely that an exception should not conflict with the normal exploitation of a work — then the result of the analysis must be the same. This is a normal exploitation and it must not be subject to a general exception.

Prejudice to the Legitimate Expectations of Authors. Actually, blank-tape levies were applied on the basis of the third criterion in the three-step test. It was found that there was a special case, that there was no conflict with the normal exploitation of the work, but that there was an unreasonable prejudice to the legitimate interest of authors, because private copying was so widespread. When we analyzed this in WIPO, our view was that if there were two possibilities — either to allow the existence of such unreasonable prejudice to the owners of rights or to eliminate such prejudice or reduce it to a reasonable level through a levy system — then we saw an obligation on parties to Berne to use that second choice.

National Treatment. We believed that that was an obligation, but that was only one thing. The second issue was national treatment, and that was the real tricky issue. It became a kind of economic issue. Calculations were made that if one were to apply national treatment, it could meant that one would have to pay out, let us say, one hundred units of money while receiving only two, so national treatment did not seem to be very good business. And there were brilliant theories invented to explain why this payment is not a copyright payment, but actually, no such theories were justified. Such levies are covered by copyright and, therefore, because there is no exception whatsoever in that respect, on the basis of Berne or TRIPs, there is an obligation to apply full national treatment. I think it is very important to stress that the levy system is

not a solution for delivery through the Internet; Internet transmission and other such delivery should be subject to exclusive rights. The levy system is an out-of-date answer to an out-of-date problem as far as the Internet is concerned.

MS. WEAVER:

Compensation for Private Copying. Even Fritz acknowledged that all the industry is trying to do is to make copying modestly inconvenient. Therefore, there will continue to be a difficulty with how to deal with the rights holders in those circumstances, circumstances in which the artists and the industry share an interest. Perhaps the existence of private copying schemes in Europe is the reason why Europeans don't have these sorts of discussions. We were saying over lunch that they don't have these sorts of discussions in Europe because it's understood that private copying is something for which rights holders should be compensated. Maybe the schemes have served the purpose of educating the public about the fact that copying is something for which compensation should be paid. As well, I hope that when we refer to direct payment schemes to copyright owners, we understand that we mean payment to *all* rights holders, including former rights holders, etc. Of course, payment should run to all those parties who hold an economic interest in exploitation of the work.

MS. VON LEWINSKI:

Compensation by Levy for Authors and Performers. Since there are not too many Europeans here, I will make a short comment from the European point of view and then ask one question in this context. The European discussion is different. It is much more focused on the levy system which is not really seen as being outdated. One of the main aspects of that system is that — here I can refer to what Katherine and Sallie talked about — under the existing levy schemes, which are established in most European countries, the creative contributors, namely authors and performers, receive an equitable remuneration which they probably would not receive otherwise. For example, regarding printed works, authors may receive seventy percent of the whole amount, publishers thirty percent. In other cases it may be fifty-fifty. In the music or audio-visual area you may have splits such as thirty percent for performers, thirty for producers, and thirty for authors. However, if you have an exclusive right, and if it is managed by the exploiting business — the producer or publisher — the authors and performers are concerned that they would not receive any comparable percentage or remuneration. If you look into contracts, you will notice that the percentages are quite

low. So this, too, is one strong concern expressed in the framework of the European discussion.

Direct Payment by Percentages? In this context I would like to pose a question to the technical experts in this group. Fritz, earlier you had said that the advantage of digital technology is that it allows direct payment per use to the rights owner. My question, from technical point of view, is: would it be possible to make direct payments according to certain percentages as we have them in Europe, to the different groups of rights owners, coordinated, perhaps, through collecting societies?

MR. ATTAWAY:

Absurdity of Fixed Levels of Compensation. I think that the whole concept of enacting legislation that dictates, by percentage, the level of compensation received by each contributor to the creation of a copyrighted work is absurd. Just think of what kind of movies would be available today if the United States passed a law that required of every motion picture budget that thirty percent go to the actors, twenty percent to the director, and some other percentage to the cinematographer — it would be ridiculous. That's the same concept that these levy systems providing "equitable remuneration" are based on. It's absurd. Compensation should be the product of supply and demand and collective bargaining or direct bargaining among the contributors to copyrighted works. This works. Sallie's constituents are compensated when the producer receives revenues, residuals are paid to the actors, and residuals are paid to the other contributors. Compensation does not need to be and should not be determined by legislation.

MR. FIELD:

Rights and Money. This discussion thread reminds me of a question my colleague, Bill Hennessey, reports being asking at an international IP conference: "Why is it that *European* artists have all the *rights* and *American* artists make all the *money*?" In reflecting on basic differences between systems, that would seem to warrant more than passing attention.

Payment of Royalties by Libraries. Second, I'm reminded that, at least in the UK, libraries pay royalties for some initial number of borrowings. Given libraries' obvious dampening effect on sales, that strikes me as fair. Yet, that's not our law. So I assume that my views are not widely shared here and, moreover, that at least some U.S. librarians would be horrified at the idea.

MR. MARKS:

Moving Beyond Levy Systems. Tom, in answer to your question, I think a lot of producers consider the levy systems to be very rough justice as well as an inaccurate and not necessarily useful way of compensating for private copying. What was heartening, at least to me, in the European directive as proposed by the Commission — I'll go recital for recital with Bryan — was Recital 27 which says "when applying the exception on private copying, Member States should take due account of technological and economic developments, in particular with respect to digital private copying and remuneration schemes, when effective technological protection measures are available, such exceptions should not inhibit the use of technological measures."

Private Copying and Technological Protection Measures. It's very important to look at the relationship between private copying and technological protection measures. If the day comes that technological protection measures are fairly effective so that unauthorized private copying is substantially reduced if not eliminated, then one would have to question whether there's any justification for the levy schemes to remain. From the perspectives of many rights holders — not only producers but also authors and performers — there is a recognition that one should not supplant or suppress the ability of rights holders to apply technological protection measures because of the existence of private copying levy schemes. If we have to choose between one or the other, we prefer to have technological protection measures to enable us to control better the exploitation of our works. We're heartened to see that the Commission seems to be going the same way. These levy systems should not inhibit the use of technological protection measures.

MR. SECOR:

Blanket Licenses. Just to provide a bit of a real world anecdote for how some of this plays out in the print community, we don't have levies, per se, but we have these blanket licenses which tend to function very much the same way. There's a payment made to a collective which then distributes money it collects on the basis of some very rough calculations. Print publishers generally don't share royalties from photocopy permissions, for instance, with authors. They just don't do it. It is not part of the compensation scheme. That may change now with a court case that's now going on, *Ryan v. Carl Corp.*[19] Carl is a document delivery service, and the judge has ruled, in response to a motion for

[19] 23 F. Supp. 2d 1146, 48 U.S.P.Q.2d (BNA) 1626 (N.D. Cal. 1998) (granting plaintiffs partial summary judgment, based on a favorable construction of 17 U.S.C. § 201(c)).

summary judgment, that Carl did not have permission to be selling articles one-off because the authors did not give the publisher the right to sell individual articles. Authors gave their publishers only the right to publish articles within the context of a journal.

Impediments to Precise Direct-Payment Schemes. But my point is that right now the commercial mechanism, at least in our industry, excludes all of these neighboring rights holders, if you will, and there is no incentive and no desire, unless there becomes a legal imperative to do so, to build direct-payment schemes that are going to reflect the granularity of rights holders that we're talking about here. These direct payment schemes could wind up developing just like the collectives or levy systems where gross payments are made to some sort of centralized agency and then redistributed publishers or distributors, but no further than that.

MR. KEEFAUVER:

Anonymity of Levy Systems. I guess I'm speaking as a member of the public at this point. One thing levy systems have going for them, if nothing else, is a high degree of anonymity. I just wonder how long the public would sit still for any scheme which permits retention, in some computer database, of information indicating that on a given day, a particular person had access to a certain work. I have Easypass. It's a thing I put on my car that automatically pays my tolls when I go through the Holland Tunnel or over the George Washington Bridge. At the end of the month, of course, somebody can see where I've been. It doesn't bother me, because I don't go places that I mind people knowing about. But such a system bothers a lot of people. There's a heightened concern about privacy. Also, there are cookie problems. I'm sure you're all aware of that. Try to defeat the cookies, and you'll find you can't get anything on the Internet if you click off your cookie launcher. You're puzzled Bernie; you know what "cookies" are I assume.

MR. SORKIN:

I ate two of them before and they were very good.

MR. KEEFAUVER:

So I just throw that out as a question. I'm sure that some of you have thought of this as you design these systems. How do you think they will pass public muster?

MR. BAUMGARTEN:

It's more a question of whether or not these systems will pass muster. One quick clarification of what Glen said and then I have a more fundamental comment. I think — and I suspect you'll agree again — that

the *Carl* case isn't much of a problem for STM journal publishers, because it's conventional that they do explicitly acquire all the rights they need.

MR. SECOR:
Well maybe.

MR. BAUMGARTEN:
Unless that practice changes.

MR. SECOR:
Yes. Unless the authors realize what rights they have.

MR. BAUMGARTEN:
Popular Perceptions of Private Copying. The decision in the case only deals with situations where somebody has not acquired a written transfer and, therefore, has to fall back on the provision in the Copyright Act that the court construed. More fundamentally, we jump quickly from the issue Mihály raised to the question of how you perfect legal recognition of the rights holders and, specifically, their rights against private copying. The question that Mihály raised is still a big problem in this country. Maybe it's a lesser problem in Europe, but there is still a notion in this country that because something is private copying, it is exempt. Mihály pointed out — and frankly many of us would acknowledge that it's largely because of him, as an individual — that at least in many instances in Europe, we seem to have gotten away from the doctrinal thought that simply because it's private, it is exempt. In fact, exemptions must fit the three Berne Convention conditions that Mihály mentioned. In this country, you still have people, of some repute, arguing that the *Betamax* case was a per se private-use exemption and ignoring the fair use analysis made in that case. In this country, I think we still haven't overcome the problem of people thinking that private use is a per se exemption from the rights of the copyright holder. As for the levies that have been mentioned, you only get into the levy question when you realize that there's some obligation to compensate the rights owner.

MR. WILLIAMS:
Cultural Attitudes Toward Remunerating Copyright Owners. I was thinking along the same lines, Jon. It's one thing to say there might be technology that could render the levy collection system for remuneration obsolete, but there is an important cultural question that lies beyond the question of whether a levy system can provide some remuneration. At the same time the levy system gives a kind of legitimacy to private

copying that might make someone say: "We know what the content owners want and prefer, and we understand that, but we reject their position because we are drawing the line at a certain place." It goes back to the private use versus commercial use distinction, and I wonder to what extent, on either side of the Atlantic, there is going to be a cultural force that continues to argue that people should have these private copying rights and that the technology, therefore, should be resisted.

MR. FIELD:

Sony Betamax *and Users' Rights.* I feel compelled to comment on the *Sony Betamax* case. It is supremely ironic that anyone (including the Supreme Court) would use that case as a source of law governing copyright *users'* rights. As discussed by the district court, *one* individual defendant, William Griffiths, was *named* in that suit. Yet he was recruited by a *plaintiffs'* law firm and was unrepresented (because, having agreed in advance that he would suffer no adverse consequences, he had no need to be)! Hence, any reference to users' rights in that case constitutes, at best, raw dicta. If that's what "case or controversy" now means in the United States, anyone can make any kind of law they want to. Each time I see that case cited, I shudder.

MS. SAND:

The European View on Total Content Availability. The point you raise about a cultural force is an interesting one. I've sat through many discussions in the European context, even very recently, where people have said that everything *can* be available, so everything *should* be available, and that everything should be available to everybody for nothing. In the European context, there's a discussion very much promoted by the broadcasters, who are not insignificant producers of material, but who have a sort of double vision of themselves. On the hand, they're asking for inclusion in a private copying levy, but on the other hand, they're saying that in the interest of public access, everything should be made available for free to everyone. They propose blanket licensing for the programming, so that they would be able to put out anything that they have ever made or ever shown on their broadcasts for nothing, to everybody. The European way of looking at things shouldn't be underestimated. There is an enormous tendency to want to make everything available to everyone, never mind what the underlying rights holders or the copyright owners within those productions might feel about it.

MR. STRONG:

Copying in the Asian Context. It's a very interesting question. The question of culture is not just a domestic question; it's an international question as well, although we're tending to focus on it in the national context through most of this discussion, and now the European context. When you get outside of the western democracies and Japan into the rest of the world, you find, I think, no cultural background whatsoever for the kind of rights that pay all of our salaries. Copyright, for example, in the Chinese tradition is a complete anomaly. In China it was always felt that the greatest respect you could pay was to copy, and the thought that copying should be prohibited sits very oddly. Now there have been many countries that have been more or less forced to adopt copyright schemes as the quid pro quo for gaining access to western markets, but that doesn't mean that they've adopted them with great enthusiasm. We're going to have problems as we try to export some of these concepts to Asian and other non-western trading partners.

The Culture of Copying in the United States. The question of culture, on the domestic front, and this whole discussion within the last two minutes, underscores a certain measure of irony in that there seems to be an implicit recognition, among even those who are arguing most strenuously for these schemes that have been recently legislated, that the public-at-large does not support them. And yet, this is supposed to be legislation by representatives in Congress acting on behalf of the public. I'm not saying that it's bad legislation as a result of that, but I am saying we're in an ironic situation, and I don't know quite how to address that. I think the education point that Chris made and brought us up short with, that observation is clearly part of it. If the public doesn't get the message about copyright it's going to be very hard to enforce these schemes. We have, sitting around this table, representatives of some of the industries who have the greatest capacity to educate the public, and I think there's much more that they can do. I would love to see the motion picture industry come out with a propaganda piece about copyright, but that's just an observation.

MR. OPPENHEIM:

Recording Industry Educational Campaign. Following up on the earlier discussion of educational campaigns, the recording industry has launched an educational campaign geared to colleges and cutely called "the Sound Byting Campaign." Its goal is to convince the Netizen community that they shouldn't be copying. We will see what kind of success it has. This campaign is ultimately looking to move down the chain to high schools. We're going to have to keep moving down the chain, because people learn copying at earlier and earlier ages. Ulti-

mately, when you look at this campaign, what it says is that you really shouldn't copy, and if you do, you could be in a whole lot of trouble. It describes all the civil and criminal penalties. I note that we've brought a number of actions, but not a huge number, against Netizens who have made content available. I'm curious to know whether other rights holders and representatives of rights holdlers around this table have considered bringing actions for violations over the Internet in order to strengthen the message so that educational campaigns will have some impact.

MR. BRILL:

In the UK, one part of their Copyright Act, I think it's Section 99, has a black box provision. To the best of my knowledge it's never been used. It may have been used once. But it's structured in such a way that a company like Macrovision has no standing so we, obviously, couldn't sue under it.

MR. WILLIAMS:

Bernie, do you have any comment from Time Warner's point of view on the idea of going after people using the Internet?

MR. SORKIN:

Beyond the Economics of Copyright. I think we should, but as has been noted, such a strategy presents a lot of practical problems. In this connection, however, I'd like to express a bit of disquiet about a theme that's been running through the discussion today, which is that the importance of copyright protection lies in economics, in protecting the compensation of authors and others. This is, of course, an important concern. But if we limit ourselves to that issue, then we run into arguments that I'm sorry to say I've encountered, arguments about the validity of piracy statistics and arguments over the proposition that every pirated copy represents a displaced sale. When you're facing those arguments, it's very hard to rely solely on economics. Some years back, I was very taken with an article called *The Harm of the Concept of Harm in Copyright.*[20] The article was written by Marybeth's and Ralph's predecessor, David Ladd. In the article, Mr. Ladd made the point, very persuasively I thought, that copyright serves a significant societal function. It's an important aspect of civilization, and for that reason alone, should be protected. That perspective should also be part of any educational program.

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[20] David Ladd, *The Harm of the Concept of Harm in Copyright*, 30 J. COPYRIGHT SOC'Y 421 (1983).

MR. OMAN:

I have a vivid recollection of *The Harm of the Concept of Harm*, and the topic of that article has been a recurring theme in American copyright debates over the past few years. It came up in the debate over the Digital Copyright Millennium Act, and it will continue in the future.

Anti-Copyright Sentiments and the New Technology. The cultural bars that we have to strong copyright protection won't disappear with the new technology, but I think the new technology offers us opportunities to avoid a lot of the arguments from the past by allowing the copyright owners, as Fritz said a few minutes ago, to eliminate the need for rough justice concepts like fair use and compulsory licensing because the market had somehow failed. We do have in the United States a populist approach to copyright. The concept of free private use is with us and has been with us for a long time, but that doesn't mean it's right. I think that the Digital Millennium Copyright Act is an important breakthrough in that it does establish the right of access for the first time, and that's something we should be repeating. It's a very positive step forward. We shouldn't make excuses for it, and I think it's going to clear the way for a stronger affirmation of the rights of creators in the years ahead.

The United States as a Model for the World. I asked Mihály at lunch whether or not the Europeans and those in other countries around the world are going to be looking to the United States and its law for models to follow in enacting their own legislation. He said that would certainly be the case, that other countries would at least look at U.S. law. If Mihály's prediction should come to pass, we should make it clear at the front end that our law does establish the right of access and that it does not exempt online service providers or the Internet access providers from liability on the Internet. It may somehow change the remedies that are available, but providers still have liability under traditional copyright, and that's an important concept. They will be subject to impoundment of their equipment, and they'll be subject to declaratory judgments. They may be given a safe haven as far as damages are concerned, but they have full copyright liability, and that's a point that we should emphasize so our European colleagues will make sure that that they appreciate the limited nature of the exemption.

The Free Market. I'm glad that the DMCA did give these new rights of access and control. The drafters of the U.S. Constitution gave authors an exclusive right, a property right. Authors should have the right to authorize the use of their materials on the Internet or to prohibit the use of their materials on the Internet if that is their wish. We have great faith that the workings of the free market will solve these problems and that the librarians' arguments that they need a right to browse in

order to decide what they want to buy will be shown to be fundamentally dishonest. I'm sorry that our librarian has left; I was going to use him as a foil.

Special Considerations for Librarians. It's been my experience that both the United States Congress and the courts treat children, drunken sailors and librarians as wards of the state who are to be given special considerations. The argument that librarians need the right to browse was, in many ways, a false argument that they really should not have been making. The market mechanism, especially in the library area, works beautifully. The publishers want to sell works to the librarians, so the publishers give out free copies, send flyers, provide online access — even full text access if that were going to prompt a sale to the 5,000 or so libraries that are the principal market for books that are published. But even in the face of all these sources of information, the librarians press their point. The danger is not so much from that side of the argument but rather, from the corollary — that if librarians have the right to break through the anti-copying codes in order to effectuate their right to browse and decide whether or not to buy a copyrighted work, then some other company has the right to make the machines that are going to allow the librarians to break through the codes. That, I think, was the ultimate dishonesty of the librarians' argument.

Protecting the Creative Process. Pam Samuelson and Jessica Lipman — I've participated on panels with them and have heard their arguments in person — they are in many ways disdainful of the creative process. They say over and over again, "There's nothing new under the sun. Everyone is building on works that have already been created. We've given copyright protection that's too strong, stronger than needed to 'promote the progress of science and the useful arts'." I disagree. I think the best copyright laws have always protected the power of the creator against the power of the owners of the technologies that exploit those copyrighted works. That's been so whether it's been the printing press or the photocopying machine, satellite transmitters, personal computers or, ultimately, the Internet. The debate over technology and the interests of authors is the very essence of copyright thinking. It's the core of copyright that makes copyright law historically unique, socially revolutionary and worth fighting for. And I hope that the DMCA furthers that battle in a positive way. On balance, I think that it does.

MR. SECOR:

Digital Technology is Very Different. I'm not exactly from the library community, but I guess I'm close enough. I'm not sure that we can take where we've been in the past and say, "We had a particular

technology, this is how we dealt with it and this is how the rights balanced out and, therefore, what worked for the old technology, and continued to work for the next technological development will also work for this newer technology, too." I think that the technology we are being confronted with today, whether you consider it to be a threat or an opportunity, is substantially different from those that have come before.

The Importance of Economic/Commercial Considerations. I will go back to something that I said this morning, you can't just look at the legal side of this. The economic side of these issues is absolutely critical. A comment was made this morning that a lot of infringement goes unpursued because it would be impractical to go after the infringers. I also made the argument that infringers also go unpursued because the economics are being dealt with sufficiently.

Library Copying. The people who sell materials to libraries do not have an economic imperative today to go after libraries for copying that the library might consider to be justified and covered by inter-library loan provisions but which, in reality, is not. Nobody follows the rule of five, but libraries do coordinate collection development. There are library consortia that are developing today in which libraries agree, "you subscribe to these journals, we'll subscribe to these journals, they'll subscribe to those journals, and then if one of your patrons needs an article from this journal, just give us a call and we'll get it over to you." So my problem with our discussion over the last few minutes is that I think that there are fundamental policy issues and societal issues that are not yet settled. I'm one of these people who reads the *Sony* case and thinks that it is a private-use case and not a fair use case because the fair use logic is so tortured in that opinion that I can't believe that that's actually what the Court meant. They must have meant something else; they must have meant that if it goes on in your home, we're not going to worry about it. I would make the same argument from the library perspective. Again, similarly, that I don't think we've really dealt with the policy issues

MR. ATTAWAY:

Protection as Incentive to Make Works Available. Jeremy, I'd like to take this opportunity to clarify an important point: the objective of both the technological and legal measures that we've been discussing is not to help rights owners to prevent people from accessing their works. The very opposite is true. The whole purpose of both these technological and legal measures is to provide an incentive to rights owners to make their works more readily available to consumers. A good illustration is the history of the DVD negotiations that have consumed a great deal of my life and Dean Marks' life and that have provided for the security of

Jon Baumgarten's financial future. Jon, you knew that was coming sometime today.

MR. BAUMGARTEN:

You say it enough that you now are estopped from denying it. When we conclude those negotiations we'll have to reopen other digital matters.

MR. ATTAWAY:

Technology/Content Synergy. What started those negotiations was a realization by the inventors of digital technology that no one was going to buy their devices if there wasn't software to play on them. So they looked at the movie companies and they said, "Well, what's going to encourage them to release software to this new medium?" Then they came to the correct conclusion. What is going to encourage the movie companies is some assurance that they will be able to protect their rights as content owners. With that understanding, we embarked on a lengthy negotiation, that's still going on, to develop a system to provide some modest level of assurance that we will be able to protect our rights. The result is that the public now has a new way of viewing motion pictures that they didn't have before. As technology develops, more and more opportunities are going to be made available if, along with the advancing technology, we develop concurrent advancements in the means for protecting against unauthorized uses which would otherwise disincentivize rights owners from making their works available to the new media. The whole purpose of everything that we've been talking about is not to prevent access but rather, to provide access, and to get paid for it, which is a part of the incentive.

MR. MEURER:

Sharing the Profits Created by New Technologies. The comment that Fritz just made about access reminds me of some comments from this morning. One thing that we should recognize is that access is an important issue, but there is also the issue of dividing the gain that is created by the new technology. Maybe it was Shira who said this morning that new technology creates gains that can be shared between copyright holders and users. Ideally, the gains from broader access will be shared, but that is not assured. It is possible that some parties will lose despite broader access. Methods of marketing that expand access don't necessarily mean that the users, especially the current users, are going to benefit.

MS. BESEK:

Encryption and Valid Online Agreements. I want to talk further about Fritz's point concerning broader access, because that's very important for my company. We publish highly sophisticated financial information, and a lot of our customers are large corporate users, investment banks and the like. We would like to be able to make our information more broadly available over the Internet to individuals and smaller users, but we have concerns about republication of our information, concerns we don't have when our customer is a major investment bank with a long-term contract. To allay those concerns, we need effective technology, encryption techniques and things like that, to protect our information. The other thing we need has been alluded to here, but not discussed directly: valid online agreements that we can rely on. The state of the law in this area is somewhat uncertain. Those two things together will allow us to make much more information much more readily available to a broader customer base, to customers who now don't have any realistic ability to have ready access to certain information.

MR. JORDA:

Intellectual Property Rights and Human Rights. In connection with the discussion of copyrights and culture, and Bernie Sorkin's concern that economics should not be the whole story, I'd like to mention that this past week, on Monday (November 9, 1998), there was a program at WIPO in Geneva. Mr. Masuyama was present and Dr. Silke von Lewinski was one of the panelists. It was a program on intellectual property rights and human rights that I consider rather historic and trail-blazing. We have known now for some time that intellectual property rights are very important, in fact as important as human rights. As somebody stated quite poetically: "Intellectual property rights today are the new frontier as were human rights yesterday." At this WIPO program, there was, for the first time, a strong equation of intellectual property rights and human rights.

The Right to Culture. Incidentally — and this is why I mention it — the second talk on the program covered intellectual property and the right to culture. The speaker was Christine Steiner, the General Counsel of the J. Paul Getty Trust in Los Angeles. Let me read you one sentence from her paper, which addressed the manner in which the right to culture is both embodied within the copyright scheme how it reacts against it. Ms. Steiner stated: "American intellectual property law is contained within the body of the U.S. Constitution. The Constitution also contains the First Amendment, the right of all persons to enjoy the right of speech, the right of religion, the right of assembly and the other rights commonly cherished as American cultural ideas. Thus, although not

expressly acknowledged as a 'right to culture,' the United States system provides a balance of economic and non-economic cultural ideas."

MR. ATTAWAY:

Just an observation, there must not have been any French representatives to this discussion, because the French would never suggest that protection of our copyrights would, in any way, advance culture.

MR. WILLIAMS:

You mean protection of American copyrights?

MS. BLAUSTEIN:

An Alternative Compensation Scheme. We've placed some emphasis on two interests of the rights holders, and I draw a distinction here between interests and rights. Those two interests are the interest that the rights holders have in people accessing their work and the interest that they have in receiving compensation for that access. We've also discussed the strategy, embraced by the European Community in particular, of imposing levies. Along with technology, which may moderately inconvenience potential copiers, there is also the possibility that we could fold the cost of the perceived loss of those private copies into the price of the copies that are sold, in much the way an insurance company might do things. Given that the cost of subsequent digital copies is essentially nil, the ability to fold the cost into the price should be a lot more palatable in this area than the same device would be in the realm of tangible goods. I ask those of you who are in the industry, what is the amount of loss we're looking at and could that cost be folded into the cost of the actual purchase prices?

MS. BESEK:

Fairness: Payment for Actual Use, not Predicted Piracy. Why should we do that? Why is that fair? Wouldn't it be fairer to charge the people who actually use the work? I was recently buying a magazine subscription, just for myself, and I was dismayed at how much it cost. I realized I would be paying for the people who are going to copy the magazine and reproduce it, and I decided I wasn't going to pay for their uses, too. Why should I have to pay for them? It doesn't seem right. It seems that if you could more closely track and collect payment for actual use, it would be fairer than forcing some people to pay for the uses made by others. So I don't know whether what you suggest could be done, but my first question is: Why should it be done?

MR. KEEFAUVER:

When you shop at K-Mart you're paying for the thievery of other people.

MS. BESEK:

I don't like that either.

MR. WILLIAMS:

Direct Compensation and the Costs of Piracy. I was going to say that's something like the argument Fritz was making about levies as a second-best, or maybe fourth-best, solution but not as desirable as direct compensation. Spreading the cost of doing business — if you want to use that term — that is attributable to piracy is probably done, if not directly with careful calculations, then indirectly, but this is a second-best solution. The recording industry has done some studies along these lines, haven't they, Matt, calculating the loss of revenues over the years from traditional audio home taping? I don't know whether these studies have resulted in conscious cost structures or whether this information is taken into account some less formal way. Do you have any insight into that?

MR. OPPENHEIM:

Calculating the Costs of Internet Piracy. "Yes" to your first question and "no" to your second question. I don't know whether piracy has been taken into consideration in cost structures. Studies were done on the cost and impact of home taping quite some time ago. I know that some consideration has been given to how this kind of activity can be measured on the Internet, and everybody pretty much throws their arms up in the air and says, "How do you measure that?" We've been in discussions with a number of groups on that issue and nobody, I think, has come up with an ideal way of measuring such uses when they take place on the Internet.

MS. BLAUSTEIN:

Multiple Compensation Schemes. I appreciate that folding in costs is clearly a second-best option, but the various options are not necessarily mutually exclusive. If we use options like direct compensation, and take advantage of all the technology that is available, I believe we've conceded here that there is still going to be private copying. So, in order to best compensate for that reduced amount of profit, we could fold in that cost — not instead of, but in addition to, using the other options.

MS. WEAVER:

Compensation by Contract or Legislation. The issue of making the user pay is a difficult one — and please don't perceive that I'm

advocating a private copying levy in the U.S.; I'm not authorized to do so at the moment. But one of the difficulties is that if you want the party who is getting the benefit of making the copy to pay, then you have to have some sort of legislative solution, because you don't have a contractual relationship with the user. That's part of why the Digital Home Recording Act provides that you're going to pay when you purchase the media on which you're going to record, because the goal is to have the user pay if the user is going to get the benefit of making a copy. I'm not coming up with any solution; I think it's a very difficult problem and there is no easy resolution that doesn't create some difficulties for us.

MR. STRONG:

Jeremy, I don't know if you were planning to move onto something else, maybe I'm going to derail that but . . .

MR. WILLIAMS:

I wanted to move on to the OSP issues, but go ahead.

MR. STRONG:

Technology, Fair Use, and Privacy. I'll just point out that there are two issues that have been left hanging which we really ought to address, if we have the time, at the end of the afternoon. One of them Bernie brought up before lunch, and that's the question of fair use and how fair use functions in a pay-per-view environment, particularly a pay-per-view environment that's protected with a lot of follow-on encryption, such as Glen was describing, where the box follows the material around. How do you preserve fair use in that context? The other issue is the question that Bill brought up concerning privacy and how we reconcile, in a pay-per-view environment, the interests of privacy with the interests of copyright? I just point out that we haven't really dealt with those issues.

MR. WILLIAMS:

Do some people want to comment on those issues? We don't have to follow a formal schedule.

MR. SECOR:

Direct Payment and Privacy. I'm not sure that the technologies that give rise to some of the direct payment schemes we're talking about, by definition, compromise privacy. They don't have to, I guess, depending on how they're structured and what sort of payment mecha-

nisms are used. It isn't necessary, I don't think, to keep records of who copied what.

MR. TANENBAUM:

But records will be kept.

MR. SECOR:

Records don't have to be kept and records won't be kept if someone decrees that they shouldn't be.

MR. TANENBAUM:

But there are too many computers in the chain. The question is whether you're going to pay with a credit card, which is identifiable money to the payer, or with some kind of cash that is not identified with a particular person, in some digital format.

MR. SECOR:

Okay. Yes, in terms of being able to say, "I entered into a transaction on such and such a date, used my credit card," and, "the ten dollars that I'm going to pay is to make its way to Franklin Pierce Publishing versus Playboy Enterprises."

MR. TANENBAUM:

Right, but will Franklin Pierce know that the order came from Bill Tanenbaum, that it was my credit card, that it was my mirco payment? It seems to me that the transaction that will authorize my use is the same transaction that will confirm that authorization by executing a payment. If your book publishers in Frankfurt do not want to identify authors of individual articles, I'm not sure they're going to want to strip out a transaction and say, "this is authorized" without then keeping that portion of the transmission that says "here's the payment from Mr. X."

MR. SECOR:

I'm not sure that the payment in that scenario needs to be identified by individual. It depends, I guess, on what kind of transaction we're talking about. Professor Karl is building a course pack for his course, and he's acquiring photocopy permissions from different publishers to be able to do his course pack. I don't think that a permanent record of that permission necessarily needs to be kept.

MR. TANENBAUM:

But there's a strong incentive for the middlemen in this market to take information about the demographics of their purchasers and then resell it.

MR. SECOR:

If we allow that. And I think there is an issue here, if we've all paid attention to what's going on in Europe with privacy initiatives and the fact that we in the United States approach this issue very differently.

MR. TANENBAUM:

Information is, in fact, one of the economic benefits to those companies taking part in this chain of transactions; they get information that they can turn around and sell.

MR. WILLIAMS:

A Copyright Problem or an Information Problem? To what extent, though, is that a distinct problem arising from copyright protection mechanisms as opposed to the problems that we're going to have to deal with generally anyway? So much of what we do now is electronic. We think of it as old fashioned, but every time your credit card is swiped through the reading machine, you're in the information age with all kinds of information about you being sent off somewhere. People worry about using their credit cards on the Internet, but you call L.L. Bean and you give your credit card number freely to someone you don't know. I'm not saying that this isn't a serious problem; I am just asking to what extent the problem is really being raised by the copyright protection issues that we're concerned about and the mechanisms that we're going to use, rather than being something that we have to deal with anyway given the realities of the information age?

MR. SECOR:

Tracking Reading Habits. I might argue that privacy is more critical when we're talking about information on individual access to copyrighted works than when we're talking about data on what sort of boots you ordered from L.L. Bean. If Ken Starr had subpoenaed the shoe store to find out what sort of shoes Monica bought on a given day, I don't think we would have the hue and cry that we did. With these mechanisms that we're talking about you can track what I was looking at, you can track what I was reading, you can track what I wanted to use, you can track what I did with it. So whether it's books or magazines or films or whatever, it hits a nerve that some of the other e-commerce transactions don't necessarily hit. I just want to put one question on the table. I

don't know if we'll have time at the end to deal with it, but I'm wondering if we will conclude that private copying is compensable in the United States.

MR. BAUMGARTEN:
But we have already.

MR. SECOR:
I don't see how, Jon. How have we decided that?

MR. BAUMGARTEN:
It's the Audio Home Recording Act. We have one levy system, in principle, in this country.

MR. WILLIAMS:
Although in a technology that has not penetrated . . .

MR. BAUMGARTEN:
You could say there's a declaration of Congressional policy that private copying is to be compensated.

MR. SECOR:
In audio. Is it going to be that way with everything? We also have a court case that we've been talking about that tried to convince us that time shifting is a form of fair use.

MR. WILLIAMS:
Although the tradeoff for that in the Audio Home Recording Act was an acknowledgment — at least de facto, and pretty close to all the way — that private copying is an acceptable act.

MR. SECOR:
No, it was a compensated act.

MR. BAUMGARTEN:
Acceptable if very limited and compensated.

MR. OPPENHEIM:
I just want to argue that I think it is still an open issue.

MR. SECOR:

I think the real problem is whether this previous discussion will inhibit Bill Keefauver from using his Easypass to go to places that he would rather not talk about.

MR. SORKIN:

And I was thinking, Glen, if the inquiry had been Monica Lewinsky and Victoria's Secret you might have had a similar act.

MR. SECOR:

Copyright and Privacy in Conflict. I think Bill's argument is that absent some sort of legislative intervention, like the EU privacy initiative, you do have a conflict, or the potential for a conflict, between copyright and privacy. And I think he's right in that argument, because there is a lot of incentive for everyone in the middle to accumulate and resell that information. I don't think it's specific to copyright, but I agree that it's because of the copyrightable subject matter and some of the nerves that it touches — concerns that others may know what I am reading or watching or listening to — that privacy issues exist in this area that don't necessarily exist in most types of e-commerce.

MR. POLITANO:

Protecting Privacy. I have a great deal of sympathy with the privacy concerns that have been raised but, again, there's a way to circumvent every protection measure. You can still pay cash and go through the Lincoln Tunnel. Even if you have Easypass, you can still pay cash. Soon, if not already, you will be able to buy a Smartcard that's anonymous, so you'll be able to use credit without giving up your personal information in each transaction. If you have to conduct a transaction on the Internet and you don't want anyone to know about it — for whatever reason — you'll soon be able to do so. So there are ways around the privacy problem, and I think there always will be.

MR. OMAN:

Fair Use for the New Millennium. I want to respond to the fair use question, and raise the possibility that we're still thinking in the old paradigm rather than the new paradigm where fair use may not be necessary in the conventional sense, where photocopying is the primitive technology. Online, we'll download materials onto our screens, make hard copies if we want, pay a bill at the end of the month, and not have it be that much of a burden or even an inconvenience. In a lot of ways, as Shira mentioned earlier, many of the fair use concepts are a response to what were perceived as market failures — that there was no way for a

copyright owner to collect from someone standing in a library pumping ten cents at a time into the photocopy machine. But that's no longer going to be the case in the new online environment. Wouldn't it be wonderful if, in the future, rather than splitting that dime into two cents for the electric utility company, two cents for the maintenance man, two cents for the Xerox company, two cents for the library, and two cents for the paper manufacturer, wouldn't it be wonderful to be able to give the author a penny or two out of that dime? That's going to be possible in the new electronic environment, and that's why I don't think fair use will not be an issue. These incidental uses will be permitted and encouraged because they will be another source of revenue for the author.

MR. STRONG:

It might also be possible for the author to charge twelve cents. Your optimism is based upon an assumption that pricing will be benign, which I don't think is necessarily a fair assumption.

MR. OMAN:

It arises from my ultimate faith in the market mechanism.

MR. STRONG:

New Kinds of Fair Use. There are other kinds of fair use. Your comments are really directed to verbatim or simple reprographic copying. I'm concerned about other kinds of fair use as well. For example, there have been a couple of cases in recent years where it's been held legitimate for someone to reproduce an entire article from a newspaper and circulate it as part of a political commentary or for the distributor's self-defense in response to criticism. I think those cases were correct. I'm not sure how those cases will be replicated in an online environment where the material is tagged or encoded in such a way that it cannot be further distributed without paying a price, no matter what one's motive for redistributing it might be. I don't have answers to these questions. I just have questions.

MR. OMAN:

We should always keep in mind Justice O'Connor's admonition that "copyright is the engine of free expression."

MR. WILLIAMS:

Why don't we take a brief break, and then we'll come back for our last session and discuss the OSP issue, maybe starting with the question "What was the problem in the first place? What did it solve, if anything?" So let's take ten minutes.

[The conference takes a break.]

MR. KEEFAUVER:

It has been suggested that I assume fast-track authority and have the meeting close at around 4:30, for those of you who would like to continue sidebar discussions or who have other endeavors in mind. Some would like a nap, for example. So notwithstanding the five o'clock closing time in the published announcement we will try to target a 4:30 finish.

VII. ONLINE SERVICE PROVIDER LIABILITY

MR. WILLIAMS:

We have a brief period of time to discuss the OSP legislation which, as many of you know, started out as a fairly short proposal. If I remember correctly, some versions were less than a page. Yet we ended up with a very lengthy section of the DMCA which in the later weeks, if not months, of the DMCA process was left fairly untouched, having been arrived at through various inter-industry negotiations. That fact alone reflects the questions I posed before the break, asking what was the provision was really all about and whether it was really necessary.

The outline in front of us, which we don't have follow precisely, suggests three different viewpoints from which the OSP issue may be examined. To begin, there are the viewpoints of online service providers and content owners which should be examined to answer the question what was gained and what was lost that wouldn't have been gained or lost had there been no new legislation. Then, equally important, there is the question of the impact of this legislation on the user community. Finally, I'd like to hear some discussion, if possible, about what's going on in Europe. So I open that discussion up. What did this legislation accomplish? Was it a win or a loss for one side or the other? Or was this one of those famous win/win situations?

MR. POLITANO:

The Importance of Ownership. I never characterize legislation as win/win. It's always lose/lose. When I was in law school, I had a law professor who used to come in all the time and exhort us, "Possession is nine-tenths of the law. Possession is nine-tenths of the law." He did that for half a semester, and he asked, "Do you know what that means?" We were first year law students, and we said, "Well, yeah, if you own something, and I possess it, the law is going to side with me and say that I own the thing." That's not what it means. What it really means is the

study of possession, who owns what rights and property, is nine-tenths of the law. He was a property professor and that's the point he wanted to make.

Who Gets Stuck With Liability? The way I see this issue relates not so much to possession but rather, to who's going to get stuck with liability. Is it the online service provider, or is it the person who's actually doing the infringement? Who has the deep pockets, and where are we going to dig for the money? I think that a compromise was reached. I am prejudiced because I represent a service provider, AT&T, and we have our AT&T World Net Service, which is essentially a conduit for information and messages. We try to strike a balance between our interest in not being liable for stuff we don't even know about and our recognition that copyright owners have a very legitimate interest in stopping infringements, and that often times they can't even find who the infringers are on the Internet because it's such an anonymous system. Thus we view the legislation as an attempt to solve a problem, and we hope it will work. We hope that the notice provisions will work. We hope that the information that's provided to us will enable us to decide whether or not a site should be taken down, and we hope that by doing this we will be able to avoid, at least for the time being, any liability for being a pipeline that simply delivers but does not produce content.

MR. OPPENHEIM:

Subpoena to Identify Infringer Provision. One provision of the OSP section that is of particular interest to those of us in the recording industry is the Subpoena to Identify Infringer provision. In the past we've done two things. One is we've gone, ex parte, to federal district court seeking TROs and asking the court to order the OSP to tell us who is running sites that contain infringing material. That is a relatively onerous way for us to get at the infringers. The other thing that we've done is to send cease and desist letters to the OSP, and the OSP, more often than not, will take down the infringing sites. The problem with that is that those sites just go up again somewhere else, because the infringers simply keep the content and mirror it somewhere else. It's a little bit like that Whack-A-Mole game at the carnival, when you hit one, another one pops up somewhere else. We're very hopeful that this new provision will help us eliminate some of the rampant infringement of music copyrights on the Internet by eliminating a large part of the anonymity that has so greatly facilitated this type of infringement.

MR. ATTAWAY:

Existing Law was Adequate. In the interest of stimulating the discussion, my view of this is that there really wasn't a problem. Existing U.S. law with regard to vicarious and contributory infringement was doing, and would have continued to do, an adequate job of creating or dividing responsibility for preventing online infringement between the copyright owners and the service providers. However, the telephone companies having in 1996 spurred the enactment of legislation that preserved their various monopolies, needed something else to do, so they decided that they had to have online service provider liability legislation, and they held our WIPO treaties hostage until they got it.

MR. POLITANO:

You're talking about the regional Bell operating companies, right, those monopolists?

MR. ATTAWAY:

What happened was that a lot of lawyers got together and what had been a relatively simple and straightforward concept of vicarious and contributory infringement in the case law was altered into God knows how many pages of statutory language that reached essentially the same result, but it did so in a way that will keep lawyers busy for the foreseeable future trying to figure out exactly what the law says.

MR. MURPHY:

Isn't it possible, though, that this section could be used by, let's say, someone who wants to protect material from getting out in the public domain? I think of the Church of Scientology issue of notifying the online service provider. What's their response going to be? — "I'm taking it off to protect myself." I sense that there's something extra here that's not what we had before, but now we've got a true incentive on behalf of the online service providers to pull off any controversial materials unless somebody sends them a little letter that says, "Excuse me, I think you're violating my copyright."

MR. ATTAWAY:

I think the incentive was always there because the online service provider, under the old law, had to consider liability under contributory or vicarious infringement if it didn't take infringing material down. You may not like the particular people making the request to take down material, but even the Scientology material is copyrighted.

MR. MURPHY:

It seems like there might be an extra provision that says no liability. Let's say they take down something that wasn't copyrighted. It looks like the online service providers snuck in some additional protection, a way to avoid liability for wrongfully taking down material not protected by copyright. That seems to be a little bit beyond where we were.

MR. WILLIAMS:

Self-Help "Injunction." Well there's one respect in which I would agree, and I'll play the user role for the moment. Since there is a safe harbor for taking material down, and if the person whose material was removed sends a counter notice, the content owner can then file a lawsuit within thirty days and the online service provider can keep the material down with impunity. I think we may have enacted — and I'm not saying it's a bad thing — a kind of a self-help injunction remedy for content owners, to the extent that you don't need a court anymore to make whatever findings you'd need to get an injunction. It seems to me essentially automatic unless the service provider is willing to really go out on a limb and say, "We so believe in the publication of this material that we will relinquish our safe harbors and take our chances in the court."

MR. MARKS:

But there are penalties.

MR. WILLIAMS:

For doing that?

MR. MARKS:

Protection Against Unilateral Self-Help. Two points. First, there is the possibility for the counter notification procedure to restore something that's been taken down. Second, there is the burden on the complaining party to file a court case in order to keep the stuff down. This provides some protection against a unilateral type of injunctive relief. Beyond that, if you file a false notification, you subject yourself to fairly severe penalties.

MR. WILLIAMS:

That's true, if the claim is fraudulent.

MR. MARKS:

Right. If the claim is fraudulent, aren't you even subject to criminal penalties for the fraudulent claim?

MR. POLITANO:

But Jeremy, what you're saying is, in effect, if someone has a good faith claim they get at least a thirty day take-down unless the OSP is really going to put themselves on a limb. That's what you're saying isn't it?

MR. WILLIAMS:

Right, but I'm also saying that if you're willing to file the lawsuit within the thirty days — and I agree that filing a lawsuit is something of an inhibition — it does seem to me that the material will automatically remain off the system if the OSP is not willing to go out on a limb for the user, whereas before I would have had to actually make some demonstration of likelihood to prevail on the merits, which is essentially the standard for getting a preliminary injunction. Some users would argue that that's a chilling effect. I'm not defending that; I'm just pointing out the position.

MS. PERLMUTTER:

I have two thoughts in response to the comments that have just been made.

Online Service Providers in the Middle. First, the reason for that provision is to avoid putting service providers in an impossible situation where they are damned if they do and damned if they don't. They were coming to Congress and saying, "We can't be at the center of everyone's complaints, where on the one hand the person who put the material up can sue us, and, on the other hand the copyright owner can sue us." This provision is an attempt to give service providers some realistic out.

Little Real Change from the Old System. Second, it's important to bear in mind that we're comparing this new system to the current system, where the way it generally works is that claims are made and material is taken down by cautious service providers in response to the claims. So we were in a situation, even before the DMCA, where there were, in essence, TROs without court intervention. The DMCA probably gives more protection to users than they would have had before, because there is a counter notification procedure. People are talking about this as if it's some new system that just came into being. But we had, before the DMCA, a voluntary-notice/take-down system in effect that led to material being taken down by those who didn't want to get into the middle of a legal dispute, whether it was over copyright, libel, or other forms of potential liability.

MR. FICSOR:

Problems in the Eye of the Beholder. I don't want to express any view as to whether this legislation is a win/win or lose/lose proposition from the viewpoint of the various interest groups in the United States. But clearly, there are two victories, because the United States now has the implementation legislation, and there is a decision about the ratification. Was there was a problem or not? Our perception was that there was no problem. However, if there is no problem, but only something perceived as a problem, or something made into a problem, there's a problem. So I understand the position of the U.S. service and access providers that they wanted to start this new era with appropriate legal protection.

New Technology, Old Problem, Judicial Solutions. To answer the question why we didn't perceive that there was problem, I refer to history. In many countries similar issues emerged in the past and those issues were settled through jurisprudence. This is not a new problem. It emerged with printing and publishing. Who is liable, the printer or publisher? It emerged in connection with public performances. Who is liable, those who lend the instruments to the performers, the performers themselves, the conductor, the organizer of the concert, the person who sits in the box office, the usher? National courts were able to respond to these questions. Certainly they would have been able to give appropriate response to these new liability issues also.

International Approaches. At the international level, there will probably be different solutions. It seems that at least three options will be studied and, perhaps, applied. First, there is the option chosen in the United States. Second, there is what seems to be the choice of Europe, namely that this will issue be addressed by a horizontal regulation dealing not only with copyright but also with all the other related issues. The third option is not to legislate. Countries that choose not to legislate will simply trust their courts. But when the courts do address the issue, some people will certainly draw attention to solutions adopted by statute in other countries. So the U.S. solution will certainly have a great influence in all the countries.

MR. FIELD:

Economic Harassment and Restraints on Speech. I haven't studied this situation, but it seems very similar to the problem faced by NSI with regard to conflicts between trademarks and domain names. I have great sympathy for parties such as NSI who get caught up in the disputes of others. Yet canceling or suspending domain names because someone waves a trademark registration, or pulling Web pages or closing down sites because someone waves a copyright registration, creates too much potential for economic harassment and restraint of speech. So, any

deterrent to frivolous complaints seems to be a long overdue step in the right direction.

MR. WILLIAMS:

Jurisdiction-Hopping Infringing Material. Matt talked about the carnival game with the animal popping up, Whack-A-Mole. Absent some broad international resolution, what about the problem of material popping up in various jurisdictions, given how easy it is to upload to a server somewhere else? How do we see that working, either in the absence of an international solution or with an international solution in terms of liability? Am I able to put the infringing material up on a Website in some distant place and not be liable under this bill? Is there much practical significance to this beyond the very short term until we solve the problem internationally? That question applies to a great many things, but it seems particularly relevant to this point.

MR. FIELD:

Is the ISP to stop it at the border?

MR. ATTAWAY:

Offshore Websites Beyond Our Reach. That issue was debated endlessly, and I think the answer is that there is nothing that we can do to prevent someone from establishing a Website offshore for accessing infringing material. What we hope we've provided for in this new statute is the possibility of enjoining a U.S. citizen's OSP to block access to an offshore Website if we can establish that that Website is delivering infringing material into the United States. But there is nothing we can do about the offshore Website until other countries adopt similar levels of protection.

MR. OPPENHEIM:

International Cooperation. This is a serious problem. To date, a lot of OSPs abroad have been relatively helpful in working with our international counterpart, IFPI, in taking down sites that mirror U.S. sites, that have content that we have found to be infringing in the United States, or that have their own independently infringing content.

MR. WILLIAMS:

On what basis have they been taking those sites down?

MR. OPPENHEIM:

Voluntarily.

MS. PERLMUTTER:

New Cause of Action for Wrongful Take-Down. It's true that the service provider is immune from being sued for the take-down, but the bill also creates a new cause of action for the person whose material has been taken down to sue the person who provided the notice. That's a totally new cause of action. The plaintiff wouldn't have to establish the elements of a separate claim, as would be necessary to sue the service provider, and could get reimbursed for any costs her or she incurs as a result of the material being taken down. So in some respects, that person might be better off than if he or she still had an unspecified cause of action against the service provider.

UNIDENTIFIED:

Wouldn't they have a tortious interference claim in the absence of this legislation?

MS. PERLMUTTER:

I don't know how hard it is to establish that.

MR. WILLIAMS:

That might also be a state-by-state situation.

MR. OMAN:

Electronically Isolating Pirate Countries. Could I make one technical point? I talked to a technical person a while back, and he said that in the future, it may be possible, if not to isolate a pirate country from the Internet, at least to overload the circuitry in that country to the point where the circuitry would stop functioning, and that would be the price they would pay for their pirate activities.

MR. WILLIAMS:

Has the Copyright Office already promulgated temporary regulations for OSPs to comply with the notice?

MS. PETERS:

OSP Regulations Posted on the Web. The regulations were posted on our own Website the day after the bill went into effect. We've received over one hundred of these notifications of agents, and they're available online under "WhatsHot." The filing fee is $20.00 but that's an interim provision. We will publish a notice of inquiry to get much more information, but we felt it was absolutely essential that we have a system in place.

MR. WILLIAMS:

I was going to say there must be a lot more coming in if people are aware of it.

MS. PETERS:

I don't think anybody thought we would be up and running that quickly.

MS. PERLMUTTER:

New Work for the Copyright Office. The Copyright Office had a lot of immediate work to do under the new legislation. We had to have the system for designating agents up right away. We have to have something by the end of the year, under the term extension bill, to allow copyright owners to provide notification that their works are commercially available for purposes of the library exemption. We had the vessel-hull design law, which went into effect immediately. This meant that the day after the President signed the bill, in theory, people could be registering with us under a system that didn't exist yet. So it's been quite overwhelming.

MR. WILLIAMS:

That's the trouble with formalities, right?

UNIDENTIFIED:

Intellectual Property as "TRIPs Plus." I'd like to ask a question. Our U.S. TR negotiators are, from time to time, asking us, as an attempt to open negotiations with Chile and other countries in South America, about expanding NAFTA and negotiations with other countries. Their usual starting point in IP is what they call "TRIPs Plus," which is the TRIPs package plus "What else would you like us to put in the TRIPs package?" My question is — and I ask it because of our recent discussion about offshore providers — is this issue something that should be thought of as part of the TRIPs Plus package? And second, is this issue important enough to even talk about reopening TRIPs? Of course, it's not likely that TRIPs will be reopened any time soon, so my real question is whether this issue should be part of TRIPs Plus.

MR. FICSOR:

TRIPs Plus. This is TRIPs plus elements, but at the same time not TRIPs Plus. Of course, the entire regulation about technological measures of protection and rights management information, is TRIPs Plus; it's not in the TRIPs Agreement, it's not in the Berne Convention,

which is included in the TRIPs Agreement by reference. But, as far as all the background, as far as rights and exceptions are concerned, there are not too many TRIPs Plus elements, except that, of course, the right of communication to the public has been made more complete in the two treaties, and the right of distribution has been recognized explicitly in respect to all categories of works. There are many obligations concerning online users in the TRIPs Agreement. The only real plus elements are that the communication-to-the-public right has been made complete; the gaps in coverage which exist in Berne and TRIPs have been eliminated; and there is some clarification concerning the right of reproduction. It's clear now that it applies also to transient reproduction, with appropriate exceptions, but this is just clarification. So as far as substantive provisions are concerned, there are not too many plus elements. The real plus is the obligation concerning technological measures and rights management information.

MR. WILLIAMS:

WTO-Type Enforcement? One question we have here is that if these digital threats exist, and the digital measures to attack them are so important, are we going to see more and more worldwide WTO-type enforcement of compliance with these measures? Is there going to be a ratcheting up of that whole process in order to bring about compliance and to eliminate loopholes in the technological structure around the world? Do people see that starting to happen?

MR. FICSOR:

Under the TRIPs Umbrella. I think that these new treaties, so that they may be applied appropriately, should end up under the umbrella of the TRIPs Agreement. My recommendation is that you shouldn't speak so much about this now because of the ongoing discussion about whether there should be a new round of negotiations in WTO or a piecemeal approach. It's better first to have the treaties in force, and then this issue should be raised after that. I am sure that that should be the future of these new treaties, because otherwise the same problems emerge as in the case of the other WIPO conventions. That they are there, is, as we say in Hungarian, "a sacred water," without any serious application.

MR. DESANTES:

Jurisdictional Problems. I'd like to add something regarding the issue of jurisdiction. The situation, both in the United States and Europe, is rather unsatisfactory. Dealing with non-contractual obligations, Europe did not find a clear solution as to the place where the damage has

occurred. A 1976 doctrine of the European Court of Justice applying the Brussels Convention on execution of judgments states that both the court of the place where the damaging act originated and the court of the place where the damage occurred have jurisdiction to deal with the matter. If we apply this doctrine to the international arena, we will arrive at the conclusion that American courts will have jurisdiction dealing with infringements which have occurred outside the United States anytime there are any kind of effects shown within the territory of the United States. Similarly the other way around, when approaching the problem from the European point of view. This being the theory, things are rather different in practice. The main problem is that even if one has jurisdiction, it is not worthwhile for an American company to go to an American court to sue a European company if the latter has no assets within the territory of the United States. It is not worthwhile because any judgment will be unlikely to be executed in Europe. And the other way around. Let me give you an example.

Execution of Judgment. Imagine a French enterprise that wants to sue an American enterprise that has potentially infringed its copyright. According to Article 4 of the Brussels Convention, the French company can rely on its own rules on jurisdiction. These rules come from as far back as the beginning of the nineteenth century, and say that anytime a French national is involved in a case, French courts have jurisdiction. So, even if there are no effects of the infringement in France, French courts will have jurisdiction, and the judgment will be executed all over Europe. So American enterprises should be aware that these kinds of judgments could be, for instance, executed in the United Kingdom just because some assets of the American company passed through the London Stock Exchange. Obviously, these judgments have little prospect of being executed in the United States.

A Problem for International Relations. To conclude: either we encourage WIPO or any other organization to solve conflicts regarding online copyright infringement or we should probably expect a turbulent period in our international relationships. We are not only facing a problem regarding online pirates occasionally infringing the copyright of others, but an everyday problem in the daily relations between the United States and Europe.

MR. FICSOR:

WIPO Online Dispute Resolution Systems. As far as WIPO is concerned, of course, we are considering certain online dispute resolution systems, but this is not applicable in all situations. You may use them in certain situations, but not in all. If the dispute is about, for example, the question of denying connectivity to certain sites, they may work.

THERE IS NO CYBERSPACE! I do not believe that there is such a thing as cyberspace. There's no cyberspace. I'd like to repeat: there is no cyberspace. We use certain metaphors too frequently and we tend to take them seriously. There is no cyberspace in the sense of something beyond the space where we live, since *existing* computers transmit information, protected works, through *existing* nodes to *existing* computers, and *existing* human beings undertake these tasks under the direction of other *existing* human beings. We should take this into account.

Choice of Forum. As far as applicable law is concerned, of course, it's very complex. We would like to address this issue as well as the issue of choice of forum. In Europe, choice of forum works quite well on the basis of the Brussels Convention. Perhaps we should try to think of something on a world level. It may not be possible in all aspects, but as far as the Internet and electronic commerce are concerned, we may start thinking of this somehow.

Choice of Law. As for applicable law, we will address this issue from December 16 to 18, 1998. We have dealt with this at many fora because it was first in the field of copyright that the principle of territoriality was questioned. In the case of satellite broadcasting, there were already a lot of problems so it's not new for us. We also discussed this issue at previous brainstorming meetings concerning digital technology and copyright. Now there will be a special group of consultants meeting. We have commissioned two studies, one from Jane Ginsburg and another from a French professor, André Lucas. We have invited several consultants to this meeting, and it's open to all NGOs, IGOs and governments. What I'd like to say about this is that I think the choice of law/applicable law discussion probably will change direction. I think that there will be a development away from the traditional categorical analysis and in the direction of functional analysis, and I believe that the beautiful cynicism of private international law will be fully applied. In the field of copyright, the basic principle is still lex loci protectionist. Just where on the earth a certain act is carried out, that is the question. In the case of an Internet transmission, we are in the machine. We are in the machine. It is the world where it happens; it happens everywhere. So you are free to choose between various fora without rightly being accused of forum shopping.

MR. FIELD:

Jurisdictional Concerns. Manuel's concern about jurisdiction does not strike *me* as far-fetched. In the United States, remedies for willful copyright infringement can range up to $100,000, and can include costs and attorneys' fees. Assuming, as I do, that posting an unauthorized

copy on a foreign server constitutes U.S. copyright infringement, those doing so can face unpleasant choices. Assuming, secondly, that suit would be filed here, they could either go to the expense of defending (say on the basis of fair use) or run the risk of a very large default judgment. If such a judgment could be enforced abroad, it would certainly be worthwhile for a U.S. copyright holder to pursue it.

Cyberspace Should Exist. Thus, even if cyberspace does not yet exist in a jurisdictional sense, it should. It should become a forum where such disputes could be resolved without parties' having to travel abroad to defend unwarranted suits or, equally bad, suffer severe consequences for failing to do so.

MR. MARKS:

Extraterritorial Application of U.S. Copyright Law. My memory is murky on this, and I'm hoping that Bernie and Chris will help me out, but, Manuel, I thought you had said that — at least under European principles — if a U.S. work, for example, were infringed abroad, American law might apply in terms of remedies. Maybe I misunderstood, but the U.S. courts have been very reluctant to apply copyright law extraterritorially to acts of infringement abroad. I'm thinking of several cases the Ninth Circuit where the authorization was given in the United States to distribute or make videocassettes copies of the film *Yellow Submarine*, and the district court said that that was enough, i.e., that authorizing the infringing activity from the United States was enough to give the court jurisdiction to apply U.S. Copyright law. The court of appeals reversed and said that U.S. copyright law is territorial in nature and only applies to acts of infringement on U.S. soil.[21] Chris and Bernie do I have that right?

MR. SORKIN:

Location of Infringement on the Internet. I think you do, but I think we also have to consider where the infringement takes place. In the *Reuters*[22] case, for example, where there was an infringement here and the infringed product was distributed abroad, the court looked to the law here. When we're talking about infringement on the Internet — I may be the only one here so handicapped — I'm not at all clear as to where the infringement takes place.

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[21] *See* Subafilms, Ltd. v. MGM-Pathe Communications Co., 24 F.3d 1088, 30 U.S.P.Q.2d (BNA) 1746 (9th Cir. 1994) (en banc), *vacating and remanding* Nos. 91-56248, 91-56379, 91-56289, 1993 WL 39269 (9th Cir. Feb. 17, 1993) (unpublished table decision).

[22] Los Angeles News Serv. v. Reuters, 149 F.3d 987, 47 U.S.P.Q.2d (BNA) 1349 (9th Cir. 1998).

MR. BAUMGARTEN:

The Complexity of International Litigation. American courts have also accepted jurisdiction here over infringement claims based on acts occurring abroad and measured by foreign law, and have accepted domestic jurisdiction to adjudicate the debate as a transitory tort under foreign law. There was the *London Films*[23] case in the Southern District of New York, but there's been a much more recent case that the court accepted over a forum non conveniens argument.[24] We have to be careful in all these areas to separate the questions of jurisdiction, whose law applies, enforceability of the judgment, and whether you're invoking the forum court to determine the question of domestic infringement under domestic law or asking the forum court to adjudicate foreign infringements under foreign law on a transitory tort basis. It raises a lot of intriguing questions.

Enforcement of Court Judgments and Arbitral Awards. Earlier today we mentioned DVD, which can be used to show some of the practical impacts of these procedural issues. In the stage of DVD negotiation that we're now approaching the conclusion of, one question is whether there will be a new entity to license the relevant technology. A related question is whether adjudication or arbitration should be utilized to resolve enforcement disputes with licensors. Among the factors coming into play in that determination is that there is no general multilateral treaty on enforcement of judgments. However there is a multilateral treaty on enforcement of arbitral awards. And although there is a general hesitancy to submit to arbitration, particularly in the computer industry, there's a general acknowledgment that in cases where the result is likely to be a default judgment against a foreign licensee, or a failure of such a licensee to actively defend, that the plaintiff might be better off electing arbitration because of the increased likelihood of enforcement of the award in foreign countries. So all these theoretical questions have very practical implications.

MR. DESANTES:

Private International Law. This is the reason why I didn't talk on applicable law before. I spoke on the first and the third parts of what we understand by private international law, that is to say, on jurisdiction

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[23] London Film Prods., Ltd., v. Intercontinental Communications, Inc., 580 F. Supp. 47, 223 U.S.P.Q. (BNA) 381 (S.D.N.Y. 1984).

[24] Boosey & Hawkes Music Publishers, Ltd. v. Walt Disney Co., 145 F.3d 481, 46 U.S.P.Q.2d (BNA) 1577 (2d Cir. 1998).

and on execution of judgments. And this is so because I also wanted to come to Mr. Ficsor's three conclusions, with which I concur.

Distinguishing Between Jurisdiction and Choice of Law. The first one is that when dealing with copyright infringements online, maybe the U.S. doctrine should start considering the possibility of establishing a difference between the jurisdiction and the applicable law.

Rethinking Jurisdiction. The second is that we in the United States and in Europe should change our minds on these jurisdiction issues, in order to achieve what we are actually looking for. If what we are actually looking for is the protection of copyright owners from infringement, then we should give them various jurisdictional options to keep infringers from forum shopping, and we should provide copyright owners with at least the same tools that any other enterprise has when using the New York Convention on execution of arbitral awards. Once upon a time, thirty years ago, it became clear that the market needed a kind of arbitration system which actually guaranteed the execution of the judgment. Both the academics and the business world lobbied for it and obtained it. And this system avoids a lot of potential conflicts. So my second conclusion is that we should open again the jurisdiction issue.

Functional Analysis. Finally, my third conclusion is that the functional analysis is only possible dealing with applicable law. We should put the lex loci protectionist principle away because this means in fact no more than lex fori. We should start thinking of a more functional analysis, if possible, within the framework of an international organization such as WIPO.

MR. WILLIAMS:

We have just about ten minutes or so left, and actually I think we've done a remarkably good job of getting through our agenda and also discussing many other side issues. So I want to ask if there is anyone who wants to raise any new issues or make any closing remarks before we finish?

MR. SECOR:

I just want to remark that I think there is one item on the first page of the agenda that we haven't really gotten to, namely: What will be the nature and role of licensing in the digital world? It seems like the 2,000-pound elephant in the room that we haven't really acknowledged. One of the biggest issues that we're going to have to face when we talk about digital technology and copyright is the very fundamental policy issues being raised by UCC Article 2(b) in terms of preemption.

MR. WILLIAMS:

We sort of touched on it in the technological market-failure/fair-use sense. We didn't touch on it in the commercial law sense. We could have a few minutes of comments. It is definitely a 2,000-pound statute and a 2,000-pound issue. Does anybody want to offer any further thoughts on that or any other issues? Closing remarks?

MR. SECOR:

Where's Pam Samuelson when you need her, right?

MR. OMAN:

You might want to ask Mr. Ficsor to comment on the other meeting that's taking place in December, 1998 at WIPO, on new methods of licensing and collective management of works in the digital age, which might touch on some of these issues.

MR. FICSOR:

WIPO Meeting on the Management of Copyright and Related Rights in the Digital Environment. We will be having a lot of meetings on a lot of issues. On Monday and Tuesday, December 15 and 16, we will hold the first session of a new Advisory Committee on the management of copyright and related rights in the digital environment, particularly on the Internet. At that meeting, we will concentrate mainly on rights management information and electronic copyright rights management systems. We have commissioned two studies for that meeting too, one from Daniel Genais, who is not here today, but who was supposed to come, and another one, from Kaoru Okamoto, who is the number one representative of Japan at the international level. The reason we have commissioned two studies is that we must cover all the existing systems and systems under development. There are many, and in competition, because many groups consider that their proprietary systems could and should be made standards at the international level. They are competing, and they are jealous. One of the reasons why we have convened this meeting is to offer a neutral forum for them to come together and to discuss their projects and try to cooperate better. But there are some categories of works which are not covered by the various systems. The Japanese government was thinking of that, and prepared a national project to establish a database and make it available for licensing purposes on the Internet. So they took care of those categories of works which are not covered by the existing copyright management systems. We also invited various experts working on these systems.

Other Upcoming Meetings at WIPO. I'd like to add that we originally wanted to convene the first session of the signatories of the two

new treaties at the end of January, 1999, but then we decided to postpone the meeting because some countries are not ready yet. In the European Community, the discussion is still on. The European Parliament hasn't taken a decision about the draft directive. We will convene that meeting later, probably in June, 1999. That meeting will probably be combined with another one, a workshop on technological measures of protection, and exceptions and limitations, and the interface between the two — many of the same issues we have discussed here today. We have already commissioned two studies for that meeting. The first study is by Victor Nathan, President of ALAI, the International Leader Artistic Association. Mr. Nathan will certainly be able to use the very rich material generated by the last series of ALAI study days that took place in Cambridge in September, 1998. The second study is by Lewis Flocles, Director of Legal Affairs of IFPI, who I understand will use input from some other experts in various industries. We will also be holding an international forum on the issues of licensing and protection of multimedia productions. There's no decision yet where and when, but next year certainly.

MR. KEEFAUVER:

I think this is a good time to inject a personal observation which, with your indulgence, I will do now. Mihály Ficsor has let it be known that he will be leaving WIPO in, unfortunately, the very near future. Although I have met him personally for the first time at this meeting, I have known of him for many years, and I have done business with him by telephone. I certainly know of his reputation in leading the development of copyright law at the international level in a very outstanding way for these many years. So Mihály, on behalf of Franklin Pierce Law Center and all of today's conference participants, I'd like to take this opportunity to wish you the very best of luck. We know we are going to continue to see you in copyright matters here or somewhere, and we look forward to that.

[Applause.]

Do you co-chairs have any closing remarks? Would you like to sum up?

MR. WILLIAMS:

I don't have anything to add other than my sincere thanks to all who came here today. I've enjoyed participating in these discussions, and hope you have too. We're all very grateful to all of you for coming and contributing.

MS. VON LEWINSKI:

I can only join Jeremy in what he said. It is really a great honor for the Law Center to have had the *crème de là crème* of copyright here — all the number ones, including the number one of copyright and WIPO, Mihály Ficsor, and the number ones of the U.S. Copyright Office, Marybeth Peters and Shira Perlmutter, as well as many other number ones. Some of you traveled a long way to be here, and each of you sacrificed your Saturday, gave your time, and made most valuable contributions. All we can offer is our thanks, and we do thank you, very much.

MR. KEEFAUVER:

Thank you, Silke. This has, I believe, been a very useful conference. I urge each of you who have opinions about the management and organization of the conference to leave your comments either with Karl Jorda or myself or to send them to him. We will certainly be planning conferences in the future, and any observations you might have would be very helpful. I too would like to thank each of you. We've had fantastic representation here from Japan, from Europe and, of course, from the United States. I'm particularly grateful that we had representatives from our own government, Marybeth and Shira. We appreciate your being with us, and our thanks go to all of you. I look forward to seeing those of you who are remaining for dinner this evening, and for all of you who are departing, I wish you a safe journey and I thank you, once again, very much, for being with us.

SPECIAL PATENT PROVISIONS FOR PHARMACEUTICALS: HAVE THEY OUTLIVED THEIR USEFULNESS?

A POLITICAL, LEGISLATIVE AND LEGAL HISTORY OF U.S. LAW AND OBSERVATIONS FOR THE FUTURE

ALFRED B. ENGELBERG*

I. INTRODUCTION

The Drug Price Competition and Patent Term Restoration Act of 1984[1] ("the '84 Act") was an unprecedented attempt to achieve two seemingly contradictory objectives, namely, 1) to make lower-costing generic copies of approved drugs more widely available and 2) to assure that there were adequate incentives to invest in the development of new drugs. According to a recent study released by the Congressional Budget

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1 Pub. L. No. 98-417, 98 Stat. 1585 (1984). At the time of its enactment, the '84 Act was commonly referred to as the "Waxman-Hatch Act." *See* F-D-C REPORTS, "THE PINK SHEET," Sept. 10, 1984. In recent years, with Republican majorities in Congress, the Act is now often called the "Hatch-Waxman Act" despite the fact that the legislation originated with Rep. Henry Waxman (D-Cal.) and was first introduced into the House of Representatives as House Bill 3605 in June, 1984. H.R. 3605, 98th Cong. (1984). Sen. Orrin Hatch (R-Utah) agreed to sponsor the Waxman bill in the Senate, and his involvement was critical to the ultimate enactment of the law.

Office[2] ("CBO"), by 1996 forty-three percent of the prescription drugs sold in the United States were generic, as compared to just nineteen percent in 1984. Moreover, substitution of generic drugs for brand-name counterparts saved consumers roughly $8 to $10 billion in 1994. Although not mentioned in the CBO study, the size and wealth of the research-based pharmaceutical industry has grown enormously since 1984. Financial publications abound with reports that sales and earnings in the industry are at record highs, and annual returns on equity and profitability continue to reach levels that far exceed the returns in other industries.[3] Most importantly, the re-investment of those profits in research, both in total dollars and as a percentage of sales, are at their highest points in history. Innovation is also being spurred by an enormous and rapidly growing federal expenditure for health-related research that now exceeds $10 billion and is headed for $20 billion per year over the next several years.

The '84 Act includes several modifications to conventional patent law including:

- Provisions allowing for the extension of the normal term of a patent for up to five years to compensate a patent owner for the marketing time allegedly lost in satisfying government regulations requiring proof that a drug is safe and effective before it can be marketed.[4]

- A novel statutory exemption from claims of patent infringement for those acts of making, using, or selling a patented invention which are reasonably related to seeking FDA approval to market a drug, provided that no commercial use of a patented invention occurs before the patent expires.[5]

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2 *How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (visited Mar. 23, 1999) <http://www.cbo.gov/showdoc.cfm?index=655&sequence=0&from=1>.

3 Since 1991 the market capitalization of the seven largest pharmaceutical companies has increased by $655 billion (536%). *Will 1999 Be As Kind to Pfizer As 1998?*, F-D-C REPORTS, "THE PINK SHEET," Jan. 11 1999, at 7.

4 *See* 35 U.S.C. § 156 (1994). In recognition of the fact that some of the lost marketing time results from necessary development effort rather than government delay, the maximum extension was limited so as not to exceed a maximum of fourteen years of market exclusivity from the date of FDA approval.

5 *See* 35 U.S.C. § 271(e)(1) (1994). This provision is commonly referred to in the United States as the *Bolar* exemption because it overruled the decision of the Court of Appeals for the Federal Circuit in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858, 221 U.S.P.Q. (BNA) 937 (Fed. Cir. 1984). Internationally, this provision is called the "safe harbor" provision.

- Special procedures for challenging the validity or infringement of drug patents which, in effect, guaranteed the patent owner a statutory preliminary injunction for a period of thirty months unless the adjudication was completed in a shorter time.[6]

- A "bounty" for challenging patent validity, infringement or enforceability in the form of 180 days of market exclusivity to the first generic applicant to file a patent challenge against any approved drug.[7]

It is tempting to conclude that these unprecedented changes in patent law were responsible for producing an economic miracle in which the explosive growth in availability of generic drugs coexists with record profits and record investment in innovation by major pharmaceutical companies. Thus, until now, Congress has avoided revisiting the '84 Act on the theory that it was a delicately balanced compromise which was working well. However, Sen. Hatch (R-Utah), a critical sponsor of the '84 Act, has now joined the chorus of voices questioning the effectiveness of one or more of the patent provisions[8] and has promised congressional action during this session of the 106th Congress. This promised legislative initiative comes at time when 1) the Canadian version of the *Bolar* exemption is under formal attack before the World Trade Organization as an alleged violation of the patent exclusivity guarantees embodied in the intellectual property agreement (TRIPs) of the Uruguay Round of the GATT Treaty and 2) the Federal Trade Commission is investigating alleged misuse of the thirty-month statutory preliminary injunction by pharmaceutical patent owners and the 180-day generic exclusivity provision by generic drug manufacturers.

Each of the patent provisions of the '84 Act was born as part of a unique legislative process which, in reality, was a congressionally supervised negotiation between the generic and brand-name pharmaceutical industries in which the parties were compelled to reach a compromise by the legislature. Not surprisingly, a combination of mutual mistrust and fears about the uncertain economic impact of making generic drugs more readily available led to the creation of a law which was inelegantly

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[6] *See* 21 U.S.C. § 355(c) (1994) & 35 U.S.C. § 271(e)(2)-(4) (1994). Collectively these provisions are commonly referred to as the "patent certification" procedures of the '84 Act.

[7] 21 U.S.C. § 355(j)(5)(B)(iv) (1994).

[8] 144 CONG. REC. S12846-03 (1998).

drafted[9] and extremely complex.[10] Over the last fourteen years, this law has created an economic boom for lawyers specializing in pharmaceutical issues who have parsed the vague language of the '84 Act and reconstructed or reinvented legislative intent in order to achieve desired economic results in particular cases.

For all of the foregoing reasons, this is a particularly appropriate moment to revisit the history of the negotiations leading to the '84 Act in order to provide a clear picture of how and why the patent provisions of the '84 Act were created, and what they were intended to accomplish. It is also the right time to examine whether these provisions are, in fact, responsible for maintaining an environment which simultaneously fosters investment in innovation and the widespread availability of generic drugs. In this author's view, such an examination leads to a rather surprising conclusion, namely, that the patent provisions of the '84 Act are not relevant to the current economic environment in the pharmaceutical industry and should be repealed.

Patent-term extensions and the *Bolar* exemption are self-canceling provisions which, taken together, have no net effect on the length of the exclusive marketing period of most new drugs. The patent certification procedures are being abused by both sides and produce no public benefit that would not otherwise occur. International differences in pharmaceutical patent law are causing the migration of pharmaceutical manufacturing to developing regions of the world where it is more difficult to maintain control over quality. There is mounting evidence that the real spurs to investment in innovation are 1) the loss of profits from old drugs which accompanies the expiration of patents and 2) the potential for earning the enormous profits which accompany the development of a new blockbuster drug that is a true advance in treating a disease and that can easily achieve sales in excess of $1 billion per year.

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[9] This was noted by U.S. Supreme Court Justice Scalia in *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 679, 15 U.S.P.Q.2d (BNA) 1121, 1130 (1990) ("No interpretation we have been able to imagine can transform § 271(e)(1) into an elegant piece of statutory draftsmanship.").

[10] *Id.* at 669, 15 U.S.P.Q.2d at 1126 (explaining that the statute's language is "not plainly comprehensible on anyone's view").

II. U.S. LAW AND DRUG DEVELOPMENT PRIOR TO 1984

A. *The Notion That A Patent Entitles Its Owner To a Guaranteed Period of Marketing Time Was Contrary To Existing Law*

Patent law does not provide a positive grant of the right to commercially exploit an invention for the life of a patent. Rather, a patentee is only granted the right to exclude others from making, using, or selling the claimed invention during the life of the patent. Whether or not the patent owner derives a commercial benefit from that exclusion is a matter that is totally divorced from the patent system. Commercial success actually depends upon a multitude of other factors including the commercial practicality of the invention, the state of development, the existence of a market and the existence of other federal and state laws which regulate the conditions under which products or services may be offered for sale. For example, since 1962 federal law has required pharmaceutical manufacturers to establish that their products are safe and effective before they can be marketed.

A patent can only be obtained if the invention described is useful.[11] Accordingly, after the food and drug laws were amended to require proof of safety and efficacy in 1962, the United States Patent Office took the position that a patent which asserted that a compound had therapeutic utility would not be granted absent proof that the compound was both safe and effective.[12] This position was quickly overruled by the Court of Customs and Patent Appeals which held that an invention could be "useful" within the meaning of the patent law even though it might not be commercially saleable under other laws.[13] The court noted that a fundamental purpose of the patent grant is to stimulate the capital investment necessary for further development and marketing of an invention.[14] Thus, for patent purposes, a compound was deemed to have utility based solely on a showing of activity in laboratory animals.[15]

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[11] 35 U.S.C. § 101 (1994).

[12] *See, e.g., In re* Hartop, 311 F.2d 249, 135 U.S.P.Q. (BNA) 419 (C.C.P.A. 1962).

[13] *In re* Anthony, 414 F.2d 1383, 1396, 162 U.S.P.Q. (BNA) 594, 605 (C.C.P.A. 1969).

[14] *Id.* at 1460, 162 U.S.P.Q. at 606.

[15] The position of the Patent Office was subsequently expressed as follows: "If there is no assertion of human utility, or if there is an assertion of animal utility, operativeness for use on standard test animals is adequate for patent purposes." U.S. PATENT AND TRADEMARK OFFICE, *Guidelines for Considering Disclosures of Utility in Drug Cases, in* MANUAL OF PATENT EXAMINING PROCEDURE § 608.01(p) (3d ed. rev. 1973).

This, of course, made it common practice to file patent applications covering potentially useful therapeutic compositions many years before anyone knew whether the drug would be safe and effective in humans. To do otherwise would have resulted in the intolerable risk that the information would become generally known and thereby preclude the grant of any patent at a later date. More importantly, the early issuance of a patent containing broad claims serves to discourage potential competitors from investing in research involving similar compounds.

These basic principles of patent law and the practices that arose pursuant to these principles made it clear that there was no legal or logical relationship between the life of a patent and the commercial life of any product claimed in a patent. This, of course, did not prevent skillful lobbyists for the pharmaceutical industry from convincing legislators who lacked a basic knowledge of patent law that government regulations requiring proof of safety and efficacy were depriving inventors of exclusive marketing time to which they were entitled as a matter of law. The argument gained easy acceptance because it was consistent with the conventional wisdom that government "red tape" is a root cause of most business problems. Moreover, disguising corporate welfare as "remedial" legislation gives legislators the opportunity to assert that they are motivated by fairness rather than the influence of political benefactors.

B. *The Weight of Legal Authority Supported the Belief That the Non-Commercial Activity Involved in Generic Drug Development During the Life of a Patent Was Not Infringement*

Under U.S. patent law prior to 1984, there was ample authority for the proposition that a party who makes and uses a patented product or process does not infringe if the use is for purposes of research or experimentation and not for profit.[16] This so-called "experimental use" doctrine is simply an extension of the equitable concept that a court will not redress a de minimus use of a patented invention. Therefore, to support a finding of infringement, the law required the alleged infringer to derive a benefit at the expense of the patentee, i.e., to encroach on the patentee's commercially valuable use of the patent.[17]

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[16] 5 DONALD S. CHISUM, CHISUM ON PATENTS § 16.03[1][a] & [b], at 16-102 to 16-109 (rel. no. 61, Mar. 1997).

[17] Kaz Mfg. Co. v. Cheesborough-Pond's, Inc., 211 F. Supp. 815, 818, 136 U.S.P.Q. (BNA) 65, 67-68 (S.D.N.Y. 1962).

It was common practice, prior to 1984, for generic drug companies to seek FDA approval to market generic versions of patented drugs before the relevant patents expired, even though it was necessary to make and use the patented invention and thus commit acts amounting to literal infringement as part of the process of seeking FDA approval. Yet there are no reported cases in which a patent owner sought to prevent such activities. To the contrary, in a 1975 case, *Hoffman-LaRoche, Inc. v. Zenith Laboratories, Inc.*,[18] involving VALIUM — then one of Roche's most commercially successful products — Roche acknowledged that it did "not seek to interfere with Zenith's legitimate activities in seeking FDA approval"[19] for VALIUM. Roche apparently did not believe that its patent gave it the right to prevent Zenith from developing a generic copy of the patented drug during the life of the patent, even though the development was solely in preparation for post-expiration competition.

In *Smith, Kline & French Laboratories v. A.H. Robins Co.*,[20] Smith, Kline & French ("SK&F"), moved to strike a claim of patent infringement, as a matter of law, on the ground that the manufacture or use of a patented drug product for the purpose of conducting tests to obtain FDA approval is an experimental use and not an infringement.[21] The SK&F motion was denied only because the court lacked evidence as to whether the FDA approval process involved any distribution of the patented drug, which, arguably, might constitute a commercial activity.[22]

The 1982 decision in *Pfizer, Inc. v. International Rectifier, Inc.*[23] is the first reported case which arguably supports the proposition that the use of a drug for purposes related to seeking FDA approval is an act of infringement that is not entitled to protection under the experimental use doctrine. In *Pfizer*, an injunction had previously been granted because the defendant was engaged in clearly commercial activities with respect to the patented drug.[24] That injunction contained broad language barring any manufacture or use of the patented drug.[25] In a subsequent action for contempt of the injunction, the defendant was unsuccessful in arguing that the injunction did not extend to activities related to seeking FDA

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18 No. 75-2221 (D.N.J filed Dec. 23, 1975).

19 *Id.*

20 61 F.R.D. 24, 181 U.S.P.Q. (BNA) 12 (E.D. Pa. 1973).

21 *Id.* at 34, 181 U.S.P.Q. at 18.

22 *Id.*

23 217 U.S.P.Q. (BNA) 157 (C.D. Cal. 1982).

24 *Id.* at 158.

25 *Id.*

approval to market the patented drug.[26] Since the *Pfizer* decision involved the literal violation of a pre-existing court order, its value as precedent on the drug development exemption was questionable.

The October, 1983 decision by the district court in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*[27] was consistent with earlier precedents and common practice. The court embraced the notion that the activities involved in seeking FDA approval to market a patented drug did no economic harm to the patent owner during the life of a patent and were exempt from a claim of infringement as a de minimus activity. In the court's view:

> the court can not find a basis for holding that Bolar's limited experimental use of flurazepam hcl [sic] would constitute infringement. First, Bolar realizes no benefit during the term of the patent; its activities are in no way connected with current manufacture or sale here or abroad. Nor do its activities lessen Roche's profits during the patent's term. Second, post-expiration delay in competition unintentionally imposed by FDA regulation is not a right or benefit granted by the patent law. This court will not act to protect the right or benefit that is without legal basis. Third, Roche can point to no substantial harm it will suffer from Bolar's FDA studies before the patent expires. Bolar's threatened activity is at best *de minimus* and will not support an action for infringement.[28]

Although an appeal of the lower court's *Bolar* decision seemed certain, on the eve of the negotiations which led to the '84 Act, the weight of judicial authority and common industry belief and practice supported the view that it was not an act of patent infringement to make or use a patented drug solely for the purpose of seeking approval to market a generic copy of the patented drug.

C. *There Was No Established Process for Approving Generic Drugs*

The 1962 amendments to the food and drug law, which required proof that a drug was safe and effective before it could be approved for marketing,[29] contained no provisions for a separate approval process for drugs which were identical to drugs which had been previously approved. Thus, a party seeking approval to market a generic version of an existing drug was compelled to file a New Drug Application ("NDA") and to

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[26] *Id.* at 162.

[27] 572 F. Supp. 255 (E.D.N.Y. 1983).

[28] *Id.* at 258.

[29] 21 U.S.C. § 355(b) (1994).

independently prove that the drug was safe and effective.[30] Many drugs were approved based on a so-called "paper" NDA in which the applicant relied upon published data concerning the safety and efficacy of the previously approved drug as the proof that its own, identical product was safe and effective. However, such data were not readily available for all approved products. Moreover, nothing in the FDA regulations prevented the Agency from requesting additional, expensive clinical studies to deal with safety or efficacy questions that may have arisen from adverse reaction reports or other published information pertaining to the approved product between the time of its approval and the time of the paper NDA filing. Often, the paper NDA applicant lacked the financial resources or expertise required to respond to such requests.

For the foregoing reasons, by the early 1980s the approval of generic versions of existing drugs was an uncertain process. The patents on many important drugs had expired or were about to expire, and the prospect of competition in the sale of those products and of inevitably lower prices for consumers was dim.

III. THE POLITICAL ENVIRONMENT LEADING TO THE '84 ACT

During the first session of the 97th Congress (1980-82) legislation was introduced in both the U.S. Senate (S. 255) and the House of Representatives (H.B. 1937) which would have provided patent-term extensions of up to seven years in duration for pharmaceutical patents in order to compensate pharmaceutical patent owners for marketing time allegedly lost due to government delays in determining that a drug was safe and effective. The Senate version of that legislation was passed, with minor amendments, in July, 1981.[31] Subsequently, in February, 1982, the House of Representatives held hearings on the issue, at which time various studies on effective patent life conducted by private sources representing the Pharmaceutical Manufacturers Association ("PMA") and by the Congressional Office of Technology Assessment were the subject of scrutiny.[32]

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30 *See generally*, Alan H. Kaplan, *Fifty Years of Drug Amendments Revisited in Easy-To-Swallow Capsule Form*, 50 FOOD & DRUG L.J. 179, 188-89 (1995).

31 Alan D. Lourie, *Patent Term Restoration*, 66 J. PAT. OFF. SOC'Y 526, 529 (1984). This article provides a comprehensive summary of the legislative events relating to the efforts to enact patent-term restoration legislation.

32 *See, e.g., Patent Term Extension and Pharmaceutical Innovation: Hearing on H.R. 1937 Before the Subcomm. On Investigations and Oversight of the Comm. on Science and Technology*, 97th Cong. (1982). A good summary of the arguments presented by the opposing sides was published in 1 HEALTH AFFAIRS (Spring, 1982).

On September 15, 1982, in the closing days of the 97th Congress, an amended version of the 1981 Senate bill, H.R. 6444, was placed before the House under an expedited procedure for non-controversial legislation which required a two-thirds majority for passage.[33] There were 250 votes in favor of passage, but the bill fell five votes short of the required two-thirds majority.[34] Rep. Henry Waxman (D-Cal.) and Rep. Albert Gore, Jr. (D-Tenn.) were credited with mustering the critical "no" votes needed to prevent passage.[35] But for their efforts, patent-term extensions for pharmaceuticals would have become the law of the land without any infringement exemption for generic drug development or any streamlined procedure for approving generic drugs.

In the 98th Congress, which commenced in January, 1983, the momentum had clearly begun to shift in favor of generic drugs. In July, 1983, Rep. Waxman, Chairman of the House Subcommittee on Health of the Committee on Energy and Commerce introduced new legislation (H.R. 3605) to reform the FDA's generic drug approval process in order to expedite approvals and stimulate competition which would lead to lower drug prices for older drugs.[36] Although the patent-term extension proposals from the previous session of Congress were also reintroduced, it was apparent that the extension proposals would go nowhere without the support of Chairman Waxman. By the Fall of 1983, the stage was set for a compromise involving a blending together of patent-term extension legislation with a new expedited FDA approval process for generic versions of previously approved drugs. By sheer coincidence, the negotiations between Rep. Waxman and representatives of the brand-name and generic drug industries began at about the same time (October, 1983) that the district court rendered its decision in *Roche*.[37]

IV. THE EVENTS LEADING TO THE ENACTMENT OF THE '84 ACT

By late January of 1984, Rep. Waxman had reached an agreement in principle with representatives of the PMA and the Generic Pharmaceutical Industry Association ("GPIA"). The agreement was based on an outline of a proposed new law which would amend the food and drug law

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33 Lourie, *supra* note 31, at 532.

34 *Id.*

35 *Id.*

36 *Id.* at 533.

37 Roche Prods., Inc. v. Bolar Pharm. Co., 572 F. Supp. 255 (E.D.N.Y. 1983).

to provide for an expedited generic drug approval process[38] and amend the patent law to provide for patent-term extensions. For the next several months, the staff of Mr. Waxman's subcommittee conducted intense negotiations on the detailed language of the proposed legislation with representatives of the GPIA and the PMA. Early on, this author, acting as patent counsel to the GPIA, urged that the proposed patent-term extension law should codify the district court decision in *Bolar*.[39] It was my contention that a reversal by the Court of Appeals for the Federal Circuit ("Federal Circuit") would amount to a two-to-three-year extension of market exclusivity for patented drugs beyond their patent expiration date thereby reducing, if not entirely eliminating, the need for any patent-term extension legislation. Fortunately, the PMA negotiators were of the view that the district court decision in *Bolar* did not change existing law and that codification of that decision merely preserved the status quo. Accordingly, the first draft of the Waxman legislation, which was released on April 4, 1984, contained Section 202 which read:

> Section 271 of title 35, United States Code, is amended by adding at the end the following:
>
> "(e) It shall not be an act of infringement to make, use or sell a patented invention solely for experimental use in connection with the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs."[40]

Although the April 4 draft left several important areas of controversy unresolved, it did not produce any immediate protest with respect to the *Bolar* exemption. Rather, the major unresolved patent controversy related to how the new ANDA procedure would function, if at all, if a generic drug manufacturer believed that a patent covering the innovator's compound was invalid or not infringed. This was a topic of major concern to pharmaceutical patent owners because most generic drug manufacturers were quite small and could not afford to pay significant damages if they were found to be liable as infringers.[41] During the next

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[38] The proposed new approval process eliminated the need for independent proof of safety and efficacy. Instead, an Abbreviated New Drug Application (ANDA) could be filed in which the applicant would prove that its product was chemically identical and bio-equivalent, i.e., that it produced comparable amounts of the active ingredient in the body.

[39] Letter from Alfred Engelberg, Patent Counsel to the GPIA, to David Beier, Counsel to the Subcomm. on Patents of the House Judiciary Comm. (Feb. 15, 1984) (on file with author).

[40] The draft was never published. A copy is on file with the author.

[41] Prior to the '84 Act, there were only a few patent infringement controversies between brand-name and generic drug manufacturers due to the difficulty of obtaining FDA approval to market a generic copy. Many of these cases resulted in

several weeks, representatives of the GPIA and the PMA hammered out a tentative agreement, which included the following key elements:

(a) If a generic manufacturer seeks approval for an ANDA and intends to challenge a patent, it would be required to notify the patent owner and NDA holder.

(b) Either party could file a declaratory judgment action at any time after notice.

(c) The patent owner would be entitled to seek a preliminary injunction. In any such proceeding, the fact that ANDA approval was being sought would satisfy the requirement for irreparable harm and the presumption of validity would be proof of the patent owner's likelihood of success. Therefore, the burden would be on the generic manufacturer to prove by clear and convincing evidence that it was likely to prevail on the ultimate merits of the case. Otherwise a preliminary injunction would be granted.

(d) No ANDA could be approved for one year in order to provide sufficient time for adjudication of a preliminary injunction motion.

(e) Damages for commercial infringement by the ANDA holder would be the lost profits of the NDA holder.

By April 24, sufficient progress had been made on the outstanding issues to cause the president of the PMA, Lewis Engman, and his outside counsel, Peter Barton Hutt, to commit themselves to "sell" the compromise to the executive committee of the PMA and to the full board, both of which were scheduled to meet later that month. At almost the same moment, the Court of Appeals for the Federal Circuit handed down its

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settlements in which the generic infringer consented to a permanent injunction on the eve of trial in exchange for a waiver of damages for past infringement, thereby assuring the generic manufacturer a profit. This was a practical solution, from the patent owner's viewpoint, since the infringer lacked the financial ability to pay any significant damage award, and the risk of a declaration that a patent was invalid was high in many jurisdictions. The simplified ANDA approval process threatened to produce greater opportunities for this type of hit-and-run infringement and was a major concern to PMA.

decision in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*[42] The Federal Circuit concluded that the ultimate commercial purpose underlying the development activities necessary to seek FDA approval for a generic drug made such activities an act of infringement. Therefore, it reversed the district court and held that the development of the data to support an ANDA could not begin until a patent expired.[43]

Not surprisingly, the unexpected *Bolar* reversal caused a major rift at the highest levels of PMA. Those representatives directly involved in the negotiations, who had previously agreed to codify the lower court's decision in *Bolar*, could not credibly withdraw from that agreement without also agreeing to a drastic reduction in the proposed length of patent term extensions. On the other hand, the CEOs of the major pharmaceutical companies quickly recognized that the proposed legislation had become a terrible bargain. In their view, the combination of: 1) the creation of an expedited generic drug approval process, 2) the *Bolar* exemption, and 3) the provisions allowing for challenges to the validity of pharmaceutical patents more than offset any possible gain which would be realized from the highly restrictive patent-term extensions which had been proposed.[44] Therefore, the major pharmaceutical patent owners believed they would be better off with no legislation of any kind. The stage was set to kill the legislation before it was even formally introduced.

On May 3, 1984, in an attempt to pressure the PMA Board of Directors to accept the compromise, Rep. Waxman and Sen. Hatch, who had by then committed to sponsor a Senate version of the Waxman draft legislation, wrote a joint letter to the PMA threatening to enact the

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[42] 733 F.2d 858, 221 U.S.P.Q. (BNA) 937 (Fed. Cir. 1984).

[43] Nothing in the court's opinion was intended to prejudice the proposed exemption to its decision that was then pending before Congress. In fact, the court went out of its way to state:

> It is the role of Congress to maximize public welfare through legislation. Congress is well aware of the economic and societal problems which the parties debate here, and has before it legislation with respect to these issues. No matter how persuasive the policy arguments are for or against these proposed bills, this court is not the proper forum to debate them. Where Congress has the clear power to enact legislation, our role is only to interpret and apply that legislation.

Id. at 865, 221 U.S.P.Q. at 942 (citations omitted).

[44] The draft legislation generally limited the availability of a patent extension to the first approval of a product and to the first patent which claimed that product. The cumbersome provisions of the proposed legislation were designed to prevent patent owners from "evergreening," i.e. using a series of related patents (divisionals, continuations) covering different aspects of the same basic product invention in combination with patent term extensions to unduly prolong the exclusive market period.

proposed ANDA approval process for generic drugs without any patent-term extension provisions unless the PMA agreed to the compromise. That letter had its intended effect. It caused a fragmented PMA to generally endorse the Waxman draft over the objection of several of its largest members. Nevertheless, the PMA continued to express strong objections to the patent challenge procedures, particularly the proposed declaratory judgment and expedited litigation procedures. The PMA also made clear that it would not support any legislation that did not provide its members with a clear opportunity to fully adjudicate a patent claim before a generic drug could be marketed.

For a brief period of time, the PMA's patent litigation demands appeared to present an insurmountable obstacle to agreement since both parties recognized that the federal courts were not compelled to either hear or expedite declaratory judgment actions. However, by mid-May, the GPIA's patent counsel had conceived and proposed a solution to the impasse that contained all of the elements relating to patent challenges that were ultimately enacted into law. The centerpiece of that solution was the creation of an "artificial" act of patent infringement, which would compel the courts to take jurisdiction. Specifically, it was proposed to create an exception to the *Bolar* infringement exemption in those instances where an applicant for an ANDA declared an intent to seek immediate FDA approval for marketing without regard to the expiration date of a patent.[45] The certification procedure contained the following elements:

- Each holder of an approved NDA would file a list of product and method-of-use patents that might be infringed if a generic drug was marketed before the patent expired. This list of patents would be published by the FDA in its list of approved products, i.e. *The Orange Book*.[46]

- An applicant filing an ANDA would be required to make a certification of its intent with respect to each listed patent. In those instances where the patent was not being challenged, the certification would state that the approval was being sought as of the expiration date of the patent. If the patent was being challenged, the ANDA applicant would certify that

[45] As enacted, the *Bolar* exemption to infringement became 35 U.S.C. § 271(e)(1) (1994) and the artificial act of infringement was codified as 35 U.S.C § 271(e)(2) (1994).

[46] 21 U.S.C. §§ 355(b)(1), 355(j)(2)(A)(vi) (1994).

it believed that the patent was invalid or would not be infringed and would request immediate approval.[47]

- If a certification challenged a patent, the ANDA applicant was required to serve a formal notice on the patent owner and NDA holder setting forth the specific grounds for the assertion.[48] The patent owner would then have forty-five days from the date of the notice to commence an action for infringement.[49]

- If a patent infringement action was commenced, the FDA was prohibited from approving the ANDA for eighteen months,[50] thereby assuring the patent owner of sufficient time to either fully adjudicate the patent issues or obtain a preliminary injunction.

In short, patent owners received statutory assurance that there would be no generic competitor on the market unless and until their patent rights were adjudicated. The generic drug manufacturers received several benefits as an inducement to accept these patent limitations, including assurances that 1) the ANDA giving rise to the patent challenge would be preserved for approval upon patent expiration even if the challenged patent was found to be valid and infringed[51] and 2) no damages could be awarded for infringement unless there were commercial acts.[52] Most important, the patent challenge compromise included a "bounty" provision that prohibited the FDA from approving a second ANDA until the earlier of 180 days after 1) the first ANDA applicant who asserted a patent challenge commenced marketing or 2) the entry of a judgment declaring the challenged patent to be invalid, not infringed or unenforceable.[53] This provision was requested by the generic drug manufacturers to insure that the successful challenger of a patent would have an opportunity to recoup its litigation costs before other generic manufacturers

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47 21 U.S.C. §§ 355(b)(2)(A), 355(j)(2)(A)(vii) (1994).

48 21 U.S.C. §§ 355(b)(3)(B), 355(j)(2)(B)(ii) (1994).

49 21 U.S.C. §§ 355(c)(3)(C), 355(j)(5)(B)(iii) (1994).

50 H.R. REP. No. 98-857, pt. 1, at 27 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2660. This time period was increased to thirty months in the final version of the Act. 21 U.S.C. §§ 355(c)(3)(C), 355(j)(5)(B)(iii) (1994).

51 21 U.S.C. §§ 355(c)(3)(C)(ii), 355(j)(5)(B)(iii)(II) (1994).

52 35 U.S.C. § 271(e)(4)(C) (1994).

53 21 U.S.C. § 355(j)(5)(B)(iv) (1994).

could take advantage of the elimination of the patent as a barrier to competition. The PMA apparently did not recognize that this provision was a significant incentive to challenge patents and, therefore, it voiced no objection to this provision.

With a compromise in place, Rep. Waxman convened an open session of the Committee on Energy and Commerce, Subcommittee on Health and Environment on June 12, 1984 and offered the compromise as a substitute for H.R. 3605.[54] The substitute bill and the Committee report pertaining thereto were published on June 21, 1984.[55] On June 12, Sen. Hatch introduced identical legislation referred to as "The Drug Price Competition and Patent Term Restoration Act of 1984" (S. 2748).

Although the proposed legislation was endorsed by the PMA, many of its larger and more influential members, including Merck, Squibb, Johnson & Johnson, Hoffman LaRoche and American Home Products, immediately formed a coalition in opposition to the legislation. In a paper released on June 16, 1984, these companies expressed strong opposition to the *Bolar* exemption, the patent certification procedures, and the restrictive rules relating to the availability of patent-term extensions. On June 25, 1984, the *New York Times* entered the fray with an editorial endorsing the Waxman-Hatch compromise and noting that the dissenting coalition stood to profit if the compromise failed to be enacted into law.[56] The battle lines were clearly drawn and the likelihood of achieving a compromise before Congress adjourned for the 1984 elections seemed slim.

The first skirmish in the battle took place on June 27, 1984 when the House Committee on the Judiciary, Subcommittee on Courts, Civil Liberties and the Administration of Justice held a hearing on H.R. 3605. These hearings and subsequent hearings and mark-ups of H.R. 3605 did not produce any significant changes in the proposed law but did provide the dissident pharmaceutical companies with an opportunity to present their objections to the legislation. The centerpiece of that opposition was the assertion that the *Bolar* exemption amounted to an unconstitutional taking of the property of a patent owner without due process of law[57] — a position that was urged by two noted constitutional scholars

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[54] H.R. 3605 had been originally introduced in 1983 to deal solely with the proposed new abbreviated drug approval process for generic drugs. *New Drug Applications: Hearings on H.R. 3605 Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 98th Cong. 4 (1983).

[55] H.R. REP. NO. 98-857, pt. 1, *reprinted in* 1984 U.S.C.C.A.N. 2647.

[56] *How Much Haven for Drug Pioneers?*, NEW YORK TIMES, June 25, 1984.

[57] H.R. REP. NO. 98-857, pt. 2, at 27-30, *reprinted in* 1984 U.S.C.C.A.N. 2686, 2711-14.

retained by the major pharmaceutical companies, Professor Norman Dorsen of NYU School of Law and Professor Larry Tribe of Harvard Law School.[58]

By early August 1984, it had become clear that no law would be enacted unless a compromise could be negotiated directly between the generic and brand-name factions. Accordingly, Sen. Hatch placed heavy pressure on representatives of the two sides to reach agreement and ultimately acted as a referee and arbitrator on the final points of disagreement. The compromise left the *Bolar* exemption intact. It did, however, make the following major changes (and several more minor changes) that benefited the brand-name drug industry:

- The elimination of many of the restrictive rules relating to patent-term extensions. Although the compromise allowed only a single patent to be extend a single time in connection with the first approval of a new chemical entity,[59] it gave the patent owner a choice as to which patent could be selected for extension.[60]

- A provision barring the FDA from approving an ANDA for thirty months (previously eighteen months) in the event of patent challenge litigation.[61]

- The addition of several exclusive marketing provisions that were not based on patents — 1) a provision barring the filing of an ANDA for five years from the time of first approval of an NDA for a new chemical entity,[62] 2) a provision prohibiting the approval of an ANDA for three years following any NDA approval for a new use or new dosage form that was based on new clinical tests[63] and 3) a provision granting two years of exclusivity for those NDAs approved between January 1, 1982 and the date of enactment that were not already

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[58] The hearings are also of historical interest because the compromise was fully supported by Lew Engman, president of the PMA, and vigorously opposed by Gerald Mossinghoff, the Commissioner of Patents. Within a year after enactment of the '84 Act, Mossinhoff replaced Engman as the president of the PMA. Many years later, Engman became the president of the GPIA.

[59] 35 U.S.C. § 156(a)(5) (1994).

[60] H.R. REP. 98-857, pt. 1, at 38 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2671.

[61] 21 U.S.C. §§ 355(c)(3)(C), 355(j)(5)(B)(iii) (1994).

[62] 21 U.S.C. §§ 355(c)(3)(D)(ii), 355(j)(5)(D)(ii) (1994).

[63] 21 U.S.C. §§ 355(c)(3)(D)(iii) & (iv), 355(j)(5)(D)(iii) & (iv) (1994).

entitled to the ten years of exclusivity accorded to NDAs for new chemical entities as part of the Act.[64]

- A provision stating that if any provision of the legislation is declared unconstitutional, the remainder of the law would survive. This provision was designed to facilitate a challenge to the *Bolar* provision on constitutional grounds.

Beyond question, the five-year non-patent exclusivity, which effectively guaranteed that every new drug would have an exclusive marketing period of about seven years (counting the usual time required to obtain approval of an ANDA) whether or not it enjoyed any patent protection was the key to the compromise. This provision assured innovators of a reasonable opportunity to recoup development costs and to make a profit irrespective of the existence of patents.[65] It did not deprive generic manufacturers of any important economic right since there is no real incentive to develop a generic drug until a market has been established and any post-approval issues of safety and efficacy have been resolved by broad use in the general population. Although some might argue that the establishment of monopoly rights outside the boundaries of the patent system is unconstitutional, the grant of such rights had already been established for pesticides as a means of compensating innovators for the disclosure of safety and efficacy data upon which generic manufacturers would subsequently (indirectly) rely in seeking marketing approval from the Environmental Protection Agency.[66]

The compromises in the summer of 1984 did not make any change in the two-year limit on patent extensions for "pipeline" drugs, i.e. drugs that were already under development. Nor was any such change actually sought by the dissident pharmaceutical manufacturers. The short-term economic needs of the brand-name drug companies were protected by a ban on the use of the abbreviated new drug application process for ten years with respect to new drugs which had been first approved between January 1, 1982 and the date of enactment of the new law. In any event, Congress "established different maximum periods of

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64 21 U.S.C. §§ 355(c)(3)(D)(v), 355(j)(5)(D)(v) (1994).

65 It is of more than passing interest that a seven-year period of market exclusivity was a key provision of the 1983 Orphan Drug Act, Pub. L. No. 97-414, 96 Stat. 2049 (1983), that sought to encourage companies to invest in the development of drugs for diseases with relatively small patient populations. 21 U.S.C. § 360cc(a) (1994).

66 *See, e.g.*, Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. § 136 et. seq. (1994); Ruckelshaus v. Monsanto Co., 463 U.S. 1315 (1983).

extension to provide greater incentive for future innovations."[67]

The incorporation of these negotiated changes into H.R. 3605 and S. 2748 led to their immediate approval by the House and Senate in September 1984. The Drug Price Competition and Patent Term Restoration Act of 1984 was signed into law by President Ronald Reagan in a Rose Garden ceremony on September 24, 1984.

V. CONTROVERSIES RELATING TO THE PATENT PROVISIONS OF THE '84 ACT AFTER 1984

A. *The* Bolar *Exemption in the Courts*

Despite the attempt by the major pharmaceutical companies to derail the '84 Act by claiming that the *Bolar* exemption was unconstitutional, the constitutionality of that provision has never been challenged. Yet there have been numerous reported cases in which the interpretation of that provision has been critical to the outcome of a controversy. Moreover, since 1984, hundreds of ANDAs have been given actual or tentative approval by the FDA prior to the expiration of a patent. Apparently, the arguments presented to Congress were merely part of an attempt to defeat the enactment of the *Bolar* exemption and were not based on a serious belief in the merit of the constitutional argument.

In any event, the United States Supreme Court has construed the *Bolar* exemption in an analysis that would appear to undermine any notion that an attack on constitutional grounds would ever have succeeded. In *Eli Lilly & Co. v. Medtronic, Inc.*,[68] the Federal Circuit held that the 35 U.S.C. § 271(e)(1) exemption for use reasonably related to the development and submission of information under federal laws regulating the manufacture, use or sale of "drugs" is not limited to drugs, but it also extends to medical devices that are subject to FDA approval. The Supreme Court granted certiorari and affirmed.[69]

In his opinion for a majority of the Court, Justice Scalia concluded that the 1984 Act "was designed to respond to two unintended distortions of the seventeen-year patent term produced by the require-

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[67] H.R. REP NO. 98-857, pt. 1 at 41 (1984). Thus, the recent claims by pipeline patent owners that they were inadvertently shortchanged by the 1984 Act and deserve additional extensions as a matter of equity is contradicted by the legislative history of the Act.

[68] 872 F.2d 402, 406, 10 U.S.P.Q.2d (BNA) 1304, 1307 (Fed. Cir. 1989).

[69] Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 679, 15 U.S.P.Q.2d (BNA) 1121, 1130 (1990).

ment that certain products must receive premarket regulatory approval."[70] Justice Scalia went on to explain, stating:

> First, the holder of a patent relating to such products would as a practical matter not be able to reap any financial rewards during the early years of the term. When an inventor makes a potentially useful discovery, he ordinarily protects it by applying for a patent at once. Thus, if the discovery relates to a product that cannot be marketed without substantial testing and regulatory approval, the "clock" on his patent term will be running even though he is not yet able to derive any profit from the invention.
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> The second distortion occurred at the other end of the patent term. In 1984, the Court of Appeals for the Federal Circuit decided that the manufacture, use, or sale of a patented invention during the term of the patent constituted an act of infringement, even if it was for the sole purpose of conducting tests and developing information necessary to apply for regulatory approval. Since that activity could not be commenced by those who planned to compete with the patentee until expiration of the entire patent term, the patentee's de facto monopoly would continue for an often substantial period until regulatory approval was obtained. In other words, the combined effect of the patent law and the premarket regulatory approval requirement was to create an effective extension of the patent term.
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> The 1984 Act sought to eliminate this distortion from both ends of the patent period. Section 201 of the Act established a patent-term extension for patents relating to certain products that were subject to lengthy regulatory delays and could not be marketed prior to regulatory approval. . . .
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> The distortion at the other end of the patent period was addressed by § 202 of the Act. That added to the provision prohibiting patent infringement the paragraph at issue here, establishing that "[I]t shall not be an act of infringement to make, use, or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." This allows competitors, prior to the expiration of a patent, to engage in otherwise infringing activities necessary to gain regulatory approval.[71]

Justice Scalia also correctly and precisely characterized the relationship between the *Bolar* exemption of 35 U.S.C. § 271(e)(1) and the new act of infringement described in 35 U.S.C. § 271(e)(2) in the following manner:

> The function of [Sections 271(e)(2) and (4)] is to define a new (and somewhat artificial) act of infringement for a very limited and technical purpose that relates only to certain drug applications. As an additional means of eliminating the de facto extension at the end of the patent term in the case of drugs, and to enable new drugs to be marketed more cheaply and quickly, § 101 of the 1984 Act amended § 505 of the FDCA, 21 U.S.C. § 355, to authorize abbreviated new drug applications (ANDAs), which would substantially shorten the time and effort needed to obtain marketing approval. An ANDA may be filed for a generic drug that is the same as a so-called "pioneer drug" previously ap-

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[70] *Id.* at 669, 15 U.S.P.Q.2d at 1126.

[71] *Id.* at 669-70, 71, 15 U.S.P.Q.2d 1126-27 (citations and footnotes omitted).

proved, or that differs from the pioneer drug in specified ways. The ANDA applicant can substitute bioequivalence data for the extensive animal and human studies of safety and effectiveness that must accompany a full new drug application. . . .

These abbreviated drug-application provisions incorporated an important new mechanism designed to guard against infringement of patents relating to pioneer drugs. Pioneer drug applicants are required to file with the FDA the number and expiration date of any patent which claims the drug that is the subject of the application, or a method of using such drug. ANDAs and paper NDAs are required to contain one of four certifications with respect to each patent named in the pioneer drug application: (1) that such patent information has not been filed, (2) that such patent has expired, (3) the date on which such patent will expire, or (4) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.

This certification is significant, in that it determines the date on which approval of an ANDA or paper NDA can be made effective, and hence the date on which commercial marketing may commence. If the applicant makes either the first or second certification, approval can be made effective immediately. If the applicant makes the third certification, approval of the application can be made effective as of the date the patent expires. If the applicant makes the fourth certification, however, the effective date must depend on the outcome of further events triggered by the Act. An applicant who makes the fourth certification is required to give notice to the holder of the patent alleged to be invalid or not infringed, stating that an application has been filed seeking approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent, and setting forth a detailed statement of the factual and legal basis for the applicant's opinion that the patent is not valid or will not be infringed. Approval of an ANDA or paper NDA containing the fourth certification may become effective immediately only if the patent owner has not initiated a lawsuit for infringement within 45 days of receiving notice of the certification. If the owner brings such a suit, then approval may not be made effective until the court rules that the patent is not infringed or until the expiration of (in general) 30 months, whichever first occurs.

This scheme will not work, of course, if the holder of the patent pertaining to the pioneer drug is disabled from establishing in court that there has been an act of infringement. And that was precisely the disability that the new § 271(e)(1) imposed, with regard to use of his patented invention only for the purpose of obtaining premarketing approval. Thus, an act of infringement had to be created for these ANDA and paper NDA proceedings. That is what is achieved by § 271(e)(2) — the creation of a highly artificial act of infringement that consists of submitting an ANDA or a paper NDA containing the fourth type of certification that is in error as to whether commercial manufacture, use, or sale of the new drug (none of which, of course, has actually occurred) violates the relevant patent. Not only is the defined act of infringement artificial, so are the specified consequences, as set forth in paragraph (e)(4). Monetary damages are permitted only if there has been "commercial manufacture, use, or sale." Quite obviously, the purpose of (e)(2) and (e)(4) is to enable the judicial adjudication upon which the ANDA and paper NDA schemes depend.[72]

[72] *Id.* at 676-78, 15 U.S.P.Q.2d 1129-30 (citations and internal quotations omitted).

Unfortunately, the language of § 271(e)(1) was not limited to activites related to seeking an approval for a generic drug, but rather broadly protected activities which are "solely" for purposes "reasonably related" to the development and submission of information under any federal law that regulates the manufacture, use or sale of drugs.[73] This broad language has been the subject of much dispute and judicial interpretation. As Chisum has noted, § 271(e)(1) is awkwardly worded and requires a two-pronged analysis to determine if an alleged activity is "solely" for uses "reasonably related" to the development and submission of information to the FDA.[74] Thus, a body of case law has developed that seeks to broaden the scope of the broad language of the *Bolar* exemption to cover situations where the alleged infringers' activities are not directly related to seeking approval for a copy of a previously approved drug.[75] A discussion of the limits of the *Bolar* exemption as it relates to research and development activities unrelated to generic drugs is beyond the scope of this article.

B. *The Impact of the* Bolar *Exemption on International Treaties and Trade*

The European Union has asserted that the *Bolar* exemption is a violation of the exclusive rights conferred on a patent owner under Article 28 of the TRIPs Agreement. This argument is totally lacking in substance and appears to represent an attempt by the multi-national pharmaceutical industry to use the European Union in an effort to

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[73] 35 U.S.C. § 271(e)(1) (1994).

[74] 5 CHISUM, *supra* note 16, § 16.03[1][d][iii], at 16-126 (rel. no. 61, Mar. 1997).

[75] *See, e.g.*, Scripps Clinic & Research Found. v. Genentech Inc., 666 F. Supp. 1379, 1396-97, 3 U.S.P.Q.2d (BNA) 1481, 1494 (N.D. Cal. 1987), *aff'd in part, rev'd in part*, 927 F.2d 1565, 18 U.S.P.Q.2d (BNA) 1001 (Fed. Cir. 1991); American Std., Inc. v. Pfizer Inc., 722 F. Supp. 86, 103, 14 U.S.P.Q.2d (BNA) 1673, 1686 (D. Del. 1989); Scripps Clinic & Research Found. v. Baxter Travenol Labs., Inc., 7 U.S.P.Q.2d (BNA) 1562, 1565 (D. Del. 1988); Telectronics Pacing Sys., Inc. v. Ventritex, Inc., 982 F.2d 1520, 1523-24, 25 U.S.P.Q.2d (BNA) 1196, 1198-99 (Fed. Cir. 1992); Ortho Pharm. Corp. v. Smith, 18 U.S.P.Q.2d (BNA) 1977, 1992 (E.D. Pa. 1990), *aff'd*, 959 F.2d 936, 22 U.S.P.Q.2d (BNA) 1119 (Fed. Cir. 1992); Intermedics, Inc. v. Ventritex, Inc. 775 F. Supp. 1269, 1277-78, 20 U.S.P.Q.2d (BNA) 1422, 1427-28 (N.D. Cal. 1991), *aff'd*, 991 F.2d 808, 26 U.S.P.Q.2d (BNA) 1524 (Fed. Cir. 1993) (unpublished table decision); NeoRx Corp. v. Immunomedics Inc., 877 F. Supp. 202, 206, 31 U.S.P.Q.2d (BNA) 1423, 1426 (D.N.J. 1994); Elan Transdermal Ltd. v. Cygnus Therapeutic Sys., 24 U.S.P.Q.2d (BNA) 1926, 1932-33 (N.D. Cal. 1992) (unpublished table decision); Abtox Inc. v. Exitron Corp., 888 F. Supp. 6, 9, 35 U.S.P.Q.2d (BNA) 1508, 1510 (D. Mass. 1995).

undermine the compromise that led to the '84 Act. Article 30 of the TRIPs agreement specifically recognizes that "Members may provide limited exceptions to the exclusive rights conferred by a patent. . . ."[76] There is ample evidence that this provision was designed and intended by the United States to preserve the *Bolar* exemption.

In a letter of March 9, 1993, while the TRIPS treaty was still being negotiated, Sen. David Pryor (D-Ark.) requested that the U.S. Trade Representative take steps to insure that the international treaties not only preserve the *Bolar* exemption but also promote its adoption by U.S. trading partners so as to enhance the availability of active ingredients required for generic drug development efforts. The PMA, which represents the multi-national pharmaceutical industry in the United States, immediately wrote to the U.S. Trade representative to oppose Senator Pryor's attempt to internationalize the *Bolar* exemption.

Referring to the draft version of Article 30 in the Dunkel text of what later became the TRIPs agreement, the president of the PMA stated:

> PMA remains troubled by the language in Article 30 in that the conditions for exceptions may be met provided that they do not "unreasonably conflict" with the normal use of the patent and "unreasonably prejudice" the patent owner's interest. There is concern that the combination of "unreasonably conflict" and "unreasonably prejudice" could be abused by some developing country governments in such a way as to go beyond Bolar-type exemptions and violate patent rights. *Nonetheless, we understand that Article 30 is included in the Dunkel text precisely to preserve the* Bolar *amendment in U.S. law. Clearly any country can also include such exemptions to its patent law if it determines them to be in their national interest.*[77]

Not surprisingly, the official Statement of Administration Action by the President of the United States, which accompanied the GATT Implementing legislation,[78] states (with respect to the scope of patent rights):

> The Agreement permits limited exceptions to the exclusive rights conferred by a patent if certain conditions are met. United States law contains some

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[76] General Agreement on Tariffs and Trade: Multilateral Trade Negotiations Final Act Embodying the Results of the Uruguay Round of Trade Negotiations, Apr. 15, 1994, 33 I.L.M. 1125, 1209.

[77] Letter from Gerald R. Mossinghoff, President, Pharmaceutical Manufacturer's Association, to Michael Kantor, United States Trade Representative 4 (Apr. 6, 1993) (emphasis added) (on file with author).

[78] MESSAGE FROM THE PRESIDENT OF THE UNITED STATES TRANSMITTING THE URUGUAY ROUND TRADE AGREEMENTS, TEXTS OF AGREEMENTS IMPLEMENTING THE BILL, STATEMENT OF ADMINISTRATIVE ACTION AND REQUIRED SUPPORTING STATEMENTS, H.R. DOC. No. 103-316, at 986 (1994).

such exceptions, such as those set out in section 271(e) of the Patent Act (35 U.S.C. 271(e)).[79]

The TRIPs Agreement was designed and intended to be a major step toward the harmonization of international intellectual property law. It is unfortunate that the multi-national pharmaceutical industry sees the process as nothing more than an opportunity to recapture the concessions it willingly made in the United States in order to get the benefit of patent-term extensions. Fortunately, neither the U.S. Trade Representative nor the U.S. Congress has shown any willingness to abandon the *Bolar* exemption based on such tactics. In any event, the *Bolar* exemption, and comparable international safe harbor provisions, appear to fall squarely within the plain language of the exemption language of Article 30 of the TRIPs agreement since they do not impinge on any significant economic interest of the patent owner. Under the circumstances, it seems highly unlikely that the European Union will ultimately succeed in its attempt to challenge national patent laws which contain such provisions.

It is becoming increasingly clear that the international business of developing and manufacturing generic drugs will soon exist only in those countries which recognize safe harbor provisions unless uniform international rules are developed. As the U.S. experience demonstrates, in the typical case, a generic drug will be approved and available for distribution on the day that patent rights expire. Moreover, as international reciprocity between health authorities becomes the norm, pre-existing FDA approval will result in expedited local approval. Therefore, unless the European Union wins its legal battle against the *Bolar* exemption or adopts safe harbor provisions, it cannot expect to maintain a viable domestic generic drug industry. Drug products developed and manufactured in safe harbor countries will clearly be on the market in European countries years before domestic counterparts can legally be developed. The economic incentives to develop generic drugs locally will ultimately disappear and so will the jobs related to such activities.

Notwithstanding the foregoing, the adoption of laws permitting generic drug development during the life of relevant patents does not guarantee domination of generic drug development and manufacturing activities in the international market place. This is due to the fact that the development of pharmaceuticals is critically dependent on the availability of the active chemical entity in a drug product. Few, if any, active pharmaceutical ingredients are manufactured by the makers of generic drugs in the United States. For many years, such active ingredients were readily available from European countries whose laws did not

[79] *Id.*

permit patents on chemical entities. In recent years, those sources have dried up due to changes in the patent laws, leaving developing nations in Asia and Eastern Europe as the primary sources for newer active ingredients. Unfortunately these sources are sometimes of questionable value due to their inability to comply with FDA quality control procedures. U.S. companies could, of course, develop active ingredients under the *Bolar* exemption but thus far have not demonstrated any significant desire to do so.

The production of raw material in Country A in aid of product development in Country B is not protected if a safe harbor exemption is narrowly drafted so as to permit only those acts carried out in pursuit of a domestic health authority registration. Thus, for example, the current U.S. *Bolar* exemption does not permit a U.S. manufacturer to produce and sell experimental quantities of a raw material to a foreign entity engaged in the development of an application to register a drug in its home country. The only exempted activities are those which relate to seeking a drug registration in the United States. Therefore, those nations which seek to dominate worldwide commerce in the manufacture and sale of both raw materials and finished drug products must enact a *Bolar* exemption which permits the making, using or selling of a patented invention for all uses reasonably related to seeking a registration in any nation and not merely a registration in their own country. Israel has recently enacted such legislation. It would provide an exemption from patent infringement for the export of research quantities of patented raw materials in aid of drug development activities in a country, such as the United States, which recognizes a *Bolar* exemption. Ultimately, in the absence of international harmonization of patent-term extension provisions and safe harbor provisions, the efforts of TRIPs to provide for a system in which patents expire more or less simultaneously around the world will be inapplicable to pharmaceutical patents. The end result is that countries, such as Israel, which permit generic drug development to begin before relevant patents expire and which also limit the length, if any, of patent-term extensions will "own" the business of developing and manufacturing generic drugs. Clearly, the intent of the laws providing for patent-term extensions was to insure the existence of adequate incentives to produce pharmaceutical innovations and not to deprive countries of viable domestic competition after those patents expire. Therefore, the time is ripe for the nations that have enacted lengthy patent-term extension provisions without safe harbor provisions to revisit those laws and find other ways of providing incentives that do not undermine the existence of a viable domestic generic drug industry.

C. *Patent Challenges and Generic Exclusivity*

No area of the '84 Act has caused more controversy than the special provisions pertaining to the enforcement of patents, i.e., the provisions of the '84 Act relating to the listing of patents claiming approved drugs, the procedures for challenging a patent, and the provision giving the first applicant to challenge a patent to a 180-day headstart in the marketplace before other ANDAs can be approved by the FDA. Largely as a result of ongoing uncertainty as to how to deal with the many new patent issues created by vague provisions in the '84 Act, it took the FDA more than ten years to enact "final" regulations.[80] It is now clear that the patent provisions of the '84 Act, particularly the provisions creating 1) a statutory thirty-month, non-adjudicated, preliminary injunction for any pharmaceutical patent listed in the *Orange Book* and 2) a 180-day period of exclusivity for the first ANDA applicant to challenge any listed patent, had many unintended consequences. A significant number of lawyers now devote their full time to the manipulation of the statutory language and regulations relating to these subjects for the purpose of creating economic benefit for individual brand-name and generic drug manufacturers – usually without regard to the question of whether any public benefit is produced.

The '84 Act required the holders of NDAs to identify all patents claiming an approved drug product or a method of using such a product as to which a claim of patent infringement might reasonably be asserted if a person not licensed by the patent owner engaged in the manufacture, use or sale of the approved drug. An applicant seeking approval for an ANDA must either wait until all listed patents expire or file a so-called "Paragraph IV" certification asserting that a listed patent is invalid, unenforceable or would not be infringed. However, if a Paragraph IV certification is filed, the patent owner can automatically keep the ANDA from being approved for thirty months merely by starting an action for infringement.[81] The purpose of that provision, as previously noted, was to create a system in which the rights of the patent holder would be adjudicated before any economically damaging competition would occur. Unfortunately, the Act naively presumed good faith on the part of patent holders in selecting the patents that would be listed. Therefore, it provided no guidance whatsoever as to what patents should or should not be listed and no mechanism for determining if a patent was properly or

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[80] Application for FDA Approval to Market a New Drug, 21 C.F.R. pt. 314 (1998).

[81] The FDA is prohibited from approving an ANDA for thirty months after litigation begins except in the unlikely event that there is a final judgment disposing of the patent in less than thirty months.

improperly listed. Moreover, the drafters of the Act failed to recognize that the automatic thirty-month injunction inadvertently created a powerful incentive for the holder of an NDA to list any and every patent related to a drug product irrespective of whether such patent was a significant barrier to legitimate competition. Thus the '84 Act automatically enables a patent owner to prevent competition irrespective of the merits of the patent being asserted and without any meaningful penalty for a wrongful assertion save for the possible award of the opposing party's legal fees. These fees are nominal as compared to the hundreds of millions of dollars in monopoly profits that can be earned during the thirty months a competitor is held off the market.

Not surprisingly, the opportunity to extend market exclusivity by merely listing a patent in the *Orange Book* has encouraged brand-name drug companies to seek, obtain, and, ultimately list a great variety of patents of little scope or merit except for their ability to delay legitimate competition. A cursory inspection of the FDA *Orange Book*'s patent and exclusivity listings will reveal that most approved products have more than one listed patent. Sometimes, there are five or six listed patents for a single product. Some of these patents claim unapproved uses, special crystalline forms of the active ingredient, specific formulations, tablet shape or other subject matter which can easily be circumvented while still producing an equivalent generic version of an approved drug. These patents nevertheless prevent competition for at least thirty months.

In those circumstances where the patent challenge is filed simultaneously with the filing of the ANDA, there would, of course, be no generic competition in any event until the FDA reviews and approves the ANDA — a process which normally consumes anywhere from nine months to two years. However, the '84 Act does not prevent an NDA holder from listing a newly acquired patent on the eve of an ANDA approval and there have been instances where a new patent first appears in the *Orange Book* shortly before the basic patent protection for an approved drug expires thereby delaying the onset of generic competition.

On its face, it would appear that the existence of so many listed patents is a major hindrance to generic drug manufacturers. Until recently, that was not the case. During the 1980s, many of the smaller generic manufacturers were relatively unsophisticated and simply accepted the patent expiration dates listed in the *Orange Book* at face value. This created an economic benefit for the more sophisticated generic companies since the cost and time involved in challenging a weak patent is insignificant as compared to the large profit windfall which results from being the first (and perhaps only) approved generic manufacturer able to compete for market share with a high-priced brand-name

product.[82] The wholesale price of a generic drug which is available from a single source is likely to be seventy percent or more of the price of the branded product. In contrast, when a generic drug is available from many sources, the wholesale price is likely to be thirty percent or less of the name-brand price. In these circumstances, all of the early challengers, in addition to the party receiving the 180-day exclusivity, gained the benefit of a smaller field of competitors and higher profit margins than would have existed if they had waited until the listed patent expired.

In recent years, the 180-day exclusivity provision has become a barrier to generic competition rather than the spur to competition which was intended by the '84 Act. Generic companies now routinely employ patent lawyers and screen every patent listed in the *Orange Book* looking for patents susceptible to attack on the ground of non-infringement or invalidity. As a result, multiple challenges to the same patent have become commonplace. Indeed, the listing of a weak patent of dubious coverage, e.g. a patent claiming a formulation, polymorph, metabolite, etc. in an attempt to extend market exclusivity after a basic chemical entity patent expires routinely provokes a challenge from several different generic companies almost simultaneously.[83] Under the '84 Act, the 180-day exclusivity belongs to the first ANDA applicant who simply files a Paragraph IV certification challenging a patent. There is absolutely nothing in the statute which requires that applicant to diligently 1) pursue a judgment with respect to the patent, 2) meet all technical requirements for approval of the ANDA, or 3) market a product once the ANDA approval is granted. Nevertheless, the Act prohibits the FDA from approving a subsequently filed ANDA until 180 days after one of two events occurs, namely, 1) the entry of a judgment declaring the challenged patent invalid, not infringed or unenforceable or 2) the actual entry into the market by the first ANDA challenger.

Experience has shown that the first ANDA applicant to file a patent challenge may never trigger the start of the 180-day period, thereby blocking the FDA from granting approval to any generic product. More often than not, the first generic challenger will enter into a lucrative cash settlement with the patent owner that results in a judgment

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[82] Indeed, in some instances, the non-infringement was so apparent that the patent holder simply succumbed to the challenge and never filed a suit for patent infringement. This was true, for example, with respect to the patents covering a particular formulation of MAXIDE, a polymorph of MINIPRESS, and a sustained release version of INDERAL.

[83] Multiple challenges are not the result of one company "free-riding" on the patent challenge commenced by a competitor. It normally takes a period of six to twelve months to develop the data required before an ANDA containing a patent challenge can be filed.

in favor of the patent and prohibits the challenger from marketing a product under its ANDA until the patent expires. Therefore, the 180-day exclusivity period never starts.[84] And no subsequently filed ANDA can be approved unless a final judgment adverse to the patent is obtained by one of the subsequent applicants.[85] But even in that circumstance, the winning party would be compelled to wait 180 days before enjoying the fruits of its victory and would not receive any exclusivity of its own. This result is dictated by the fact that, under the language of the statute, the 180 days of exclusivity belong solely to the first challenger and not to the first winner.

The likelihood that a patent challenge will result in an actual judgment that triggers the 180-day exclusive period is, in fact, very small. Of the approximately two dozen or more patent challenges filed since 1984, only a handful have resulted in an actual judgment after a full trial. These include the unsuccessful challenge involving AZT (RETROVIR), successful challenges involving cyclobenzaprine (FLEXERIL), HCT/amiloride (MODURETIC), tenormin (ATENOLOL) and ranitidine (ZANTAC), and the challenge to tamoxifen (NOVALDEX) which was settled on appeal after the district court declared the patent to be unenforceable. The vast majority of patent challenges have resulted in a settlement involving either a cash payment to the challenger in exchange for an agreement to forego the challenge or the grant of a deferred license, i.e, a license which would allow the generic challenger to begin competition on an agreed-upon date before the actual expiration of the patent, typically six months or more. In a pending case involving a sustained release version of diltiazem, the patent owner (Hoechst-Roussel) is paying the challenger (Andrx) the sum of $10 million per quarter to refrain from entering the market unless and until a final judgment is entered in pending litigation even though more than thirty months have lapsed and Andrx is free to enter the market under its approved ANDA. Despite these self-help arrangements which produce little or no public benefit, the literal language of the '84 Act appears to

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[84] This is precisely what has occurred in the case of Tamoxifen. In that case, the settlement provided Barr with the right to distribute a generically labeled version of Tamoxifen manufactured by the patent owner. Similarly, in the series of cases involving ZANTAC, the first challenger settled with Glaxo but nevertheless claimed entitlement to the 180-day exclusivity following the entry of judgment adverse to the patent in a case involving a subsequent challenger.

[85] In a pending controversy involving Hoffman LaRoche's TICLID (ticlopidine), the first ANDA filed by Torpharm has been unable to garner FDA approval and Roche elected not to sue any of the subsequent challengers. As a result, there is no possibility of any judgment and no possibility of an approved generic product unless and until the Torpharm product is approved.

grant the generic manufacturer a 180-day exclusivity period despite the existence of an agreement between the patent owner and the generic challenger which upholds the patent.

In an effort to combat the foregoing inequitable result, the FDA has sought to non-literally construe the '84 Act so that the prize of 180 days of exclusivity would only be available to the first successful litigant rather than the first challenger, i.e., the first ANDA applicant who actually obtains a judgment disposing of the patent. While this approach has some merit it would deny exclusivity to the first challenger in those circumstances where the first challenger is never sued and, therefore, acquires the right to immediate approval. This was clearly not the intent of the statute and ignores the plain language of the statute. Accordingly, a series of judicial decisions have concluded that the FDA lacks the authority to enact regulations that are contrary to the plain language of the Act.[86] In June, 1998, the FDA issued formal guidelines in which it abandons any further attempt to prevent the misuse of the 180-day exclusivity rule.[87]

In a public filing with the FDA in July, 1998, this author suggested that at least some of the unintended consequences of the misuse of the 180-day rule could be eliminated by the enactment of regulations which would require a generic challenger to amend its ANDA and withdraw the challenge as soon as any agreement is reached between the challenger and the patent owner.[88] This approach would at least insure that only a true challenger would get the benefit of the 180-day exclusivity although the benefit would only be available to the first such challenger. The FDA has not adopted this proposal, and recently granted Barr Laboratories a 180-day period of exclusivity for Tamoxifen despite its withdrawal of a patent challenge.[89]

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[86] *See, e.g.*, Mova Pharm. Corp. v. Shalala, No. 97-5082, 1998 U.S. App. LEXIS 7391 (D.C. Cir. Apr. 14, 1998); Granutec, Inc. v. Shalala, Nos. 97-1873, 97-1874, 1998 U.S. App. LEXIS 6685 (4th Cir. Apr. 3, 1998); Inwood Labs., Inc. v. Young, 723 F. Supp. 1523, 12 U.S.P.Q.2d (BNA) 1065 (D.D.C. 1989), *vacated as moot*, 43 F.3d 712 (D.C. Cir. 1989) (unpublished table decision).

[87] *See* Guidance for Industry on 180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act, 63 Fed. Reg. 37890 (1998).

[88] The FDA clearly has the authority to require applicants to amend an ANDA to insure that all statements made are truthful. A paragraph IV certification stating that a patent is believed to be invalid or non-infringed would no longer be truthful after a patent challenge is withdrawn by settlement.

[89] F-D-C REPORTS, "THE PINK SHEET," Mar. 15, 1999, at 4.

VI. THE PATENT PROVISIONS OF THE '84 ACT NO LONGER SERVE ANY USEFUL FUNCTION

Armed with fourteen years of experience under the '84 Act, there are many who now argue that it is time to revisit the issues which gave rise to its existence, examine its impact, and make adjustments. A thoughtful analysis of those questions could well lead to the conclusion that all of the special patent provisions of the '84 Act should now be repealed. This would include patent-term extensions, the *Bolar* exemption, and the special patent certification and litigation procedures.[90] A careful examination of the facts reveals that these provisions no longer contribute to the original goals of the Act, namely, increasing the availability of generic drugs or stimulating investment in innovation.

A. *The* Bolar *Exemption and Patent Term Extensions*

The controversy over safe harbor exemptions masks the underlying central question, namely: "How much marketplace exclusivity should a drug enjoy before competition is permitted?" The available evidence strongly supports the notion that patent-term extensions and the *Bolar* exemption are self-canceling, i.e., their combined effect on the length of exclusive marketing periods is negligible. In July, 1998, the Congressional Budget Office of the Congress of the United States issued a report entitled *How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry.*[91] That report concludes, inter alia: "[t]he Act's provision for extending patent terms merely compensated for the loss of the average three-year delay between patent expiration and generic entry that existed before the act (in cases where generic entry occurred)."[92]

The CBO report also concludes that "[t]he average length of time between when a brand-name drug enters the market and when its patent expires rose by more than two years – from an average of about nine

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[90] The non-patent exclusivity which prohibits the filing of an ANDA application for five years after the first approval of an NDA for a new chemical entity should be preserved. This would insure a period of about seven years of market exclusivity for a new drug, irrespective of the existence of any patents and would insure that investments would continue to be made to develop unpatentable new drugs.

[91] *How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (visited Mar. 23, 1999) <http://www.cbo.gov/showdoc.cfm?index=655&sequence=0&from=1>.

[92] *Id.*

years before 1984 to 11 to 12 years."[93] That conclusion actually grossly understates the true period of market exclusivity being enjoyed by most new drugs because it wrongly assumes that market exclusivity ends when the extended patent expires. In actuality, many drug products have more than one patent listed in the *Orange Book* and the last patent to expire is not the patent that received an extension. Moreover, an analysis of recent patent-term extensions issued by the U.S. Patent and Trademark Office shows that the vast majority of new drugs are actually receiving an extension which results in fourteen years of patent life commencing with the date of FDA approval.[94]

The situation with respect to blockbuster drugs demonstrates that brand-name drug companies know how to achieve lengthy exclusive marketing periods without government intervention when their vital economic interests are at stake. An examination of the top twenty-five selling drugs (Appendix) reveals that half of them have exclusive marketing periods greater than fourteen years without any patent extension whatsoever, and that most of them have multiple patents which will extend exclusive coverage well in excess of fourteen years. Indeed, only two products appeared to have exclusive market lives of less than fourteen years (11 and 13.5 years).

The CBO report correctly notes that "[t]he act tried to balance two competing objectives: encouraging competition from generic drugs while maintaining the incentive to invest in developing innovative drugs."[95] It has clearly done so. The CBO concludes that without the '84 Act, U.S. consumers would be paying in excess of $10 billion per year more in prescription drug costs.[96] Yet the market capitalization of the seven largest pharmaceutical companies has grown by an astounding $665 billion (536%) in the last eight years as a result of record sales and earnings.[97] More importantly, the portion of their income re-invested in research and development has never been greater. Apparently, the

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[93] *Id.*

[94] *Patent Terms Extended 35 USC § 156* (visited Mar. 23, 1999) <http://www.uspto.gov/web/offices/pac/dapp/opla/term/156.html>.
The last patent to receive a full five-year extension is U.S. patent No. 4,639,436 issued in 1987. The seventy patents issued since that date which have received extensions have been extended for less than five years, normally due to the fourteen-year cap.

[95] *How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (visited Mar. 23, 1999) <http://www.cbo.gov/showdoc.cfm?index=655&sequence=0&from=1>.

[96] *Id.*

[97] *Will 1999 Be As Kind to Pfizer As 1998?*, F-D-C REPORTS, "THE PINK SHEET," Jan. 11 1999, at 7.

swifter pace of development of new drugs more than offsets the loss of profit resulting from generic competition against older drugs. All of this is happening in an environment where, according to the CBO study, the patent-term extensions of the '84 Act have been wiped out by the *Bolar* exemption.

In short, the fear that the expedited ANDA process for approving generic drugs would undermine innovation has not materialized. To the contrary, corporate managers are acutely aware of the fact that their own financial futures are directly tied to the price of their shares and that price is determined by earnings. The precipitous drop in earnings which now accompanies the expiration of a patent on a blockbuster drug has created an environment which spurs the search for a new generation of products which begin to produce equal or greater profits as the prior patents expire.[98] In 1984, Congress believed that it was necessary to extend the life of patents in order to spur innovation. Today, a powerful case can be made for the notion that it is the looming expiration of a patent that fuels innovation. The uninterrupted growth in the sales and earnings of large pharmaceutical companies plainly supports the conclusion that the pharmaceutical industry is doing well financially and does not need additional patent-term extensions. Any such extensions would merely serve to fuel the growth of industry profits at public expense. Consumers need relief from high drug prices, and assuring generic competition at the earliest date is one way of achieving that goal. The simplest way for Congress to assure the public that pharmaceutical industry profits are the result of innovation rather than political favoritism is to eliminate the ill-advised concept of patent-term extension from U.S. patent law. No other industry enjoys such a government subsidy.

By also eliminating the *Bolar* exemption, yet another special legal privilege for pharmaceutical patents will disappear thereby taking Congress out of the business of using the patent law to regulate competition within an industry. Moreover, the elimination of these special patent law provisions for pharmaceuticals will enhance the ability of the U.S. Trade Representative to harmonize international patent law with respect to pharmaceutical patents. Such harmonization is of importance in insuring that the business of developing and manufacturing generic drugs is not limited to a handful of nations that maximize safe harbor exemptions and minimize patent-term extensions. The elimination of

[98] The current annual report of Eli Lilly & Co. states "The PROZAC patent expiration is serving as a catalyst to bring greater intensity to everything we do." The report goes on to describe the accelerated development of new products to replace the expected loss of profits from PROZAC when its patent expires in 2004. *See* F-D-C REPORTS, "THE PINK SHEET," Apr. 5, 1999, at 10.

the *Bolar* exemption is also likely to spur both innovation and competition in a manner that benefits the public. On the generic side, it will serve to encourage the swiftest possible development of a generic drug after a patent expires since those who are first to market are likely to profit the most. On the brand-name side, uncertainty as to when market exclusivity will actually end is likely to spur the development of innovative replacement products which are ready for market before generic competition for the product of a recently expired patent begins.

B. *Patent Certification and Generic Exclusivity*

Since 1984, the Federal Circuit has firmly established the principle that preliminary injunctions are available in meritorious patent cases just as they would be in any other type of case. The Federal Circuit requires an evaluation and balancing of four factors in determining whether a preliminary injunction against patent infringement should be granted in a particular case. They are: 1) reasonable likelihood of success on the merits, 2) irreparable harm, 3) the balance of hardships faced by the parties, and 4) the impact of the injunction on the public interest.[99] There is no reason why the same test should not apply to pharmaceutical patents.

A patent is presumed to be valid and the party attacking validity has the burden of proving invalidity by clear and convincing evidence. It is often presumed that infringement of a valid patent would result in irreparable harm and, in any event, doubt concerning the alleged infringer's ability to satisfy a judgment would be sufficient to prove actual irreparable harm. Therefore, if the automatic thirty-month injunction was eliminated from the '84 Act it is likely that in most closely contested cases, a preliminary injunction would still be available to the patent owner at the commencement of an action. Moreover, in those instances where the patent challenge begins when the ANDA was filed, no preliminary injunction is even necessary since there can be no commercially harmful infringement until the FDA actually approves the ANDA. That approval process normally takes at least a year, thereby leaving ample time for the parties to litigate the question of whether an injunction is warranted. Indeed, the absence of an automatic thirty-month injunction will serve to compel the parties to expedite the litigation process as a matter of mutual self-interest in getting an early definitive court ruling on the merits.

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[99] *See* Illinois Tool Works, Inc. v. Grip-Pak, Inc., 906 F.2d 679, 681, 15 U.S.P.Q.2d (BNA) 1307, 1308 (Fed. Cir. 1990).

The elimination of the automatic thirty-month injunction will do no harm to the owners of meaningful patents but will bring an end to the abuse of that provision to prevent or delay competition in non-meritorious cases. Surely, the practice of listing marginal patents and asserting them solely to delay generic competition will come to an end as soon as no benefit can be derived from that practice. In any event, there is absolutely no reason why the enforcement procedures for pharmaceutical patents should continue to differ in any respect from other patents. Unlike the situation which prevailed prior to 1984, patents are now vigorously protected by the Court of Appeals for the Federal Circuit — a court which was new and had essentially no track record in 1984; the generic drug industry has become big business and has the financial ability to pay damages for wrongful infringement, and, most importantly, fourteen years of patent litigation experience has demonstrated that the generic side prevails far more often than the patent owner when patent rights are asserted. Therefore, the public interest demands the elimination of special injunction rights for pharmaceutical patents.

It is now clear that the 180-day period of exclusivity for the first ANDA applicant merely to challenge a patent was ill-conceived. At the time it was hastily drafted and injected into the negotiations leading to the '84 Act, we foolishly believed that patent challenges would only arise in cases where the validity of a basic patent was at issue, that there was no realistic possibility that such cases could be settled, and that litigation would be expensive. We were wrong on all counts! Experience has demonstrated that a significant number of patent challenges arise from the fact that weak patents of questionable scope are commonly listed in the *Orange Book* and that generic manufacturers are now skilled at developing non-infringing products which are bio-equivalent. Moreover, a significant number of patent challenges have resulted in settlement agreements in which the potential generic manufacturer was handsomely rewarded for giving up the right to challenge a patent. Finally, even the cost and risk of patent validity challenges turned out to be far less than expected because some patent lawyers were willing to share the risks and the rewards of a patent challenge under a contingent fee arrangement. In any event, the potential profit from a successful challenge far exceeds the cost of litigation and risk can and has been minimized by careful selection of meritorious cases as well as the real possibility of settlement.

The entire purpose of the 180-day exclusivity provision, at the time it was drafted, was to insure that one generic competitor would not get a free ride on the litigation effort of another generic competitor until the party who had borne the cost and risk of litigation had a fair opportunity to recover its litigation costs. Obviously, if 1) there is no litigation or 2) the litigation does not produce a judgment that would

inure to the benefit of other generic manufacturers, there can be no free ride and, therefore, no reason to grant the exclusivity reward. Therefore, the FDA was theoretically correct in attempting to limit the exclusivity reward to a successful litigant who actually obtains a judgment which is adverse to the patent owner. That approach would at least prevent those parties who have settled litigation from reaping where they have not sown. But the remedy contrived by the FDA does not go far enough. The agency (and others) have failed to recognize that a judgment that a patent is not infringed (or, conversely, that it is infringed) does not inure to the benefit (or detriment) of anyone other than the defendant in that case. It is a fact-based decision that involves a comparison between the challenger's product and the claims of the patent. Thus, for example, one generic manufacturer's sustained-release product or polymorph may be made by using a technology which is vastly different from that of another generic manufacturer such that one product infringes a patent and the other does not. Therefore, there is no reason in logic or law that the fate of one party may be held hostage to that of another party, irrespective of the order in which the challenges were filed. Indeed, in the extreme case, the patent owner could elect to sue the first challenger for infringement and forego a suit against the second challenger based solely upon differences between the two generic products that spell the difference between infringement and non-infringement. In short, the 180-day exclusivity rule should not apply in cases based on a judgment of non-infringement since the challenger produces a result which only benefits itself.

For similar reasons, no exclusivity benefit should be granted to the detriment of an ANDA applicant who filed a patent challenge but was never sued by the patent holder. In those cases where the patent owner, for whatever reason, fails to assert its rights against a legitimate challenger, it defies logic to assert that such a challenger's ANDA should be held hostage to litigation involving an earlier-filed ANDA. If the patent owner does not object to the approval, there is no free ride and no basis for a claim that the prior challenge produced any benefit that would support exclusivity as against the subsequent challenger.

Given the foregoing limitations, there remains only the question of whether a party who procures a judgment that a patent is invalid or unenforceable, i.e., a judgment which would prevent the patent owner from thereafter asserting the patent against anyone, is entitled to the exclusivity reward. The answer is unclear and depends on the circumstances. If there is more than one party challenging a patent on the ground of invalidity or unenforceability, it can not be said that a case of free-riding exists. There may also be cases where the first challenger is the last to judgment and vice-versa. Alternatively, it is possible that

independent challenges to the same patent will be consolidated under procedural rules thereby resulting in simultaneous judgments. In short, there are few, if any, conceivable circumstances in which the failure to award exclusivity to a successful patent challenger would be grossly unfair to the challenger. More importantly, it seems highly unlikely that the elimination of the 180-day provision would actually discourage generic manufacturers from engaging in patent challenges.

It is now reasonably clear that the 180-day rule has been abused and produces no real public benefit that would not occur in its absence. Indeed, in would be difficult to identify a single actual case in the last fifteen years in which an unfairness or hardship would have been visited on a patent challenger by virtue of the unavailability of the 180-day exclusivity. On the other hand, many cases can be identified where the existence of the exclusivity either made no difference whatsoever or actually delayed generic competition. Ultimately, the decision to challenge a patent is a business decision which the government should not directly or indirectly encourage or discourage. Therefore, it is time to repeal this provision.

VII. CONCLUSION

Given the experience of the last fourteen years and the available data, the announced plan of Congress to revisit the provisions of the '84 Act presents an ideal opportunity for deregulation. The evidence is clear that the patent-related provisions of the '84 Act are no longer necessary to achieve the policy of fostering innovation while insuring public access to older drugs at competitive prices. The elimination of patent-term extensions, the *Bolar* exemption and the special procedural barriers to challenging patents that are invalid or not infringed will make it easier to achieve international harmonization and allow the marketplace to achieve maximum efficiency.

APPENDIX

This Appendix collects information on the patent extensions granted to various blockbuster drugs under the Drug Price Competition and Patent Term Restoration Act of 1984. The information is organized in descending order of sales volume, by dollar value. The first line in each entry lists the BRAND NAME, the generic name, and the dollar value of 1997 sales. The second line lists the initial date of FDA approval, the length of the extension, the extended patent's expiration date, the minimum period of exclusivity, the last listed patent's expiration date, and the actual period of exclusivity based on the last listed patent's expiration date.

BRAND NAME/Generic name		1997 Sales
Approved, extension	Ext.Pat.Expires (Min.Excl.)	Last Pat.Expires. (Actual Excl.)
PRILOSEC/Omniprazole		$2.3 billion
9-14-89, 2 yrs.	4-5-01 (11.5 yrs.)	4-20-07 (17.5 yrs.)
PROZAC/Fluoxetine		$1.95 billion
12-29-87, 2 yrs.	12-2-03 (14.9 yrs.)	12-2-03 (14.9 yrs.)
ZOCOR/Simvastatin		$1.38 billion
12-23-91, 1704 days	12-25-05 (14 yrs.)	12-24-05 (14 yrs.)
ZOLOFT/Sertaline		$1.2 billion
12-30-91, none	n/a (n/a)	8-13-12 (20.7 yrs.)
ZANTAC/Ranitidine		$1.1 billion
6-9-83, none	n/a (n/a)	7-25-97 (14 yrs.
PAXIL/Paroxetene		$950 million
12-29-92, 67 days	9-24-08 (15.8 yrs.)	9-24-08 (15.8 yrs.)
NORVASC/Amlodipine		$920 million
7-31-92, 1252 days	8-1-06 (14 yrs.)	3-25-07 (15.7 yrs.)
CLARITIN D/Loratidine		$910 million
4-12-93, 2 yrs.	6-19-02 (9.2 yrs.)	4-21-04 (11 yrs.)

VASOTEC/Enalapril $840 million
12-24-85, none n/a (n/a) 2-22-00 (14 yrs.)

IMITREX/Sumitripatin $790 million
12-28-92, 275 days 12-28-06 (13.7 yrs.) 8-6-08 (15.5 yrs.)

PROCARDIA XL/Nifedipine $780 million
9-6-89, none n/a (n/a) 11-23-10 (21.2 yrs.)

PRAVOCHOL/Pravastatin $770 million
10-31-91, 1598 days 10-20-05 (14 yrs.) 7-9-08 (16.7 yrs.)

BIAXIN/Clarithromycin $740 million
10-31-91, 1465 days 5-24-05 (13.5 yrs.) 5-24-05 (13.5 yrs.)

LUPRON/Leuprolide $710 million
1-26-89, none n/a (n/a) 7-1-14 (25 yrs.)

CIPRO/Ciprofloxin $710 million
10-22-87, none n/a (n/a) 1-15-11 (13.5 yrs.)

CARDIZEM CD/Diltiazem $700 million
12-27-91, none n/a (n/a) 8-8-12 (20.6 yrs.)

PEPCID/Famotidine $700 million
11-15-86, 293 days 10-15-01 (14 yrs.) 10-15-01 (14 yrs.)

PREVACID/Lansoprazole $670 million
5-10-95, 1381 days 5-10-09 (14 yrs.) 5-10-09 (14 yrs.)

MEVACOR/Lovastatin $650 million
8-31-87, 2 yrs. 6-15-01 (13.8 yrs.) 6-15-01 (13.8 yrs.)

RISPERDAL/Risperidone $620 million
12-29-93, 681 days 12-29-07 (14 yrs.) 12-29-07 (14 yrs.)

LIPITOR/Atorvastatin $580 million
12-17-96, none n/a (n/a) 11-11-14 (17.9 yrs.)

ZYPREXA/Olanzapine $580 million
9-30-96, none n/a (n/a) 2-25-14 (16.4 yrs.)

TAXOL/Paclitaxel		$570 million
12-29-92, none	n/a (n/a)	8-3-12 (19.7 yrs.)
GLUCOPHAGE/Metformin		$510 million
3-3-95, none	n/a (n/a)	? (?)
ZESTRIL/Lisinopril		$470 million
5-19-88, none	n/a (n/a)	12-30-01 (13.6 yrs.)

PUBLISHERS' RIGHTS AND WRONGS IN THE CYBERAGE

THOMAS G. FIELD, JR.*

In 1994, William S. Strong said at a meeting of the Association of American University Presses: "I have heard Chicken Littles say that the sky is falling . . . . in the tones once reserved for statements that God is dead."[1] He also observed that much nonsense comes out of the university community and stressed that publishers need to educate the public about the functions of copyright. Yet, more than education may be required.

Just last September, Lisa Guernsey reported that Steven Koonin, Provost at Caltech, would prefer that Caltech's professors retain copyrights and license publishers: "What's more, he said, controlling the copyrights could give Caltech faculty members — or larger groups of researchers — the chance to vet and distribute research results on line by themselves, bypassing traditional publishers altogether. At first, Mr. Koonin says, 'it was something of a joke.'"[2]

Few publishers are likely to laugh. Guernsey went on to say: "Already, journal publishers are feeling the ground shift beneath them as the Internet takes over one of their main roles: the timely distribution of written works. Compared with the speed of the Net, the months-long process of putting out a journal seems tedious."[3]

Still, Strong had explained why bypassing publishers would not be helpful: "Already most of us feel so inundated by random information that we despair of ever managing to know even the essentials of what we

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* Professor, Franklin Pierce Law Center. Prof. Field has been a prolific contributor to IDEA since 1975. His contributions include *Ovarian Epic: A Comment on 35 U.S.C. § 103*, 17 IDEA 102 (1975), probably the only poem ever published in IDEA.

1 William S. Strong, *Copyright in the New World of Electronic Publishing*, J. ELEC. PUBL'G (visited Mar. 19, 1999) <http://www.press.umich.edu/jep/works/strong.copyright.html>. These remarks were initially presented at the workshop "Electronic Publishing Issues II," at the annual meeting of the Association of American University Presses, June 17, 1994, in Washington D.C.

2 Lisa Guernsey, *A Provost Challenges his Faculty to Keep Copyright on Journal Articles*, CHRON. HIGHER EDUC., Sept. 18, 1998, at A29.

3 *Id.*

must know. Good publishers, by screening this information for quality and validating it . . . perform an enormous service."[4]

The debate now extends outside academia. For example, the *Atlantic Monthly* recently sponsored an online roundtable[5] based on the article, *Who Will Own Your Next Good Idea?*[6] Paraphrasing and responding to John Perry Barlow's argument "that in the long run the drop in costs spells the end of the 'moribund' publishing industry and the beginning of direct artist-to-public contact," Charles Mann said, in part: "According to . . . [some] e-pundits, the situation will be remedied by new services that truckle through the Net for worthy works and help present them to the attention of the public."[7] Yet, he found differences between such scenarios and traditional publishing "elusive."[8] I am equally baffled.

That writers increasingly can publish whatever and whenever they desire, signifies little in terms of capturing an audience. Who can find, much less is inclined to read, books from "vanity" presses that will publish anything at cost? Beyond that, academic and professional works in many fields receive little if any recognition without peer review. Such review is often critical. It not only has a major role in tenure decisions but also may determine the courtroom admissibility of evidence based on scientific research.[9]

Still, unless works are created in the course of employment[10] or, say, as components of much larger works,[11] authors hold copyright. Why should they give up one iota more than absolutely necessary to be published? The short answer is that authors' refusing to transfer all rights to publishers, at best, leads to wasted time and money. When publishers hold copyright, a single registration protects an entire composite work.

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4 Strong, *supra* note 1.

5 (visited Mar. 19, 1999) <http://theatlantic.com/unbound/forum/copyright/intro.htm>.

6 Charles C. Mann, *Who Will Own your Next Good Idea?*, ATLANTIC MONTHLY, Sept. 1998, at 57 (visited Mar. 19, 1999) <http://theatlantic.com/issues/98sep/copy.htm>). There is, of course, a serious problem with the title of Mann's article, insofar as copyright does not protect ideas, *see* 17 U.S.C. § 102(b) (1994).

7 Round two of three online exchanges (visited Mar. 19, 1999) <http://theatlantic.com/unbound/forum/copyright/mann2.htm>.

8 *Id.*

9 *See* Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 593-94, 27 U.S.P.Q.2d (BNA) 1200, 1206 (1993); *see also* General Elec. Co. v. Joiner, 522 U.S. 136, 145-46 (1997) (discussing the appropriate standard of appellate review for district court rulings on the admissibility of published scientific studies).

10 *See* 17 U.S.C. § 101 (1994) ("work made for hire").

11 *Id.*, ¶ (2) of the definition of "work made for hire."

Individual writers are, thus, spared the need to register separately — something most wouldn't do anyway. Also, registration — particularly prompt registration — confers benefits that are foolish to ignore.[12]

Although some argue that copyright is meaningless when digital piracy is so easy,[13] there is evidence that the public respects such rights — particularly when their function is understood. A *Boston Globe* poll, conducted shortly before Strong's, talk showed that most people regard unauthorized copying as wrong.[14]

Further, at least with regard to text and named works, it is often as easy to *catch* pirates as it for them to *be* pirates.[15] If that weren't enough, under the recent NET Act,[16] even noncommercial infringement, if willful, may be criminal.[17]

That copyrights retain vitality in the cyberage and that publishers should hold them at the time of first publication, however, does not dispose of the question of who should hold them later. After registration, rights can be transferred back. Publishers may give authors such an option, retaining, for example, rights only to reprint back volumes or

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[12] *See* 17 U.S.C. § 412 (1994) (prompt registration is a prerequisite to statutory damages and attorney fees).

[13] This situation was responsible for the No Electronic Theft ("NET") Act, Pub. L. No. 105-147, 111 Stat. 2678 (1997), and partly responsible for the Digital Millennium Copyright Act ("DMCA"), Pub. Law No. 105-304, 112 Stat. 2860 (1998). The former is discussed briefly, *infra*; the latter added § 1201 ("Circumvention of copyright protection systems") to the Copyright Act. It is interesting to note that Congress was in such a rush at the rend of 1998 that both the DMCA *and* the Fairness in Music Licensing Act, Pub. L. 105-298, 112 Stat 2827, 2831, added a different, new § 512 to Title 17 of the U.S. Code. *See* UNFAIR COMPETITION, TRADEMARK, COPYRIGHT AND PATENT: SELECTED STATUTES AND INTERNATIONAL AGREEMENTS 241-242.10 (Paul Goldstein et al, eds. 1999).

[14] Strong, *supra* note 1. As described by Strong, the poll seems to have been conducted as a result of events leading up to United States v. LaMacchia, 871 F. Supp. 535, 33 U.S.P.Q.2d (BNA) 1978 (D. Mass. 1994).

[15] This may be accomplished by using, for example, Alta Vista (a web-based search engine) <http://www.altavista.com/>. *See also* Eliot Marshall, *The Internet: A Powerful Tool for Plagiarism Sleuths*, 279 SCIENCE 474 (1998) (discussing an algorithm that is particularly helpful where more than direct copying is involved).

[16] The NET Act was primarily sparked by the blatant instance of non-commercial piracy addressed in *LaMacchia*, 871 F. Supp. 535, 33 U.S.P.Q.2d 1978. The NET Act is codified in several sections of Titles 17 and 18 of the U.S. Code. *See* H.R. REP. NO. 105-339 (1997) (visited Mar. 19, 1999) <http://thomas.loc.gov/cgi-bin/cpquery/R?cp105:FLD010:@1(hr339):>.

[17] NET Act § 2(b), *amending* 17 U.S.C. § 506(a).

authorize inclusion in online databases such as Westlaw.[18] Yet, writers who have the option of taking most of their rights back should rarely exercise that right.[19]

With the possible exception of those who earn their living from writing as such,[20] authors benefit most from the widest possible dissemination of their work. To the extent that academic or professional journals keep copyright, this is facilitated. Those who wish to reproduce, say, for classroom use or inclusion in anthologies are more apt to approach publishers. To the extent that copyright is held by easily-found publishers, both dissemination of works and respect for copyright are fostered — and writers are spared much bother. In a related context, Laura N. Gasaway has aptly observed that "[c]opyright holders need to simplify the permissions process for use of their material . . . for both nonprofit and for-profit users. Until this is done, the temptation to use the work without permission will remain strong."[21]

Further, publishers should not keep rights beyond those required for economic viability. More attention must be given to this: Sometimes reproduction is as likely to generate publicity and encourage submissions as to interfere with cost recoupment. For example, the editor of the *New England Journal of Medicine* is quoted as saying "We allow authors to freely use their material — with no charge, no penalty, nothing" for paper copies.[22] However, he apparently restricts web access to paid subscribers.[23] Why is that important? Are randomly distributed copies linked to curriculum vitae or course pages, for example, likely to erode sales of printed copies or paid access to the full contents of any given journal? It seems doubtful.

Such basic issues seem repeatedly to be ignored. As even more recently described in *Science*, a blue ribbon panel has proposed that, insofar as no copyright exists in works of federal employees, copyright in articles describing work done under federal grants should be retained by their authors.[24] How one leads to the other is difficult to see, and how

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18 *See, e.g.*, Publication Permission Form for *Risk: Health, Safety & Environment*, (visited Mar. 19, 1999) <http://www.fplc.edu/tfield/RskPerm.htm>.

19 In nearly ten years, no one who has published in *Risk* has asked for a return of rights.

20 *See, e.g.*, Tasini v. New York Times Co., 972 F. Supp. 804, 43 U.S.P.Q.2d (BNA) 1801 (S.D.N.Y. 1997).

21 *Distance Learning and Copyright in the For-Profit Environment*, IPFRONTLINE, Oct. 1998, *online at* <http://www.ip.com/ipFrontline/issues/currentguest_col.htm>.

22 Guernsey, *supra* note 2.

23 *Id.*

24 Steven Bachrach et al., *Who Should Own Scientific Papers?*, 281 SCIENCE 1459 (1998).

this would serve the committee's apparent aim of facilitating dissemination is even less clear. Yet, an accompanying editorial[25] that largely rejected the committee's proposal did no better in identifying or addressing core issues.

It would seem that publishers' charging universities to photocopy their own faculties' work is sparking needless controversy. Publishers who impose unnecessary restrictions on academics or their employers do themselves and others a disservice. It is difficult to imagine why authors, particularly ones who aren't paid, should not usually have a royalty-free license to copy for students and colleagues in hard copy or on the web. Those who fail to accord such rights without good, clearly stated, reasons seem ever more likely to disrupt a scheme that has heretofore benefited authors, the public and publishers alike.

[25] Floyd E. Bloom, *The Rightness of Copyright*, 281 SCIENCE 1451 (1998).

FRANKLIN PIERCE LAW CENTER IN THE IP SPOTLIGHT

U.S. News and World Report

For the third year in a row, *U.S. News and World Report* has named Franklin Pierce Law Center as the top law school in the country for the study of intellectual property law. FPLC shares the top spot in the 1999 survey with the University of California at Berkeley. This ranking appears in the magazine's special publication, *America's Best Graduate Schools*. Franklin Pierce Law Center has been rated among the top five intellectual property law schools ever since the survey began.

Saul Lefkowitz Trademark Moot Court Competition

Teams from Franklin Pierce Law Center had a big impact on the 1999 Saul Lefkowitz Trademark Moot Court Competition, sponsored by the Brand Names Educational Foundation. At the Eastern Regionals, Jim Laboe ('00) and Gina McCool ('00) won the award for Best Brief and finished third overall, while Molly McPartlin ('00) and Steve Zemanick ('00) were named Best Oralist Team and finished first in the region. At the National Finals, competing against teams from Hastings, DePaul, and the University of Southern Mississippi, McPartlin and Zemanick finished second overall and won the award for Second Best Oralist Team. In addition, Lebeau's and McCool's brief was named best in the nation. Both teams were coached by Professor Susan Richey, with the assistance of Dana Metes ('99), who last year, along with partner Andrew Klungness ('99), finished second in the 1998 Eastern Regionals and won the award for Best Oralist Team. One of the bailiffs at the 1999 National Finals was FPLC graduate Jim Calkins ('98), a two-time national champion in the Giles Sutherland Rich Moot Court Competition and currently a law clerk for Judge Rich of the CAFC.