

PANEL I: Do Overly Broad Patents Lead to Restrictions on Innovation and Competition?

Moderator: John Richards*
Panelists: Matthew Bye†
Mary Critharis‡
David Balto§
Herbert Schwartz||

MR. RICHARDS: Thank you, Dean Treanor.

Our first panel this morning is looking at the question of whether overly broad patents promote or harm innovation. We have as our first speaker Mary Critharis from the Patent Office; then Matthew Bye from the FTC; then two speakers from private practice, David Balto, who is an antitrust lawyer, and Herb Schwartz, who is probably the senior performing patent person in the City nowadays, right Herb?

MR. SCHWARTZ: If you say so, yes.

MR. RICHARDS: I think you probably are.

They will give both sides of this issue.

We just celebrated the centenary of the events at Kitty Hawk, the first heavier-than-air flight. Had the Wright brothers secured a patent covering any heavier-than-air machine, which they did

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not—if you look at their patents,¹ they’re really directed to the nuts and bolts of the aircraft—then would that have affected the way in which aeronautic development took place in the first part of the 20th century?

Today, we have a situation in the biotech area, where some very basic and very broad patents are being granted and both sides of the question argue very strongly that they are appropriate because this is the contribution that people have made. They made a very broad fundamental step forward; and the competition of course says, “This is stopping us from doing everything; you’re going to have to pay license fees to everybody; it’s going to make it prohibitive to make further innovation”—and that really, I think, is where the nub of the question lies.

The Federal Trade Commission (“FTC”) had a report come out approximately a year ago,² which has caused a lot of debate and concern and interest, and the Patent Trade Organization (“PTO”) has started to respond to that.

Our first speaker this morning is Mary Critharis from the PTO. Ms. Critharis is an attorney with the Office of International Relations at the US-PTO at the moment. She was previously an examiner, she is, by training, a chemist, and she will say more about herself if she wishes to. Thank you.

MS. CRITHARIS: Technical issues.

MR. BALTO: This is the first time, by the way, for everybody to see that the FTC and PTO do know how to communicate.

MS. CRITHARIS: First, I want to thank the organizers of the conference, the *Journal*. This brings back a lot of memories—some good, some not so good—from days of organizing the symposiums when I was in law school, which was a very long time ago.

¹ See U.S. Patent No. 821,393 (issued May 22, 1906), available at <http://invention.psychology.msstate.edu/i/Wrights/WrightUSPatent/WrightPatent.html> (last visited May 7, 2005).

² FEDERAL TRADE COMM’N [“FTC”], TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY (Oct. 28, 2003) [hereinafter FTC REPORT], available at <http://www.ftc.gov/os/2003/10/innovationrpt.pdf> (last visited May 7, 2005).

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I'm going to talk a little bit in this initial presentation about what the policies and practices are at the US-PTO. I think that will give us a framework for some of the later discussions.

[Slide] First, I just wanted to explain that we have seven technology centers and that's how we are organized.³ Most of the ones that we will be talking about today will be in the biotech group; then there's the chemical group; there's a computer group—that's Group 2100 where a lot of the business method patents and the Internet-related patents are examined; there's a communication group; there is a hardware-semiconductors group; and there's a group on transportation and mechanical engineering.⁴

Overall, we have over 3,500 patent examiners.⁵ To date, because this is a little old, we have hired some more examiners. So we have approximately 3,700 examiners.⁶

[Slide] Each technology center is divided up into different art units. The art units have a very specific docket where they examine cases. For example in the biotech art unit you may have a unit that just does gene therapy patents. So you can see where it's very specialized. You may have in the telecommunications art unit just printers or something of that nature.

In that art unit there are about thirteen to eighteen examiners, depending on the need for technology, that examine that very specific area, with a supervisor in that group.

[Slide] Generally, the patent examination process is a back-and-forth with the applicant and the examiner. The application is submitted to the office, and a lot of times there are claims which define the scope of the invention that are presented with the application.

³ See *Patent Technology Centers*, at <http://www.uspto.gov/web/info/pat-tech.htm> (last visited May 7, 2005).

⁴ See *id.*

⁵ See Press Release, United States Patent and Trademark Office [hereinafter "USPTO"], Agreement Reached on Patent Telework Program (Jan. 30, 2003), available at <http://www.uspto.gov/web/offices/com/speeches/03-02.htm>.

⁶ USPTO, PERFORMANCE AND ACCOUNTABILITY REPORT FISCAL YEAR 2004, at 12 (Nov. 8, 2004) [hereinafter "USPTO REPORT"], available at <http://www.uspto.gov/web/offices/com/annual/2004/2004annualreport.pdf>.

Usually what happens is there is a back-and-forth. The examiner might find some prior art. The applicant may then try to amend his claims. A lot of times applicants do come in with fairly broad claims, and then they narrow their scope of protection because the examiner has found certain references or certain disclosures that may not make it patentable.⁷

[Slide] What I'd like to do is discuss some of the patent examination criteria today.

I just wanted to give you another statistic, the number of filings. We had over 350,000 filings in fiscal year 2004,⁸ and that was 6 percent above fiscal year 2003.⁹ So we had a little dip where in 2003 there wasn't much growth,¹⁰ but applications have been growing on average from 5-to-10 percent over the years, and we, I think, predict another 5 percent increase in fiscal year 2005.

Of those applications that are filed—and this is preliminary because our fiscal year just ended and so the data is not exactly accurate—but roughly 170,000 applications are issued.¹¹ But I do want to point out that even though that looks like a very high number, this is not just applications that issue from the first application. A lot of times continuation applications are filed, divisional applications, continuation part type applications. These are new applications that are based from old prosecution, of old cases that have been filed a couple of years ago.

[Slide] The basis for examination and for protection in the United States comes from the Constitution. Section 8 says: Congress shall have power “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and

⁷ See USPTO, Frequently Asked Questions, available at <http://www.uspto.gov/web/offices/dcom/bpai/bpaifaq.htm> (last visited May 15, 2005).

⁸ See USPTO REPORT, *supra* note 6, at 17.

⁹ See *id.*

¹⁰ See generally *U.S. Patent Statistics Chart, Calendar Years 1963 – 2003* (showing a 2.6% increase in patent applications between 2002 and 2003), at http://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm (last modified Aug. 31, 2004).

¹¹ See USPTO REPORT, *supra* note 6, at 17 (reporting that the actual number was 170,637).

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Inventors the exclusive Right to their respective Writings and Discoveries.”¹²

Since 1790, we have always had a patent statute.¹³ The most recent amendment to the patent statute, the Patent Act, was in 1952.¹⁴

[Slide] These are the statutory requirements that I am going to talk about today. There are some other ones, but I think these are the ones that are germane to the discussions that have been set forth by the FTC in their review, so I think we’ll focus on these.

- There is Section 101, which talks about subject matter, what is eligible for protection, and also utility.¹⁵

- Then there is Section 102, which talks about novelty.¹⁶ We use the word “anticipation” in the patent law. This really means that something is new.¹⁷

- Then there is Section 103, which talks about, even if it’s new, was it obvious to somebody to have derived that invention.¹⁸

[Slide] So the first thing is patentable subject matter. Section 101 grants protection to those inventions that are new and useful.¹⁹ They have to be either a process, a machine, a manufacture or composition of matter, or any improvement thereof. That really is two different categories: we have processes; and machines, manufacture, and composition of matter are products. So we have

¹² U.S. CONST. art. I, § 8, cl.8.

¹³ Patent Act of 1790, ch. 7, 1 Stat. 109–12 (repealed 1793).

¹⁴ Pub. L. No. 82-593, ch. 950, 66 Stat. 792 (codified as amended in scattered sections of 35 U.S.C. (2000)).

¹⁵ 35 U.S.C. § 101 (2000).

¹⁶ 35 U.S.C. § 102 (2000).

¹⁷ See, e.g., *In re Bergstrom*, 427 F.2d 1394, 1401 (C.C.P.A. 1970) (holding that the definition of “new” within patent law should be construed in accordance with the provisions of § 102).

¹⁸ 35 U.S.C. § 103 (2000).

¹⁹ 35 U.S.C. § 101 (2000) (“Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title”).

process patents and product patents.²⁰ Those are very important because they offer different types of protection.

Generally, though, this is a very broad statement of what is eligible for patent protection. A lot of other countries have a lot of different exclusions in their law.²¹ We do not have any other exclusions in our law. Our law sets forth that any new product or process is eligible for protection.²²

That is why Congress has said that anything under the sun made by the hand of man is eligible for patent protection.²³

[Slide] The Supreme Court, though, has articulated three categories of subject matter that are not patentable.²⁴ These are laws of nature, natural phenomena, and abstract ideas.²⁵ These are things that really do not meet the criteria of invention because these things were out there all along; nobody really invented something. These are laws of nature, whether it be gravity, just some abstract idea, natural phenomena, naturally occurring products such as a plant—you can't patent that because it exists; you didn't really do anything.

So the key is intervention by man, man actually doing something with the laws of nature. Applying electricity or taking something from a plant and processing it, that application may be patented, but the idea itself, these abstract ideas, are clearly not patentable.

[Slide] One of the important areas that was briefly touched upon in the introduction is biotech inventions. For a long time, the

²⁰ See generally *id.* (stating that an inventor may obtain a patent on “any new and useful process, machine, manufacture, or composition of matter . . .”)

²¹ See, e.g., Alison Butler, *The Trade-Related Aspects of Intellectual Property Rights: What's at Stake*, 72 FED. RES. BANK OF ST. LOUIS REV., No. 6, 34, 36–37 (1990), available at http://research.stlouisfed.org/publications/review/90/11/Intellectual_Nov_Dec1990.pdf (last visited May 8, 2005) (differentiating the types of patent exclusions in industrialized and developing countries by different patentability categories).

²² See 35 U.S.C. § 101 (2000).

²³ *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (quoting S. Rep. No. 82-1979, at 5 (1952); H.R. Rep. No. 82-1923, at 6 (1952)).

²⁴ See *Diamond v. Diehr*, 450 U.S. 175, 185 (1981) (citing *Parker v. Flook*, 437 U.S. 584 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948)).

²⁵ See, e.g., *Diehr*, 450 U.S. at 185.

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policy of the US-PTO was not to give patents on naturally occurring products.²⁶ A patent application was filed on a microorganism, and it went all the way up the Supreme Court, and the Supreme Court held that this microorganism was not a naturally occurring microorganism, it was the product of man, and therefore it could be subject to protection.²⁷

[Slide] Now, on business method patents we used to also have an exception that business methods were not patentable because they were just mathematical formulations, bookkeeping methods; they were really just ideas and mental steps.²⁸ However, the Federal Circuit in the *State Street Bank* case²⁹ clearly rejected the idea that there is a business method rejection. The court went on to say that all methods should be treated fairly and equally, and as long as there is a practical application of that idea—that is, a new, useful, and tangible result—it may be patentable.³⁰ It still has to meet the other criteria, but we are talking here about whether something is just eligible for protection. The court said that in this case—this was a data processing mechanism in a computer—it is definitely patentable subject matter.³¹

[Slide] So taking our guidance from the Court, we have issued patents on various biotech inventions and as well on business method and Internet-related inventions.

[Slide] Now, once something is eligible for protection, it still has to meet the other criteria of utility, novelty, and obviousness.

I am going to talk briefly about the utility standard, because it is very important in the biotech area. Even though all of our requirements are technology-neutral and they apply to all the areas

²⁶ See generally *Chakrabarty*, 447 U.S. at 306 (stating that the Patent Office rejected the inventors patent on the grounds that “living things they are not patentable subject matter under 35 U.S.C. § 101.” This position was subsequently affirmed by Patent Office Board of Appeals.).

²⁷ See *id.* at 320–21.

²⁸ See, e.g., *In re Heritage*, 150 F.2d 554 (C.C.P.A. 1945); *In re Abrams*, 188 F.2d 165 (C.C.P.A. 1951) (applying the mental steps doctrine, which precludes from patentability, claims that recite purely mental steps).

²⁹ See *State St. Bank and Trust Co. v. Signature Fin. Group, Inc.*, 149 F.3d 1368, 1375 (Fed. Cir. 1998).

³⁰ *Id.* at 1376.

³¹ *Id.*

of technology, it has specific implications in the biotech area. That is that utility must be: “specific, credible, and substantial.”³²

This is so important in the biotech area because a lot of people were just finding different sequences or different DNA sequences or little snippets of nucleotides and they didn’t know what they were useful for.

With the Human Genome Project³³—I know everyone has heard about that—there are a lot of sequences in the human genome. Many elements of the Project do not necessarily have a function. So you can’t patent something if you don’t know the specific utility, that the gene has a very particular function. That’s why the substantial utility and specific utility are very important in the biotech area.

[Slide] For most other cases, if something has a well-established utility, it’s known in the art to be used in a certain fashion, then that would be acceptable. For example, if something is useful as a coating or adhesive, that is well accepted and that’s okay. You don’t have to establish a more specific utility than that.

[Slide] Now I’m going to talk a little bit about novelty. This is the “newness” requirement in our patent law.³⁴ In order for somebody to get a patent it must not have been known or used before. There is a very specific set of criteria about what qualifies as a printed document or a disclosure. I’m not going to really go into that because I don’t think that is so relevant to our discussion. But if somebody did discover this or it was used before, then the applicant is pretty much barred from getting a patent on that.

[Slide] I think the more relevant requirement here is obviousness.³⁵ Where are the obviousness standards set? I think

³² See Denise Casey, *Gene Patenting Update: U.S. PTO Tightens Requirements*, 11 Human Genome News (Nov. 2000), available at http://www.ornl.gov/sci/techresources/Human_Genome/publicat/hgn/v11n1/HGN11No1_2color.pdf (discussing the new rules used to govern patentability of genomic or other biotechnological inventions, which were enacted in Dec. 1999).

³³ See U.S. Dept. of Energy, *Human Genome Project Information*, at http://www.ornl.gov/sci/techresources/Human_Genome/home.shtml (last visited May 8, 2005).

³⁴ See 35 U.S.C. § 102 (2005) (setting forth the novelty conditions for patentability).

³⁵ See 35 U.S.C. § 103 (2000).

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it's pretty clear to people when something is known this is the same thing—the same application, same process—but when we talk about obviousness, we are talking about whether somebody of ordinary skill in the art would have been able to derive this invention based on what was already known.³⁶

[Slide] This is what examiners look at when they go through an obviousness determination. They look at the scope and content of the prior art. The prior art are the references, things like known patents and printed publications.³⁷ They ascertain the differences between the new art and the prior art. They have to look at what the ordinary skill in the art is; that's very important because you're not just talking about the knowledge of a lay person, you're talking about somebody skilled in the art. The examiners then consider the evidence that is presented.

I do want to point out that there is a lot of case law surrounding obviousness.³⁸ If somebody has a certain widget and someone makes it a little bigger, the case law says it would have been obvious to one of ordinary skill in the art to vary the size of certain components.³⁹ In the computer area, we also have that mere automation of a known function would have been obvious.⁴⁰ So for things like that we have certain standards that we have used in determining obviousness.

[Slide] I'm going to talk a little bit about post-grant measures because there's a lot of criticism about this. You know, we do issue a lot of patents and sometimes patents get out there that the examiner missed some prior art.

³⁶ See 35 U.S.C. § 103 (2000).

³⁷ See USPTO, MANUAL OF PATENT EXAMINING PROCEDURE, § 2142 (8th ed. 2001) [hereinafter USPTO MANUAL, available at http://www.uspto.gov/web/offices/pac/mpep/documents/2100_2142.htm].

³⁸ See generally Jean F. Rydstrom, Annotation, *Application and Effect of 35 U.S.C.A. § 103, Requiring Nonobvious Subject Matter*, In *Determining Validity of Patents*, 23 A.L.R. Fed. 326 (2004) (indexing numerous cases and issues surrounding the statutory requirement of non-obviousness).

³⁹ See generally *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1354 (Fed. Cir. 1984) (finding that, among other differences, a mere change in size was insufficient to distinguish an invention from prior art).

⁴⁰ See *Dann v. Johnston*, 425 U.S. 219, 228–30 (1976); *Parker v. Flook*, 437 U.S. 584, 594–95 (1978); see also *Diamond v. Diehr*, 450 U.S. 175, 209–220 (1981) (Stevens, J., dissenting); 69 C.J.S. *Patents* § 81 (2003).

They did a thorough search, but it's very difficult to search through all the volumes of all the databases and books to necessarily come up with something.

And in some art, it's difficult to really do searching. In the sequence art, sequences can be hundreds of pages long. In the chemical structure art, the chemical structure can be very complicated. And in the business method and Internet-related art, there are not a lot of publications, not organized as well as in the chemical arts where all structures are published very systematically.

[Slide] So we do have reexamination proceedings, reissue proceedings, and we are also considering post-grant opposition proceedings.

Reexamination is a proceeding where either the patent owner or a third party can request that the PTO reexamine an application in light of new art that wasn't considered by the examiner during the first go-around.⁴¹ So a third party may find a piece of prior art that demonstrates "this was clearly known; I want the Patent Office to revisit it."

There are two kinds of reexamination. There is *ex parte* and there is *inter partes*.

Inter partes is a very new form of reexamination that was established in 1999.⁴² It hasn't been used very much.⁴³ Here the third party can file a request with the Patent Office and have some level of participation in the reexamination process. I think the reason why it hasn't been utilized is because there are some issues regarding issue preclusion. Once the PTO has made a determination, you are precluded from appealing it in court and bringing up those issues that you could have raised in the

⁴¹ See 35 U.S.C. §§ 301–303 (2000); see also Association of Patent Law Firms, *PTO: New Guidelines For Previously-Considered Prior Art In Reexamination Proceedings* (June 8, 2003) (discussing recent changes to the Patent Reexamination Guidelines which allow reliance on "old art"), available at <http://www.aplf.org/maile/issue86.html>.

⁴² USPTO, REPORT TO CONGRESS ON *INTER PARTES* REEXAMINATION (2004), Executive Summary, available at <http://www.uspto.gov/web/offices/dcom/olia/reports/reexamreport.pdf> (last visited May 8, 2005).

⁴³ See USPTO REPORT, *supra* note 6, at 129, Table 13B (showing that only 27 *inter partes* applications were filed in 2004).

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reexamination.⁴⁴ So I think a lot of third parties are afraid to rely on it, so we really have had few instances of *inter partes* reexamination.

But just to give you an idea, of the 170,000 applications that we granted, we have roughly, on average, 300-to-400 reexaminations a year.⁴⁵ So you can see it's a fairly small number in comparison to how many applications we see annually.

"Reissue" is only used by the applicant if he wants to change the scope of the patent.⁴⁶ He finds a piece of prior art and says, "I really need narrower protection. I don't have the right to get such broad protection." So he can bring a proceeding with the US-PTO.

Post-grant opposition proceeding is something that we don't have now but we are considering. It was recommended in the FTC report.⁴⁷ It is something that, again, would have to come in the statutory form. But we are looking at trying to come up with different alternatives and different ways to have a really full-blown opposition proceeding at the PTO. It would likely involve quasi-discovery or some evidentiary level. There would be a determination where parties can come in and really bring an action against the patent on more than just prior art.

[Slide] In closing, I just want to point out some critical things.

The USPTO does not really make the law. We take our direction on what to patent, what the scope of patentable subject matter is, from Congress and the courts.⁴⁸ In doing so, though, we do try to implement these policies in a way to foster and encourage investment, innovation, development, and research.

Our patent system is technology-neutral, so the same rules have to apply across the board. This is part of our international

⁴⁴ Susan Perng Pan, *Considerations for Modifying Inter-Partes Reexam and Implementing Other Post-Grant Review*, 45 IDEA 1, 9 (2004) (noting that estoppel provisions may ward off *inter partes* reexaminations).

⁴⁵ See USPTO REPORT, *supra* note 42, at 5.

⁴⁶ 35 U.S.C. § 251 (2000).

⁴⁷ See FTC REPORT, *supra* note 2, at Executive Summary, 7-8.

⁴⁸ See generally 35 U.S.C. §§ 100-105 (2000) (defining the legislative bounds of patentable subject matter).

obligations.⁴⁹ We are not allowed to treat different areas differently—I know people have talked about shorter terms of protection in the biotech or in the business method area, but that is something we are precluded from doing.⁵⁰

We continue to revisit new situations and adapt policy principles, the principles that have come through Congress, as far as having broad subject matter protection, as we see new categories of inventions always coming. We have bioinformatics, we have nanotechnology coming down the pike, and we are always trying to incorporate the past principles to new technologies.

Thank you very much.

MR. RICHARDS: Thank you, Mary. That gives us the background on which to proceed with the rest of this morning's discussion.

Our next speaker is Matthew Bye, who is from the Office of General Counsel of the FTC. He has carried out hearings in the business method area showing what is appropriate in terms of patent protection⁵¹ and will give us the FTC's view as to where we are in that area and what, if anything, needs to be done about it.

MR. BYE: Thank you.

I'm going to talk today about the report that we issued in 2002, which is on competition and patents.⁵²

Before I go on, I just want to point out that the views I express today are my own and do not necessarily reflect those of the Commission or any individual Commissioner.

[Slide] The subject of our report was how to promote innovation. Innovation is critical to the U.S. economy, critical to

⁴⁹ See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPS Agreement].

⁵⁰ See TRIPS Agreement art. 27.

⁵¹ See Transcript, *FTC/DOJ Hearings on the Implications of Competition and Patent Law and Policy*, Transcript, 4 (April 11, 2002), available at <http://www.ftc.gov/opp/intellect/020411trans.pdf>.

⁵² See FTC REPORT, *supra* note 2.

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getting many life-saving and other technologies to people across the country.

Both patents and competition can provide innovation. They do it in slightly different ways. What is most important is that the two policies work together in a proper balance to maximize innovation.

[Slide] What's also important is that competition and patents often work well together. The antitrust agencies don't presume market power from a patent, and you can see, throughout the economy, firms compete in the sale of patented goods all the time.

[Slide] So you might ask: What's the problem? Well, in 2002 we held hearings, and we held them over about thirty days.⁵³ We had hundreds of panelists, from patent lawyers, patent academics, business experts, a whole range of representatives from patent law organizations. Many of them came to us and expressed a concern about poor-quality patents.

What's vitally important here is I'm talking about poor-quality patents that have economic significance. So every now and then you will see a press article about some sort of amusing patent that got issued, a peanut butter and jelly sandwich patent or something like that.⁵⁴ We are not talking about those because they do not really have any economic significance at all.

I have some testimony from the AIPLA stating that "large and small companies are increasingly being subjected to litigation or its threat on the basis of questionable patents."⁵⁵

[Slide] I want to talk quickly about two industries that are relevant today. But before I go on, I want to mention Chapter

⁵³ See generally *FTC/DOJ Hearings to Focus on the Implications of Competition and Patent Law and Policy* (January 30, 2002) (setting forth the initial hearing schedule), at <http://www.ftc.gov/opa/2002/01/iphearings.htm>.

⁵⁴ Sara Schaefer Munoz, *Patent No. 6004596: Peanut Butter and Jelly Sandwich*, WALL ST. J., April 5, 2005, at B1.

⁵⁵ *United States Patent and Trademark Office Fee Modernization Act of 2003: Hearing Before the Subcomm. on Courts, The Internet, and Intellectual Property of the House Comm. on the Judiciary*, 108th Cong. 13 (2003) (statement of Michael K. Kirk, Executive Director, American Intellectual Property Law Association), available at http://www.aipla.org/Content/ContentGroups/Legislative_Action/108th_Congress1/Testimony2/Testimony_on_Fee_Legislation.htm.

Three of our report⁵⁶, which discusses innovation in a whole range of industries, looking at pharmaceuticals, biotech, semiconductors, and computer software.⁵⁷

We had businesses come in from the pharmaceutical industry that essentially said that they would not have their industry without patents and they are a crucial driver of innovation. And then in other industries, such as software, there was a more mixed view. Many of the companies said, “We really don’t feel that patents are a spur to innovation.”

Anyway, in the computer hardware industry, one of the problems identified by panelists were patent thickets.⁵⁸ That’s a situation where you have so many patents that you have this unavoidable overlap.⁵⁹ One statistic we were given is there are 420,000 semiconductor patents held by about 40,000 parties.⁶⁰ So whenever you want to try to bring a new product to market, there can be many complications in terms of identifying all those parties and obtaining licenses. Then if you bring your product to market and suddenly someone enforces a patent, you can be liable for significant damages.

There are a few reasons why we are seeing this patent thicket develop.

- One is that the technology in this industry is largely incremental. We don’t often have large, breakthrough innovation. Each new innovation builds on the next.
- One of the ways that companies have responded to this problem is to essentially seek as many patents as they possibly

⁵⁶ See FTC REPORT, *supra* note 2, at ch. 3.

⁵⁷ See *id.* at ch. 3, pp. 4, 15, 30, 44.

⁵⁸ “Patent thicket” is a term attributed to a common problem that occurs when a new developer seeks to patent a complex invention that incorporates many already-patented components. In essence, the problem is that the patent applicant must seek cross-licenses from those who already hold patents to the components. For a discussion of “patent thickets,” see generally JAMES BESSEN, PATENT THICKETS: STRATEGIC PATENTING OF COMPLEX TECHNOLOGIES, at <http://www.researchoninnovation.org/thicket.pdf> (last visited May 9, 2005).

⁵⁹ See *id.*

⁶⁰ See Transcript, *FTC/DOJ Hearings on the Implications of Competition and Patent Law and Policy*, Transcript, 667–68 (April 28, 2002), available at <http://www.ftc.gov/opp/intellect/020228ftc.pdf>.

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can,⁶¹ so if a company comes to sue them, they can essentially say, “We’re now going to sue you back with these patents.” So that’s where we see this concern of the rise of defensive patenting.

Other panelists also suggested that the ease of obtaining patents at the PTO was contributing to the thicket.

[Slide] As a result, you see extensive portfolio cross-licensing and defensive patenting throughout the industry.⁶²

Similarly, the software and Internet industry is premised on incremental innovation.⁶³ Some panelists said there was uncertainty from the alleged lack of an effective disclosure requirement.⁶⁴ They suggested that the source code should actually be disclosed to the PTO, rather than publishing the idea at a more abstract level.⁶⁵

Other panelists have talked about claim construction difficulties. I just want to note an amicus brief that the PTO, Justice Department, and FTC recently submitted to the Federal Circuit on the issue of claim construction,⁶⁶ essentially looking at how words in a patent claim should be interpreted, whether they should use a dictionary or examine the context of the patent and try to illuminate your interpretation from that.⁶⁷ The agencies collectively advocated looking more at the context of the patent rather than just taking a very literal, sort of dictionary approach.⁶⁸

⁶¹ See, e.g., FTC REPORT, *supra* note 2, at Executive Summary, 6–7 (describing the practice of defensive patenting).

⁶² See FTC REPORT, *supra* note 2, at ch. 3, pp. 34–44. Defensive patenting is a practice in which inventors (normally large firms) obtain patents to discourage infringement suits by raising patent infringement counterclaims. *Id.* at ch. 3, p. 36. Cross-licensing is used to resolve this impasse whereby the potential infringers agree to license their respective technology to the other. *Id.* at ch. 2, p. 30.

⁶³ See *id.* at ch. 3, p. 30.

⁶⁴ See *id.* at ch. 3, p. 53.

⁶⁵ See *id.* at ch. 3, p. 49.

⁶⁶ Brief of United States as Amicus Curiae, United States Patent and Trade Mark Office et al., *Phillips v. AWH Corp.*, 375 F.3d 1382 (Fed. Cir. 2004) (No. 03-1269) (order granting rehearing en banc), available at http://www.uspto.gov/web/offices/com/sol/ambriefs/Phillips_03-1269.pdf (last visited May 9, 2005).

⁶⁷ *Id.* at 2.

⁶⁸ *Id.* at 9–15 (arguing that the claim construction should primarily consider intrinsic evidence rather than rely solely on standard dictionary definitions); see also Brief for the United States as Amicus Curiae United States Patent and Trade Mark Office et al.,

Patent thickets are a problem in software, as is defensive patenting. Companies are seeking patents to use as bargaining chips, and it can increase the cost of entry. One of the companies essentially came to us and said that it's allocating funds to people obtaining patents rather than spending money on research, simply so he can defend the company. He estimated that he took about 25 percent away from his research budget to increase the number of patent filings. This was done, he said, with no benefit to innovation.⁶⁹

[Slide] So clearly questionable patents are part of the problem. What are they? Well, they are patents that are likely invalid or overbroad.

A critical thing to note here is that, on the whole, the patent examiners at the PTO do a superb job. As Mary mentioned, they are flooded with nearly 1,000 patents a day. They have roughly eight-to-twenty-five hours to read an application, investigate prior art, correspond with the parties, and ultimately make a decision. Some of these applications can include thousands and thousands of pages. So in the time they are given they do a very superb job.

But, inevitably, you have questionable patents trickling through. These harm innovation and competition in a number of ways.⁷⁰

The best thing to think about is the situation where you have a small biotech company that wants to do research in an area and they see a questionable patent that stands in the way. They have a few choices:

- They can simply avoid the area, just not engage in any research, and then the economy loses because we are not getting R&D that we would otherwise have had.⁷¹

Phillips v. AWH Corp., ___ F.3d ___, 2005 WL 1620331 (Fed. Cir. 2005). (largely adopting the view for which the Agencies advocated) *available at* http://www.uspto.gov/web/offices/com/sol/ambriefs/Phillips_03-1269.pdf.

⁶⁹ See, e.g., FTC REPORT, *supra* note 2, at ch. 2, pp. 30–31 (discussing how to promote innovation through the balancing of competition with patent law and policy).

⁷⁰ See *id.* at Executive Summary, p. 8.

⁷¹ See Symposium, *Patent Rights and Licensing*, 6 B.U. J. SCI. & TECH. L. 3, para. 52 (2000) (“There is empirical evidence that the smaller start-ups with less financial resources direct their research in such a way that they avoid fields crowded with many

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- They could go to the company and seek a license, but then they are paying for something that really they should not be paying for, so you have funds being diverted from R&D.
- They can't challenge the validity of the patent unless they have been threatened with infringement.

So it can be very difficult for some of these companies, particularly when they are small, to navigate around some questionable patents.

[Slide] What are the solutions for this? Well, as a theoretical solution, we have the "but for" test. I can't emphasize enough that this is a theoretical solution. It is not one that is meant to apply to specific cases.

Patents have a cost as a means of fostering innovation, but so do other mechanisms. If you think of trade secrecy, when companies use trade secrecy they don't disclose, and so other companies lose out from the very important patent disclosures that we get.

The "but for" test essentially involves asking: would the innovation occur absent the patent? If it would occur, then it is better off being spurred by competition and that patent essentially is unnecessary.⁷²

[Slide] Practical approaches. In our report we make ten recommendations and I also point out the National Academy of Sciences released a report earlier this year, "A Patent System for the 21st Century."⁷³ It's available on-line, as is our report. It makes six key recommendations, some of which overlap with ours.⁷⁴

[Slide] Our first recommendation, as Mary mentioned, was to establish a PTO administrative procedure for challenging patents,

patents . . ."); see also S. Benjamin Pleune, *Trouble with the Guidelines: On Urging the PTO to Properly Evolve with Novel Technologies*, 2001 U.ILL. J. L. TECH. & POL'Y 365, 367-68 (discussing the effects of broad patent protection on genetic research) (2001).

⁷² See FTC REPORT, *supra* note 2, at ch. 1, pp. 10-11.

⁷³ NAT'L RESEARCH COUNCIL OF THE NAT'L ACADS., A PATENT SYSTEM FOR THE 21ST CENTURY (Stephen A. Merrill et al. eds., 2004) [hereinafter NAS Report], available at <http://www.nap.edu/html/patentsystem/0309089107.pdf> (last visited May 9, 2005).

⁷⁴ Compare *id.* at 81 with FTC REPORT, *supra* note 2, at Executive Summary, 7-15.

essentially to weed out some of these invalid and overbroad patents we are seeing.⁷⁵

Litigation is very expensive and very time-consuming. Some biotech companies estimated it can cost between \$3 million and \$5 million and take a number of years.⁷⁶

NAS makes a recommendation on this same topic,⁷⁷ and quite recently Representatives Berman and Boucher introduced a bill into the House which attempts to outline or describe what such a system would look like.⁷⁸

[Slide] There are a few basic requirements for this sort of system: It has to address important issues of patentability. They have to control costs, prevent patent holders from being abused by frivolous suits, and keep it timely.⁷⁹ How do you juggle all these things? Well, that is really the catch. The devil is in the details and it is something that needs to be worked out.

I will just give one example here. We co-sponsored a conference in April in Berkeley.⁸⁰ The question was raised, how long after a patent is issued could you seek reexamination? The people from biotech companies said, "We think nine months is a good amount of time," because they feel that they can identify a problematic patent quite quickly, and they want certainty most of all. On the other hand, people from the semiconductor industry said, "The patents we have a problem with tend to take three-to-four years to surface, often after we have issued products, and so we need a much longer timeframe." It's just one example of some of the difficulties we face in implementing this type of review.

[Slide] Moving on to our sixth recommendation: consider possible harm to competition along with other possible benefits and costs before extending the scope of patentable subject matter.⁸¹

⁷⁵ See FTC, *supra* note 2, at Executive Summary, 7–8.

⁷⁶ See *id.* at Executive Summary, 8.

⁷⁷ See NAS Report, *supra* note 73, at 82.

⁷⁸ H.R. 5299, 108th Cong. (2004).

⁷⁹ See FTC, *supra* note 2, at Executive Summary, 7–8.

⁸⁰ See *Ideas Into Action: Implementing Reform of the Patent System*, <http://www.law.berkeley.edu/institutes/bclt/patentreform> (last visited May 16, 2005).

⁸¹ *Id.* at Executive Summary, 14.

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Over the last two decades, we have seen patentable subject matter expand. We have seen patents issued on biotech and software and business method patents. This is essentially very similar to the “but for” test.⁸² However, before patentable subject matter is extended, we want to look at whether we really need patents in the particular area or whether the innovation will occur regardless.

[Slide] There are a few issues with this. As Mary mentioned, there is the Supreme Court precedent, “anything under the sun that is made by man is patentable.”⁸³ There are obviously questions at the margins here, but that’s one factor to consider.

Another one is where and when such a debate should take place. The PTO often receives patent applications on new technologies. They sort of trickle in and they might increase over time. It’s not often that a bright light goes on and says “this is now patentable,” so there is not always a clear point in time to have this debate. And also, when we do have such a debate, we need to have enough information to ask the “but for”⁸⁴ question: what would happen if we didn’t issue patents on this area?

[Slide] Moving on to our tenth recommendation, which is to expand consideration of economic learning and competition policy concerns in patent law decision-making.⁸⁵ This idea is not something that we intend to be applied by the individual examiner in the PTO. It’s more in the formation of rules, something that the courts could consider and that the PTO could consider when they are issuing guidelines. It’s also something for Congress to consider. It is important to consider because we need to ensure that competition is not unnecessarily displaced.

⁸² See *id.* at ch. 4, pp. 6–8. The “but for” test is an alternative analysis of patentability that considers the competitive effects of the patent. Rather than inquiring into whether the statutory requirements are met, the test asks whether the innovation would have occurred as soon as it did in the absence of patent rights. *Id.*

⁸³ See *supra* note 23 and accompanying text.

⁸⁴ See FTC REPORT, *supra* note 2, ch. 4, pp. 6–8 (stating that the “but for” test cannot practically be applied in the cases of individual patents given the availability and costs of the necessary information, but may be applicable in establishing general policies).

⁸⁵ See *id.* at Executive Summary, 17.

[Slide] There is a lot going on in the area of patent law reform at the moment. Coming up next year, the NAS, AIPLA, and FTC will co-sponsor a series of town meetings to discuss patent reform in four cities across the country.⁸⁶ They will essentially involve someone making a presentation about a particular area, followed by a back-and-forth discussion with the audience—so stay tuned for that.

Then, also look for the bill that was recently introduced.⁸⁷ It will be reintroduced in the next congressional session.⁸⁸

Our report, as I mentioned, is available on-line.⁸⁹ Otherwise, if you would like to give me your card or email address, I'll happily send it to you.

Thanks for your time.

MR. RICHARDS: Thank you, Matthew.

Our next speaker will be David Balto to take it from the antitrust perspective—at least that's what his background is. I don't know if he is going to speak purely on antitrust, on how the need for competition impinges on what we should be doing in the patent system.

MR. BALTO: Just so all of you know, I am in an adversarial position. I get to wear this [Red Sox baseball cap]. Somebody at the airport said to me, "Wait till next year." I said back to him, "I've been saying that for the last eighty-five years."

I want to thank the people who put this program together. I know how hard they worked at it. And I know from reading past issues of the *Journal* what a terrific journal it is, and I can only say that I am disappointed that I am not on the Janet Jackson panel.

⁸⁶ See *Agenda for Town Meeting of Patent Reform*, at <http://www.ftc.gov/ogc/workshops/patenttownmeetings/townmeetingsagenda.pdf> (providing schedules for each of the Town Meetings) (last visited May 9, 2005).

⁸⁷ H.R. 5299, 108th Cong. (2004).

⁸⁸ As of April 17, 2005, the legislation was embodied in a discussion draft being circulated among the House Subcommittee on Intellectual Property. A copy of the draft is available at <http://patentlaw.typepad.com/patent/DraftPatentStatuteDDC.pdf> (last visited May 16, 2005).

⁸⁹ See FTC REPORT, *supra* note 2.

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I wanted to say at the outset I am required—just how Matt has to give a disclaimer—to give an advertisement for my law firm whenever I speak. We’re a terrific law firm. We were named IP Litigation Firm of the Year last year.⁹⁰

I am here to tell you that antitrust and IP are at odds. Regardless of what any of these people tell you about how they serve similar masters and seek similar goals, these things are at odds. I am here to tell you that the scales are not balanced at this time.

Imagine a house that is broken-down and threadbare, lost and ignored, and in the backyard there is a big, weedy thicket. Well, the FTC report sort of suggests what you might do with parts of the thicket, to trim it down, but there are a lot of things running amok in the house at the same time.⁹¹

The pinnacle, to me, of how companies thought that IP rights gave them unfettered ability to abuse the antitrust laws was a point that Microsoft made in their litigation against the Department of Justice.⁹² They suggested that their tying arrangements were justified, and in fact, immune from antitrust scrutiny because they had a copyright over Internet Explorer.⁹³

How did the conservative en banc D.C. Circuit respond to this? It held, “Microsoft’s primary copyright argument borders on the frivolous. The company claims an absolute and unfettered right to use its intellectual property as it wishes.”⁹⁴ It also quoted the Microsoft brief: “If intellectual property rights have been lawfully acquired, their subsequent exercise cannot give rise to antitrust liability.”⁹⁵

⁹⁰ See Firm News, *The American Lawyer and IP Law & Business Names Robins, Kaplan, Miller & Ciresi L.L.P. “IP Litigation Department of the Year”*, at http://rkmc.com/firm_news.asp?newsId=185 (last visited May 16, 2005).

⁹¹ See FTC REPORT, *supra* note 2 at Executive Summary, 10–20 (setting forth recommendations designed to, among other goals, reduce the preclusive effect of patent thickets).

⁹² U.S. v. Microsoft Co. 253 F.3d 34 (D.C. Cir. 2001).

⁹³ *Id.* at 63.

⁹⁴ *Id.*

⁹⁵ *Id.* (quoting Appellant’s Opening Br. at 105 (Nos. 00-5212 and 00-5213)).

Let me tell you, if that was true, in a couple years none of you would ever have to take an antitrust course. Fortunately, it is not true. As the D.C. Circuit said: “That is no more correct than the proposition that the use of one’s personal property, such as a baseball bat, cannot give rise to tort liability.”⁹⁶

As the Federal Circuit succinctly stated: “Intellectual property rights do not confer a privilege to violate the antitrust laws.”⁹⁷

Now, what Matt didn’t tell you is that there are two parts to this story. That’s sort of like the way that Red Sox fans always feel—you know, there’s the first part and then there’s the second part that never comes. But there are two parts to this story.

The first part was the wonderful report that he has talked about. The executive summary is in your materials.

But there is a second report. It has not been issued. Every morning we energetic antitrust people, who know that antitrust stands there as the vanguard to protect you from the abuse of intellectual property rights, wake up, run to our computers, check the FTC website, and go, “Where is that report, the second report, which deals with how do the antitrust laws need to be reformed, how do the antitrust laws need to be enforced, to protect against that problem that Matthew has described?” But look as we might, we can’t seem to find that report.

But if we really want to do more than just take care of the weeds in the backyard, we need to see what kinds of actions can be taken by antitrust enforcers to set appropriate limits on intellectual property rights.

You know, the law is clear in this area: you have a right as a patent holder to exercise your patent monopoly, but you don’t have a right to go beyond that patent monopoly and abuse the antitrust laws.

All of you who have taken patent law know that there is a doctrine known as inequitable conduct,⁹⁸ that if you engage in

⁹⁶ *Id.*

⁹⁷ *Id.* (quoting *In re Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1325 (Fed. Cir. 2000)).

⁹⁸ See DONALD S. CHISUM ET AL., PRINCIPLES OF PATENT LAW: CASES AND MATERIALS, 1049 (2d ed. 1998).

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patent misuse,⁹⁹ if you defraud the Patent Office—and we now obviously know there is ample opportunity for that—if you engage in some type of inequitable conduct, your patent may be declared invalid.¹⁰⁰ But such actions also can be attacked under the antitrust laws.

So what I wanted to do is just give you some examples of enforcement actions taken by the FTC involving efforts by patent owners to get a little bit more out of their patent than they really were supposed to—these people abused the patent system or other regulatory systems. These examples demonstrate why we need, not only reform of the patent system, but aggressive antitrust enforcement. That is the second volume of the report, Matt, if I haven't mentioned that already: to properly reset the balance between IP and antitrust law.

Many of these enforcement actions, by the way, involve the pharmaceutical industry.¹⁰¹ Years ago when I was a young attorney at the Federal Trade Commission, we were doing investigations of a drug company. They had such a fragile understanding of the antitrust laws and of their obligations under the those laws, and they were rather brazen in their internal documents in describing the types of anticompetitive conduct that they planned to engage in than other types of firms.

The documents were striking. You would never find them in a well counseled company.

One of these documents we came up with was this nine-step plan by four branded pharmaceutical companies. It outlined efforts that they could take to go and expand and protect their patents, or protect their monopoly after their patents expired.

So what were a couple of these strategies that led to important FTC enforcement actions?

⁹⁹ See *Dawson Chemical Co. v. Rohm & Hass Co.*, 448 U.S. 176, 179–80 (1980); see also *CHISUM*, *supra* note 98 at 1066.

¹⁰⁰ See *CHISUM*, *supra* note 98, at 1049.

¹⁰¹ See FTC, *FTC ANTITRUST ACTIONS IN PHARMACEUTICAL SERVICES AND PRODUCTS* (Oct. 2004), available at <http://www.ftc.gov/bc/0410rxupdate.pdf> (listing numerous enforcement actions brought by the FTC against pharmaceutical firms).

The first one was deceptive patent filings and filings before the Food and Drug Administration.¹⁰² The Hatch-Waxman Act¹⁰³ sets this incredibly complicated gauntlet for generic firms to effectively enter into the market. Basically, this gauntlet provides for litigation between branded firms and generic.¹⁰⁴

Anyway, one of the things that you have to do when you are a branded firm is list your patent in an FDA book called the Orange Book.¹⁰⁵ Bristol-Myers came up with the strategy that, at the point that the patent would expire, they would return to the Patent Office, the very busy Patent Office, and say, "Here's this patent application. Please approve it. We need it right away."¹⁰⁶ And the Patent Office, of course, looking very diligently and very carefully at the application, would automatically approve it. The FDA would then automatically list the patent in the Orange Book. That prevented generic firms from being able to enter the market because of statutory requirements that said if a patent was listed in the Orange Book, you couldn't enter for an additional thirty months.¹⁰⁷

¹⁰² See *Examining Issues Related to Competition in the Pharmaceutical Marketplace: A Review of the FTC Report, Generic Drug Entry Prior to Patent Expiration: Hearing Before the Subcomm. on Health of the House Comm. on Energy and Commerce*, 107th Cong. 36–38 (2002) (statement of Timothy J. Muris, Chairman, Federal Trade Commission describing how some pharmaceutical companies have abused the parameters of the Hatch-Waxman Act to secure greater profits), available at <http://energycommerce.house.gov/107/action/107-140.pdf> (last visited May 9, 2005).

¹⁰³ Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. §355 (2000); 35 U.S.C. §§ 156, 271, 282 (2000)). The Drug Price Competition and Patent Term Restoration Act of 1984 is commonly known as The Hatch-Waxman Act. The Hatch-Waxman Act encourages generics to enter the market by providing the following benefits to generic manufacturers: (1) the filing of an abbreviated new drug application (ANDA); (2) the right to test the generic version of a drug before the expiration of the brand name patent; and (3) receipt of 180 days of exclusivity for being the first generic on the market. *Id.* §§ 101, 202.

¹⁰⁴ See *id.*

¹⁰⁵ *Electronic Orange Book of Approved Drug Products with Therapeutic Equivalence Evaluations*, at <http://www.fda.gov/cder/ob/default.htm> (last visited May 9, 2005).

¹⁰⁶ See, e.g., Francesca Lunzer Kritz, *Why You Still Can't Buy Cheaper Generics*, WASH. POST, Nov. 13, 2001, at F2. The BuSpar patent was a day from expiring when the FDA issued the new patent to Bristol-Myers. See *id.*

¹⁰⁷ 21 U.S.C. § 355 (2000).

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Bristol-Myers figured out a perfect way to game this strategy, and so they did, until one day the FTC, the states, and lots of private attorneys brought antitrust actions against them.¹⁰⁸ Ultimately, Bristol-Myers settled the case, paying substantial damages.¹⁰⁹

So that's the first thing: Is there some way we can go and manipulate the patent and regulatory system to extend a patent life that actually is supposed to end?

Second strategy: Well, let's say you really can't get the regulators involved and you don't really feel like defrauding the Patent Office. What you can do is find other ways of abusing the regulatory structure.

Now, there is this aspect of the regulatory structure that says that the first generic to file a challenge to a patent has the exclusive right to enter the market for six months.

The brand-name firms recognized, "why don't we just enter into a deal with that first generic firm and we'll settle our patent litigation; we will just agree that they won't enter the market and we will pay them, and that is what our settlement will be."¹¹⁰

Now, all of you who are students know that you settle patent litigation and typically what happens is that the alleged infringer pays the patent holder because that's the way things should work, because maybe the alleged infringer really doesn't have a right to enter the market. But the way these arrangements worked, the patent holder paid the alleged infringer; the brand-name firm paid the generic firm.¹¹¹

The FTC saw this as a guise for two firms going in, splitting monopoly profits, and creating a new barrier to entry and

¹⁰⁸ See Melody Peterson, *Bristol-Myers Held Culpable in Patent Move Against Rivals*, N.Y. TIMES, Feb. 20, 2002, at C1; see also *In re Buspirone Patent and Antitrust Litig.*, 185 F. Supp. 2d 363, 369 (S.D.N.Y. 2002).

¹⁰⁹ See Melody Peterson, *Bristol-Myers Squibb to Pay \$670 million to Settle Numerous Lawsuits*, N.Y. TIMES, Jan. 8, 2003, at C9.

¹¹⁰ See, e.g., *In re Buspirone*, 185 F. Supp. at 366 (alleging that Bristol Meyers Squibb's settlement with Schein Pharmaceuticals was a pretense whereby Bristol Meyers paid Schein to keep a generic version of Buspirone off the market).

¹¹¹ See *id.*

effectively extending the patent life.¹¹² You know, the patent would have ended at some point, but by going and entering into this arrangement they were able to abuse the patent rights and effectively extend their patent.

So let me just leave it with those two examples because I want to hear from Herb, who is a lifelong Yankees fan, and I'm sure will not agree with any of my points.

MR. RICHARDS: Thank you, David.

Herb Schwartz, a partner at Fish and Neave, as I said, the premier patent lawyer in the City these days.

MR. SCHWARTZ: Good morning. Actually, I happen to be a Brooklyn Dodgers fan. I grew up in the shadow of Ebbets Field. I must admit when the Dodgers were moved out of Brooklyn by Walter O'Malley, I decided baseball was a business. I felt robbed, cheated, and raped, and really, sort of my interest in baseball was never quite the same. My wife happens to be a Red Sox fan, and I just go to sleep when these games go on now. But hopefully they'll bring the Dodgers back to Brooklyn someday and I can really reassert my interest in the whole thing. So as far as baseball, those are my views.

As far as the FTC report and the subject of today, I have trouble with the basic thesis that the FTC uses. I don't think it makes any sense. Let me explain what I mean.

The basic thesis of the FTC is that there is something called a questionable patent.¹¹³ They say that a questionable patent is a patent that is "[a] poor quality or questionable patent"¹¹⁴ and it is either "likely invalid or contains claims that are likely overbroad."¹¹⁵

Now, I've spent a fair amount of time involved in patent litigation and teaching patent law and I know a little bit about the statutes, and you have heard about them this morning. There are provisions in the patent laws for novelty, usefulness,

¹¹² See Peterson, *supra* note 108, at C1, C19.

¹¹³ See FTC REPORT, *supra* note 2, at Executive Summary, 9.

¹¹⁴ *Id.* at Executive Summary, 5.

¹¹⁵ *Id.*

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unobviousness.¹¹⁶ I have never seen a provision that deals with a questionable patent; I have never seen a provision that deals with an overly broad patent; I have never seen a provision that deals with an incremental invention.

To me, fundamentally, this is pejorative rhetoric without any analytical basis. What it is really, is an attempt by an agency fundamentally charged with antitrust enforcement to use rhetoric rather than logic to try to take on the patent system. And so I am really troubled by that.

Then, when you get into the detail of it, you look in their report, starting at page five. They talk about what they call questionable patents deterring or raising the cost of innovation and talk about incremental innovation.¹¹⁷ I don't really see any serious support for those propositions.

What they rely on are anecdotes from people in industry. When you look at the anecdotes, to me they don't really stand up. There is an anecdotal statement of 90,000 patents generally related to microprocessors that are held by 10,000 people¹¹⁸ That's attributed to Peter Detkin, who was the Patent Counsel of Intel¹¹⁹. Intel certainly didn't operate that way. Intel had a few core patents and they kept everybody else out of the field.¹²⁰ They weren't worried about 90,000 patents.

When I represented a company called Digital, and we sued Intel on ten patents that related to their core microprocessor, they didn't have any trouble figuring out what those were. They settled very quickly.

There really aren't 90,000 patents that make a difference. There are only a handful, and people in business know who they are and what they are. So I just think ultimately, that's just empty rhetoric.

¹¹⁶ See 35 U.S.C. §§ 101, 102, 103 (2000).

¹¹⁷ *Id.* at Executive Summary, 5–6.

¹¹⁸ *Id.* at Executive Summary, 6.

¹¹⁹ *Id.* at Executive Summary, 6 n.19.

¹²⁰ See Press Release, FTC: Intel Abuses its Monopoly Power in Violation of Federal Law (June 8, 1998), available at <http://www.ftc.gov/opa/1998/06/intelc.htm>.

The other talk about patent thickets and questionable patents really misses the fundamental point. There are reasons to try to deal with patents that don't stand up. To me the fundamental problem with the patent system, which I do agree with the FTC on, is there needs to be some way to challenge patents on the conventional theories of invalidity without getting involved in a full-blown infringement suit.

Under the current law, the only way you can challenge a patent is to bring a declaratory judgment suit, which means you have to be threatened by infringement.¹²¹ As a practical matter, that doesn't really do any good in most industries because there are patents out there and you may never be threatened with a suit on them.

I think most responsible organizations—the FTC being among them, and also the National Science Foundation, and the various patent law groups—have realized that the time has come for some system in which there needs to be an administrative challenge of patents early on so that people can get rid of, or deal with, patents that are invalid.¹²²

But that doesn't mean that the system is full of “questionable” patents or “overly broad” patents or the like.¹²³ It means that our system has a hole in it, the hole being the ability to deal with those few patents that right now cannot be addressed because the only remedy is to wait until there is a full-blown infringement suit. So I think that is one significant issue that needs to be dealt with.

I think the other significant issue that needs to be dealt with, which is talked about, is the continuation practice in the patent world.¹²⁴ The continuation practice is something that is really a

¹²¹ See FTC REPORT, *supra* note 2, at ch. 3, p. 22 (discussing the difficulty in challenging a patent outside of an action for infringement and the limited availability of declaratory judgment actions).

¹²² See, e.g., FTC REPORT, *supra* note 2 at Executive Summary, 7–8 (recommending the enactment of “legislation to create a new administrative procedure to allow post-grant review of and opposition to patents”).

¹²³ *But see id.* at Executive Summary, 5–6 (describing a pervasive problem of questionable patents that harm innovation and competition).

¹²⁴ A continuation is an application that essentially restarts the examination process. It may be filed by applicant anytime prior to the patent being either issued or abandoned. See Mark A. Lemley & Kimberley L. Moore, *Ending Abuse of Patent Continuations*, 84

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creature of the last twenty years in the sense that, prior to the Federal Circuit, you could not continually write claims to cover new contributions as you saw them being made.¹²⁵ You were really stuck more with what was in your original patent application. The Federal Circuit has changed that rule.¹²⁶

There has always been the ability to file a continuation application;¹²⁷ there is nothing new about that. What is new is the ability to write claims in continuation applications, drafted specifically to cover contributions done after the patent application was filed and not really tell the Patent Office you're doing it. You don't tell the PTO that you are writing these new claims to cover newly developed things. What you do is you change the words around and suggest it was always part of your invention.¹²⁸

I find that to be a very troublesome practice and a practice that has spawned a lot of litigation—maybe not unnecessary litigation, but certainly expensive litigation—and there needs to be a cure to that.

One cure to that, which exists in other countries, is something called prior user rights, which is something that has been enacted

B.U. L. REV. 63, 66–69 (2004) It is often used where the applicant is dissatisfied with the Patent Office's decision or the narrow scope of the patent's claims. *Id.*

¹²⁵ See *Chicago & N.W. Ry. Co. v. Sayles*, 97 U.S. 554, 555

The law does not permit enlargements of an original specification any more than it does where letters-patent already granted are reissued. It regards with jealousy and disfavor any attempt to enlarge the scope of an application once filed, or of letters-patent once granted, the effect of which would be to enable the patentee to appropriate other inventions made prior to such alteration, or improvements which have gone into public.

Id.

¹²⁶ See *Kingsdown Medical Consultants, Ltd. v. Hollister Inc*, 863 F.2d 867, 874 (Fed. Cir. 1988)

It should be made clear at the outset of the present discussion that there is nothing improper, illegal or inequitable in filing a patent application for the purpose of obtaining a right to exclude a known competitor's product from the market; nor is it in any manner improper to amend or insert claims intended to cover a competitor's product the applicant's attorney has learned about during the prosecution of a patent application.

Id.

¹²⁷ See 35 U.S.C. § 120 (2000); 37 C.F.R. § 1.53(b) (2005).

¹²⁸ See *Lemley & Moore*, *supra* note 124, at 76–79 (2004) (discussing problems arising from allowing claims to be rewritten in continuation applications to track competitors products).

in a very limited fashion in this country and probably ought to be more broadly enacted.¹²⁹ Beyond that, I think there probably should be tighter restrictions on the continuation practice so that it doesn't become as much of a game of patent applications, filing a series of five or ten continuation applications.

Some of this problem has been cured with the change of the patent statute to allow a patent to be valid for twenty years from filing instead of seventeen years from issuance.¹³⁰ So I think that a piece of this problem has been cured by the twenty-year term, and I think a further piece of it could be cured by changing the continuation practice.

I think the other recommendation of the FTC, and also the National Science Foundation, that I agree with, is that there is a need to beef up the Patent and Trademark Office. More money must be spent on the Patent and Trademark Office to keep up with the increased number of applications and the increased technology.¹³¹

What I don't agree with is when you take the FTC's premise of questionable patents, their cure is to tinker with the enforcement of patents by adding essentially ad hoc remedies to devalue patents and devalue the patent system.¹³² What I mean by ad hoc remedies are things like changing the burden of proof on invalidity from clear and convincing evidence to a mere preponderance of the evidence; changing the judicial standards on obviousness to something that would be much tougher to support the validity of the patent.¹³³ I think those changes are unwarranted and uncalled for and have no analytical basis and I would be opposed to them.

Thank you.

¹²⁹ See Symposium, *Fourth Biennial Patent System, Major Problems Conference, Prior Use Rights: Introductory Comments*, 34 IDEA 117, 118-20 (1994) (statements by Sylvie A. Strobel comparing European approach to prior user rights to the U. S. approach).

¹³⁰ 35 U.S.C. § 154(a)(2) (2002).

¹³¹ See FTC REPORT, *supra* note 2, at Executive Summary, 12; NAS REPORT, *supra* note 73, at 82.

¹³² See FTC REPORT, *supra* note 2, at Executive Summary, 8-10.

¹³³ See *id.*

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MR. RICHARDS: I'll start with you, Matthew. Would you care to make any comments on anything that has been said since you spoke?

MR. BYE: First thing, questionable patents.¹³⁴ It's not empty rhetoric. It is a term that has been used by a number of the leading patent law organizations. It is a term that is used by many businesses that come and testify to us. So it's an established term that has been used throughout the industry.

In terms of support for our recommendations in this report, we have support at many different levels. There is anecdotal support, but as is said, one person's anecdotes are another person's case study. When you have all the leading businesses in many industries come and testify, and if they testify with a common theme, then there is something you can extract out of that.¹³⁵

We also rolled out a number of empirical studies that have looked at various aspects of the patent system and the ability of patents to spur innovation done over a number of years. They are the two main bases.

But I guess the thing I want to point out is we had companies like Microsoft and Intel and Cisco and Google and Symantec come to us, as well as pharmaceutical companies and biotech companies. Particularly, companies in the semiconductor industry and in software said, "There are problems with the patent system, it is harming our ability to innovate, it is harming our ability to bring new products to the market."¹³⁶

The patent system essentially exists to promote innovation.¹³⁷ It is to help these companies do what they want to do. If they are coming and telling us there is a problem, well maybe that is something that is genuinely worth listening to.

I just want to make one final point about the FTC's role. The FTC is an antitrust enforcer. We scrutinize all sorts of anticompetitive conduct. We also have a role as a competition

¹³⁴ See *id.* at 6 (discussing the filing of "questionable" patents; patents with no innovative value filed as a defensive mechanism).

¹³⁵ See *generally id.* at ch. 3 (discussing specific issues raised by industry panelists).

¹³⁶ See *id.* at Executive Summary, 5 n.16.

¹³⁷ U.S. CONST. art. I, § 8, cl. 8.

advocate. We often do studies for various industries or look at an intersection of different issues. A few years ago we looked at the Hatch-Waxman Act,¹³⁸ we've looked at the patent system,¹³⁹ we've looked at the health care industry and released a report about that earlier this year.¹⁴⁰

Our job is essentially to look at roadblocks to competition—whether they are regulatory or business conduct—and try to suggest reform to them. Doing this report is really at the very heart of our mission.

MR. RICHARDS: Thank you.

Mary?

MS. CRITHARIS: First, to address Matthew's concern, when you are talking about questionable patents, are you talking about patents that you don't feel should have been issued? Is it because the law was too broad or because the PTO didn't do a good job?

I think it is important to at least distinguish between patents that maybe weren't examined properly, that were erroneously issued, and patents that you just feel are too broad because there shouldn't be a patent on a particular gene sequence or a patent on a particular software or way of doing business over the Internet. Denial of patents in this second category is based on statute.¹⁴¹ The distinction is whether there is a concern that the USPTO is not doing a good job of examining the patent applications according to the law, or whether the law, as drafted by Congress, interpreted by the courts, and applied by the USPTO needs to be revisited.

So I think I want to make at least that distinction first. That's for any of the panel members as well.

QUESTION: In terms of questionable patents—

MR. RICHARDS: Can you please say who you are for the record?

¹³⁸ See FTC, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY* (July 2002), available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

¹³⁹ See generally FTC, *supra* note 2.

¹⁴⁰ See FTC, *IMPROVING HEALTH CARE: A DOSE OF COMPETITION* (July 2004), available at <http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf>.

¹⁴¹ See, e.g., 35 U.S.C. §§ 101–103 (defining the statutory limits of a patent).

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QUESTION: [Inaudible] Maritzi, with Jones, Day.

In terms of questionable patents, clients that we deal with and companies that are out there—in particular the pharmaceutical companies—tend to coin that phrase for patents that are used against them, but when they get them themselves, they are fine and wonderful.

MS. CRITHARIS: That was the other thing.

QUESTIONER: So I really have an issue with this category of questionable patents.

I think we can probably do a better job of enforcement. In Europe, for example, they have research use exceptions, where it is not an act of infringement if you are tinkering with the invention for a noncommercial purpose.¹⁴² In this country, we have created an exemption for actual commercial infringement with the Hatch-Waxman Act,¹⁴³ but the research to get there is not exempt. So if you really want to spur innovation, probably the way to do it would be to make pure research free of infringement, but commercial activities actionable.

I don't know what the panel thinks about that.

MR. RICHARDS: I would just make a comment on that because I did a paper at this year's Fordham Conference on that particular topic.¹⁴⁴

The situation in Europe isn't quite as you paint it because we've got some German Supreme Court decisions which say you cannot distinguish between commercial and noncommercial experimental use nowadays, which means that they are finding difficulty.¹⁴⁵ The idea that people should be able to do research

¹⁴² See, e.g., *Kilnische Versuche II*, [1998] R.P.C. 423, 431-33 (German Supreme Court 1998) “[A]ll experimental activities which relate to the object of the invention should be exempted. This exemption should be granted regardless of any additional motivations that might be taken up and to which purposes the obtained results will ultimately be determined to serve.” See *id.*

¹⁴³ 35 U.S.C. § 271(e) (2005).

¹⁴⁴ See generally *Fordham University School of Law Thirteenth Annual Conference on International Intellectual Property Law and Policy*, at <http://www.fordhamconference.com/> (last visited May 16, 2005).

¹⁴⁵ Tom Saunders, *Renting Space on the Shoulders of Giants: Madey and the Future of the Experimental Use Doctrine*, 113 *YALE L.J.* 261, 264 (2003).

and they shouldn't infringe a patent is appealing on its face. What I argued in the paper that I gave in the spring was that we need some sort of fair use exception in patent law, similar to that which exists in copyright law.¹⁴⁶ But I think it is a horribly difficult balancing test to try and work out exactly where that fair use boundary line should come out.

That is obviously one element of where the patent system may be harming innovation, but it is not the essence of what we are talking about today, which is whether overly broad patents harm innovation.

QUESTIONER: According to Article I, Section 8, inventors are supposed to be rewarded for their works. The system we have now is, if you have a Nobel Prize-winning invention, it may not become commercially important until more than twenty years after the expiration of the patent.¹⁴⁷ So we really have a system that does not serve the commercial needs or the goals of Article I, Section 8.¹⁴⁸

MR. RICHARDS: Other countries, in the past, have had provisions for extending patents where there has not been adequate remuneration during the normal life of the patent.¹⁴⁹ They have all given them up because they found bigger problems with them than having a system such as we have.

QUESTIONER: Isn't it easier just to come up with some term-of-years after granting the patent? That kind of takes care of the problem.

MR. RICHARDS: No, because that enables you to artificially delay the grant of your patent, which is what used to happen here.

I don't think you finished. If you want to finish your remarks, then we'll move on to the audience.

¹⁴⁶ See 17 U.S.C. § 107 (2000).

¹⁴⁷ See 35 U.S.C. § 154 (2005) (the term of a patent is 20 years).

¹⁴⁸ U.S. CONST. Art. I, § 8, cl. 8.

¹⁴⁹ See, e.g., Review of the Patents Act 1953: The Pharmaceutical Patent Term in New Zealand: Discussion Paper—Patent Term for Pharmaceuticals, at http://www.med.govt.nz/buslt/int_prop/pharmaceutical/discussion/discussion-03.html (noting that prior to 1994, New Zealand's patent law maintained a term of sixteen years with a possible extension of ten years if they can prove inadequate remuneration) (last visited May 15, 2005).

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MS. CRITHARIS: I have some other ones, but I thought that we would handle them as they come. That's why I asked the question about where the real concern lies. Is it the patent law, as far as accommodating a broad spectrum of technologies, or is it the way the Patent Office is perhaps issuing patents that they don't feel were properly examined.¹⁵⁰ I think that is a key distinction.

MR. RICHARDS: I agree with you. I don't think it's an "or," I think it's an "and," because I think both are really happening.

I think the Patent Office does a very good job, but some stuff does get through, inevitably, and probably we need, as Herb has said and as the FTC says, some better way of dealing with that.

But that is not the totality of the issue. The other issue is whether the law itself permits patents which are overly broad, or patents which might harm innovation, because they prevent people from doing research which would otherwise lead to other innovation.

The second half of that, I think, is outside our topic this morning and there are some other issues similar to that which might ultimately lead to the need to amend the patent law.

The question of whether the law permits overly broad patents, even if properly examined, is something which the Federal Circuit of course has been wrestling with in its desperate attempts to work out what the "written description requirement" means over the last several years.¹⁵¹ Two years ago, when Herb and I were on a similar panel, I tried to get Herb to say something about the written description requirement and he declined. I don't know if he is going to decline this morning.

MR. SCHWARTZ: About written description?

MR. RICHARDS: Yes.

MR. SCHWARTZ: I've been litigating both sides of it for companies. I guess the only thing I would say about written

¹⁵⁰ See, e.g., FTC REPORT, *supra* note 2 at Executive Summary, 8–9 (discussing how the USPTO's limited resources curb its ability to properly examine patents).

¹⁵¹ See, e.g., *Univ. of Rochester v. G.D. Searle & Co.*, 375 F.3d 1303, 1305 (Fed. Cir. 2004); *Regents of Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1566–69 (Fed. Cir. 1997) (discussing what constitutes an adequate written description).

description is I believe that there is a statutory requirement for both written description and enablement, and I think both of them have to be there.¹⁵² I think that the written description and enablement should be interpreted in a way that they don't go so far as to pick up after-occurring developments. Namely, it seems to me that if you are going to sweep something into a patent that you did five years later, it ought to be both described and enabled by the original application. That's my basic view on written description and enablement.

MR. RICHARDS: We are all sort of grappling with this sort of horror as to how broadly a patent should be allowed to be based on the original disclosure, or the original contribution to technology.

There was a time when the UK had a provision in its statute that a patent could be invalidated on the ground it was not "fairly based."¹⁵³ That's all it said in the statute.¹⁵⁴ The courts basically interpreted that as saying that you should not be entitled to a scope of protection which went beyond what could soundly be predicted based on the core content of the disclosure.¹⁵⁵ That, I think, is still the law in Australia and India and a few places.¹⁵⁶ It is gone in the UK with the Europeanization of UK law.¹⁵⁷

I have sometimes wondered whether that might be useful, but that again had its problems in its application. It is a difficult issue.

Do you want to say more?

MS. CRITHARIS: I do have a few other comments.

I think it was pointed out that companies have come forward to the FTC saying that the patent system is preventing them from entering the market. That is a fact. The patent system does do

¹⁵² See 35 U.S.C. § 112 (2005).

¹⁵³ Patents Act of 1949, 12, 13, & 14 Geo. 6, c. 87, § 5 (Eng.).

¹⁵⁴ *Id.*

¹⁵⁵ See generally *Univ. of Rochester v. G.D. Searle & Co., Inc.*, 375 F.3d 1303 (Fed. Cir. 2004); *Regents of University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997)

¹⁵⁶ See, e.g., Patent Acts 1990, § 40(3) (Austl.) ("The claim or claims must be clear and succinct and fairly based on the matter described in the specification."), available at <http://www.comlaw.gov.au/> (last visited May 16, 2005).

¹⁵⁷ See, e.g., generally Patents Act 2004 (Eng.) (updating several provision of UK patent law to conform with the European Patent Convention).

that. That is the basis of our patent law. So the fact that other people cannot enter the market with that particular invention is the basis for patent law.

We have a lot of people who come to us and say, “Our patent protection is so important, it’s indispensable to the development of my company.” The thing is, to us the benefit is the patent; even though somebody else cannot enter the market, that information is disclosed and available.

I know the question was raised about whether there is a new invention out there and someone wants to do research on it and they are precluded from doing research on it if it has got any kind of commercial purpose. There is the limited “experimental use” exception that’s not based in statute but is judicially based.¹⁵⁸

Without having the patent law and having the invention disclosed, the third party wouldn’t know it was there to even consider doing research on it. So we have to keep that balance.

We just haven’t seen a lot of evidence—you know, we have heard a lot of people talk about it and speculate—but we haven’t seen companies and researchers say that the patent law is preventing them from investing and doing research. It depends on what side you’re on, and that is important, but overall we have not seen a lot of evidence where research has not progressed as a result of the current policies.

I mean we have had huge development in the biotech industry and in the computer software industries despite patent protection.¹⁵⁹ There has been growth of new industries, predominantly in the United States, and we have probably the strongest patent protection in the world in these areas.¹⁶⁰ So I am

¹⁵⁸ See *Madey v. Duke Univ.*, 307 F.3d 1351 (Fed. Cir. 2002), *cert. denied*, 539 U.S. 958 (2003); *Integra v. Merck*, 331 F.3d 860 (Fed. Cir. 2003), *amended by* Nos. 02-1052, 02-1065, 2003 U.S. App. LEXIS 27796 (June 6, 2003), *petition for cert. filed*, 72 U.S.L.W. 3568 (U.S. Mar 2, 2004) (No. 03-1237).

¹⁵⁹ See, e.g., John Waggoner, *Biotech’s Booms Can Be Tempting*, U.S.A. TODAY, May 7, 2004, at 3B (discussing the rapid growth in the biotech industry between 2003 and 2004).

¹⁶⁰ See, e.g., Janice M. Mueller, *The Evanescent Experimental Use Exemption from United States Patent Infringement Liability: Implications for University and Nonprofit*

not really seeing the correlation between having patent protection and not having development and progress, and that is what the constitutional basis is; to have progress.¹⁶¹ I think there has been a lot of progress here.

Now, I do recognize that sometimes we do issue patents that got through the system and that there are instances where I think everyone would benefit from a post-grant examination proceeding, opposition proceeding, and that is something that we do favor in the US-PTO and we have been looking at for several years now.

But I do agree with David that the patent laws and the patentees are subject to the antitrust laws.¹⁶² That is 100 percent accurate. If there is abuse in the marketplace, then the patentee should be 100 percent liable for that. But just because there are a few bad actors, does that mean there is a need for changing the whole basis of the system?

We talked a little bit about Hatch-Waxman. I think part of the problem with talking about the pharmaceutical industry is that we do have this Hatch-Waxman law that is this very complex mixed hybrid between the patent law and the FDA rules.¹⁶³ But even then, again, there were so many generic applications filed. It was only a small percentage of bad actors again in those cases.

I think that the report reveals what I would call some very serious antitrust-type anticompetitive behavior on the part of, not only the brand name, but also the generic companies who colluded to take this money for just staying off the market.¹⁶⁴

Research and Development, 56 BAYLOR L.REV. 917, 923 (2004) (discussing the United States' lack of a broad statutory experimental use doctrine).

¹⁶¹ See U.S. CONST. art. I, § 8, cl. 8.

¹⁶² See *Chamberlain Group, Inc. v. Skylink Techs., Inc.*, 381 F.3d 1178, 1201 (Fed. Cir. 2004) (citing *CSU, L.L.C. v. Xerox Corp.*, 203 F.3d 1322, 1325 (Fed. Cir. 2000)) (“Intellectual property rights do not confer a privilege to violate the antitrust laws.”); see generally Joel I. Klein, *Cross-Licensing and Antitrust Law* (May 2, 1997), at <http://www.usdoj.gov/atr/public/speeches/1123.pdf> (discussing the intersection of antitrust and patent law).

¹⁶³ See generally Douglas A. Robinson, *Recent Administrative Reforms of the Hatch-Waxman Act: Lower Prices Now In Exchange for Less Pharmaceutical Innovation Later?*, 81 WASH. U.L.Q. 829, 836–840 (2003) (discussing the effect of the Hatch-Waxman Act).

¹⁶⁴ See A. Maureen Rouhi, *Beyond Hatch-Waxman*, CHEMICAL AND ENGINEERING NEWS, Sept. 23, 2002, at <http://pubs.acs.org/cen/coverstory/8038/8038biogenics2.html>

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And there have been some recent changes to the Hatch-Waxman law to prohibit automatic extensions—things like a thirty-month stay,¹⁶⁵ and what has to be listed.¹⁶⁶ Because the new Amendment allows for a second generic filer to obtain an exclusivity period, the first generic filer under the new regime, is not in the same bargaining position.¹⁶⁷

There are other things to be done rather than tinkering with the patent system in whole to address these really bad actors.

MR. RICHARDS: Thank you.

Now we will take from the floor here and then we'll come back to our panelists after we have heard a bit more from the floor. Could you say who you are, please?

QUESTION: Joseph Balacca.

I think part of the problem with identifying certain patents as being overly broad, or just bad patents, is the uncertainty that results from an interpretation of the claims. This is a consequence of the changes brought by the Court of Appeals for the Federal Circuit (“CAFC”) in the meaning of “doctrine of equivalents” and “file wrapper estoppel.”¹⁶⁸ You come to a point in your practice in which you spend an awful lot of money and time examining

(Marketing of generic products can be delayed through various maneuvers—in which generic companies and innovator drugmakers are either pitted against each other *or work hand in hand*) (emphasis added).

¹⁶⁵ See Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355(j)(5)(D)(IV) (2000); 35 U.S.C. §§ 156, 271, 282 (2000)).

¹⁶⁶ *Id.*

¹⁶⁷ *Id.*; see also Laba Karki, *Review of FDA Law Related to Pharmaceuticals: The Hatch-Waxman Act, Regulatory Amendments and Implications for Drug Patent Enforcement*, 87 J. PAT. & TRADEMARK OFF. SOC'Y 602, 620 (2005).

Under the ‘Forfeiture’ clause codified in 21 U.S.C. §355 (j) (5) (D) & (I), a “First Applicant” may forfeit its 180-day exclusivity if it fails to market its product within 75 days after it receives FDA approval or 30 months after ANDA submission whichever is earlier; or 75 days after a non-appealed favorable district court or favorable Federal Circuit court decision has been rendered; or 75 days after a favorable settlement has been entered; or 75 days after the patent expires or is withdrawn.

Id.

¹⁶⁸ See Symposium, *The End of Equivalents? Examining the Fallout after Festo*, 13 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 727 (2003) (discussing the effect of file wrapper and presecution history estoppel on the doctrine of equivalents).

competitors' patents and trying to determine exactly what is covered by them. Then you look at it, you order up the file wrappers, and you have no basis for telling your client exactly what is claimed because of the uncertainty brought about by claim interpretation.¹⁶⁹ The claims should be limited to what they recite and you should be able to depend upon that.

If the CAFC and the Supreme Court could produce a final, definitive statement as to what constitutes "doctrine of equivalents" and "file wrapper estoppel," and make them narrow enough to be understandable and fairly applied across all different technologies, that would go a long way to removing these questionable patents. Then, companies could then rely upon advice of counsel as to what is permitted and what is not permitted.

Any comments?

MR. SCHWARTZ: I think it is a great idea, but I don't know if it is practical. The doctrine of equivalents—people have tried to figure out how to deal with that for hundreds of years—and ultimately it's an equitable doctrine, occasionally applied on a case-by-case basis when it is needed.¹⁷⁰ It is really no more than that, and I don't see how you would define it in any precise way.

File wrapper estoppel is different. I think you can have rules for that. I think the Federal Circuit is trying to sort that out in *Festo* and its progeny,¹⁷¹ and maybe we'll get some closure on that in the next ten years, when the last few cases are decided.

So I think there will be some more certainty in file wrapper estoppel,¹⁷² but on doctrine of equivalents, I think its whole

¹⁶⁹ See *id.* (noting that the Federal Circuit reverses district courts fifty percent of the time on claim interpretation).

¹⁷⁰ See 60 AM. JUR. 2D *Patents* § 786 (noting that the doctrine is a highly factual inquiry that is applied at the time of infringement).

¹⁷¹ See *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 740 (2002) (holding that prosecution history estoppel arises when an amendment is made to secure a patent and narrow the scope of the patent).

¹⁷² See *Narda Microwave Corp. v. General Microwave Corp.*, 675 F.2d 542, 549 (2d Cir. 1982) (holding that a patent that preceded the sale of another item was not novel in design); *Square Liner 360, Inc. v. Chisum*, 691 F.2d 362, 370 (8th Cir. 1982); *Ingersoll-Rand Co. v. Brunner & Lay, Inc.*, 474 F.2d 491, 497–98 (5th Cir. 1973); 60 AM. JUR. 2D *Patents* § 291.

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purpose is not to have certainty.¹⁷³ Therefore, I think you always need it for certain cases.

MR. RICHARDS: As one who was brought up in the UK, which has a tradition of literal claim interpretation, that has its problems as well.¹⁷⁴ There is an advantage to having a penumbra around the case to deal with the exceptional circumstance where you need it, and that clearly makes it difficult to give advice. But that's what we're paid for.

PARTICIPANT: Also we're waiting for the en banc decision on claim construction.¹⁷⁵ It would be nice if the panels at the Federal Circuit were consistent, but they are not.¹⁷⁶ So it really is the luck of the draw on the day you walk in for your argument. I'm looking forward to seeing what they have to say in the latest en banc decision on claim construction.

MR. RICHARDS: It's astonishing that we have had claims since 1832, and in the present form since 1870 and the Federal Circuit sends out a request saying "please tell us what we're supposed to do with these."¹⁷⁷ It's absolutely astonishing in my view.

PARTICIPANT: Don't you think that some of the discrepancy in the written description recurrence stems from case law that interprets it before we had claims in the patent system which kind of elevated the requirements to a different level for interpreting?

¹⁷³ See 60 AM. JUR. 2D *Patents* § 786 (noting that the inquiry is highly factual and applied at time of infringement).

¹⁷⁴ See, e.g., *Festo*, 535 U.S. 722 at 731–33. "If patents were always interpreted by their literal terms, their value would be greatly diminished." *Id.* at 731.

¹⁷⁵ See *Phillips v. AWH Corp.*, 375 F.3d 1382 (Fed. Cir. 2004) (No. 03-1269) (order granting rehearing en banc); see generally Gregory A. Castanias, *Intellectual Property Commentaries: A Report on the Federal Circuit's En Banc Oral Argument on The Rules of Patent Claim Construction* (Feb. 2005), at http://www.jonesday.com/pubs/pubs_detail.aspx?pubid=39465603 (discussing the pending *Phillips v. AWH* case) (last visited Apr. 3, 2005).

¹⁷⁶ See Gregory J. Gallagher, *Recent Development: The Federal Circuit and Claim Construction: Resolving the Conflict between the Claims and the Written Description*, 4 N.C. J. L. & TECH. 121, 121 (2002) (Comparing the Federal Circuit's "canons of construction" between the written description of a claim and the claim itself. One may not read limitation into a claim from a written description or one may look to a written description to determine meaning in a claim.).

¹⁷⁷ See Patent Act of 1870, 16 Stat. 198 (1870).

You know, we have the 1952 Act,¹⁷⁸ and we do have claims, but a lot of the cases that I have seen the court relying on are from the era before the Act.¹⁷⁹

MR. RICHARDS: We have had claims in their present formulation since about 1870 and we have had claims in some form since 1832. There is not much pre-1832 case law.

MR. SCHWARTZ: I think the written description requirement stems from a fundamentally different path than the enablement requirement.¹⁸⁰ The written description requirement stems from the notion that when someone reads your patent, they should have some understanding of what your invention is.¹⁸¹ The courts said that you “possess” your invention.¹⁸²

The requirement exists so that, when reading the patent, the reader can get some idea of the scope of it by reading it apart from what the words of the claim say. That is really a different requirement than enablement, which is a requirement that says you have to teach how to do it.¹⁸³ So I think they are separate and distinct, and there are reasons for each.

¹⁷⁸ The Patent Act of 1952, Pub. L. No. 82-593, ch. 950, 66 Stat. 792 (codified as amended in scattered sections of 35 U.S.C.(2000)).

¹⁷⁹ See, e.g., *Festo*, 535 U.S. 722 at 732 (citing *Winans v. Denmead*, 56 U.S. 330, (1854)).

¹⁸⁰ See, e.g., *Noelle v. Lederman*, 355 F.3d 1343, 1348 (Fed. Cir. 2004) (noting that an applicant must convey with clear and convincing clarity in a written description that he was the first to possess it, whereas an enablement only explains how to make and use the invention).

¹⁸¹ See, e.g., *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 922 n.5 (Fed. Cir. 2004) (noting that the written requirement teaches the public how to use an invention in exchange for a limited monopoly on that patent).

¹⁸² See *Noelle*, 355 F.3d at 1348 (“The purpose of the ‘written description’ requirement is broader than to merely explain how to ‘make and use’; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention.”) (emphasis in the original); *Application of LeGrice*, 301 F.2d 929, 1134 (C.C.P.A. 1962).

We think it is sound law, consistent with the public policy underlying our patent law, that before any publication can amount to a statutory bar to the grant of a patent, its disclosure must be such that a skilled artisan could take its teachings in combination with his own knowledge of the particular art and be in possession of the invention.

Id.

¹⁸³ See *Noelle*, 355 F.3d at 1348 (noting that enablement merely requires an applicant to convey how to “make and use” an invention).

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I don't think it is just caused by the 1952 Act. There plainly are at least three judges in the Federal Circuit who would like to get rid of the written description requirement.¹⁸⁴ I'm not so sure why, but they plainly want to do that. I mean it's no mystery. It's just Judge Rader and a couple others.¹⁸⁵ Whether that will happen or not is hard to know.

But, at least at the moment, I think the requirement exists and it will continue. If you listen to the ones who want to get rid of it, they want to leave it in priority contests and get rid of it everywhere else.

MR. RICHARDS: Can you give your name, please?

QUESTION: Michelle Baker. I'm an individual.

It seems to me that the question of patent thickets is a very different issue, a very different problem, from overly broad patents.¹⁸⁶ The remedy should be very different. Generally, patent thickets are overly narrow patents or many narrow patents.¹⁸⁷ Maybe there doesn't even need to be a remedy in that case because you can invent around this problem, assuming that you get around the cost of figuring out what the patent actually is claiming. So by lumping patent thickets with overly broad patents, I think you will find the wrong remedies.

¹⁸⁴ See *Moba v. Diamond Automation, Inc.*, 325 F.3d 1306 (Fed. Cir. 2003) (per curiam), *cert. denied*, 124 S. Ct. 464 (2003).

¹⁸⁵ See *id.* at 1322–27 (Rader, J. concurring) (arguing that “by making written description a free-standing disclosure doctrine, [the Federal Circuit] produces numerous unintended and deleterious consequences”).

¹⁸⁶ Michael R. Taylor & Jerry Cayford, *American Patent Policy, Biotechnology, and African Agriculture: The Case for Policy Change*, 17 HARV. J.L. & TECH. 321, 349–50 (2004).

This pattern—the increasing number of patents, increasing patent breadth, and the issuance of patents on more basic discoveries—has created what some call a patent thicket in biotechnology: ‘an overlapping set of patent rights requiring that those seeking to commercialize new technology obtain licenses from multiple patentees.’ The patent thicket is a problem because useful innovation in biotechnology requires multiple inventive steps and technologies. The field of biotechnology is particularly dependent on the cumulative work of many researchers, and therefore is vulnerable to the ‘anticommons’ problem mentioned earlier.

Id.

¹⁸⁷ See Janet L. McDavis & Minda Schechter, *The FTC's Recent Report*, NAT'L L.J., Dec. 8, 2003, at 13.

MR. RICHARDS: I think the patent thicket issue tends to come up in those industries where you've got multiple patents on a particular product. Then, everybody needs to get their patents to trade, to get a license from somebody else to be able to put the product on the market, which tends to be the electrical end of the spectrum rather than the chemical end of the spectrum.

QUESTIONER: That's right. But if you think about the fact that each patent is presumably an innovation of some sort, when you have a patent thicket, generally those thickets are minor innovations, or you could at least make that argument. There are costs.

MR. BYE: The CEO of one of the businesses that came in to us testified that he gave a whole series of patents on a particular area of software technology to his engineers and said, "Can you get a sense of what the patent landscape is?" The engineers went away and they came back a week later and they said, "We really have no idea. We think all these patents probably infringe on each other and they probably infringe our product, and we really can't be sure either way."

Thickets definitely are a different problem to overly broad patents.¹⁸⁸ There is no clear solution to it. It is a matter of making sure that you issue patents that do comply with the statutory requirements and doing things like that. There is no master stroke, unfortunately, that you can do to solve a problem like that.

MR. SCHWARTZ: I don't know why you would rely on engineers to decide on the scope of patents. That's why you have lawyers. So that doesn't make any sense to me at all.

QUESTIONER: Well, also, patent thickets are only relevant to big firms. What they do is sort of defensive patenting and they're just trading off the rights. They do not necessarily promote innovation.¹⁸⁹

¹⁸⁸ See generally *id.* (describing patent thickets as arising from numerous narrow patents and not overly broad patents).

¹⁸⁹ See Symposium, *Biotechnology Patents Get Special Treatment, Biotechnology in the Federal Circuit: A Clockwork Lemon*, 46 ARIZ. L. REV. 441, 451–52 (2004) ("Patent thickets block follow-on innovation; an innovator must metaphorically cut her way through the underbrush in order to complete a project that she wants to accomplish.") (statement of Dan L. Burk); see also Mueller, *supra* note 163 at 944–45 n.130.

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MR. SCHWARTZ: I think the phrase, “patent thicket,” gets used in two different contexts. I agree that in one context it’s used by one person who has a lot of different patents covering different features, and that has certainly been done in the past. I think it is also used in your context, by a lot of different people that have patents that are arguably overlapping or arguably one is an improvement on the other, and that in itself becomes a “thicket.”¹⁹⁰

In a number of industries, the practical resolution of this problem has been standard-setting and licenses under standards.¹⁹¹ At least in a lot of industries that has really worked out pretty well. You don’t need the FTC to hit you over the head to decide to do that. In an awful lot of the electronic and telecommunications industries that’s what they have.¹⁹² There are standard-setting organizations and arrangements to license patents in standard-setting organizations. In most situations that works reasonably well.¹⁹³

To me, again, it’s a pejorative term that doesn’t follow as much in the real world.

QUESTION: My name is Raymond Dowd. My area of practice is copyright and trademark litigation. I am not a patent attorney.

¹⁹⁰ Compare Bessen, *supra* note 58, at 1 (stating thickets “occur when each product [involves] many patents . . .”) with McDavis & Schechter, *supra* note 187, at 13 (discussing narrow patents as the basis for patent thickets).

¹⁹¹ See Letter from Joel I. Klein, Assistant Attorney General, Department of Justice, Antitrust Division, to Gerrard R. Beeney, Esq. (Dec. 16, 1998) at <http://www.usdoj.gov/atr/public/busreview/2121.htm>. (last visited May 16, 2005) (noting how cross-licensing has allowed innovation in the DVD industry).

¹⁹² See Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, in 1 *INNOVATION POLICY AND THE ECONOMY* 119, Abstract (Adam B. Jaffe et al. eds., 2001) available at <http://faculty.haas.berkeley.edu/shapiro/thicket.pdf> (last visited May 9, 2005).

The need to navigate the patent thicket and hold-up is especially pronounced in industries such as telecommunications and computing in which formal standard-setting is a core part of bringing new technologies to market. Cross-licenses and patent pools are two natural and effective methods used by market participants to cut through the patent thicket, but each involves some transaction costs.

Id.

¹⁹³ See *id.*

I was wondering if there has been discussion over developing some sort of compulsory licensing system, particularly where the U.S. government funds the innovation that leads to the creation of a patent. Would a system of compulsory licensing make sense to any of the members of the panel as a resolution to some of these issues?

MR. SCHWARTZ: First of all, for government funding, I think there usually is compulsory licensing.¹⁹⁴ But as far as the United States goes, one of the reasons that people, especially in the pharmaceutical industry, are very much opposed to compulsory licensing is they believe that would be the death knell of innovation.¹⁹⁵

The heart of the matter is that it is not coincidental that the major pharmaceutical research in the world is done in the United States, which is one of the few countries that has a strong patent system with no compulsory license. That justifies the investment, at least in pharmaceuticals, to be worth bringing it to market.¹⁹⁶

There may be circumstances where compulsory licensing makes sense—and some countries are in favor of it—but I think the basic notion has been debated for 200 years at least and has been continually rejected up until now.

MR. RICHARDS: Sir?

QUESTION: My name is Jean-Paul Ciardullo. I'm a staff member of the Journal.

When you were talking about overlapping and overly broad patents being issued to the same companies or individuals, what do

¹⁹⁴ See The Bayh-Dole Act, Pub. L. No. 96-517, 94 Stat. 3015 (codified as amended at 35 U.S.C. §§ 200–212 (2004)).

¹⁹⁵ See Adi Gillat, *Compulsory Licensing to Regulated Licensing: Effects on the Conflict Between Innovation and Access in the Pharmaceutical Industry*, 58 FOOD & DRUG L.J. 711, 716 (2003) (noting that the grant of a license without the patent holder's authorization limits the exclusivity period and allows the recipient to engage in competitive imitation, which would lessen the original incentive to innovate).

¹⁹⁶ See Alan M. Fisch, *Compulsory Licensing of Pharmaceutical Patents: An Unreasonable Solution to an Unfortunate Problem*, 34 JURIMETRICS J. 295, 304 (1994) (attributing the financial growth of the pharmaceutical industry to exclusivity provided by patent law).

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you think the role of terminal disclaimers could play in abating that problem?¹⁹⁷

MR. SCHWARTZ: I think terminal disclaimers are useful and you have them when they are appropriate, but I don't think they really deal with what the FTC is talking about.

MS. CRITHARIS: Terminal disclaimers are filed only by the same applicant, so you cannot have them for different companies.¹⁹⁸ It is only when there is double-patenting involved and it is the same inventive entity.¹⁹⁹ So the fact that you have different companies out there, you really do not have terminal disclaimer practice.

QUESTIONER: Even for, let's say, the same company, if you have one pharmaceutical company that is coming in and trying to get perhaps unfair extensions on what is effectively the same product?

MR. SCHWARTZ: I think nowadays you are really stuck with a twenty-year term.²⁰⁰ I think the twenty-year term has really eliminated all of that. You are stuck with a twenty-year term from date of application and that does offer you protection within that time.²⁰¹

I think you have to terminally disclaim. You've got to terminally disclaim the continuations because you're stuck with it anyway.

QUESTIONER: Just one more comment. When we talk about extensions of patents, especially in the pharmaceutical area, that is really no longer innovation; that is just trying to keep the product on the market that has already been innovated maybe twenty years earlier. So I don't see that activity as putting a chilling effect on true innovation where you have to look at projections into the future. The technology developed today may not become a

¹⁹⁷ See 37 C.F.R. § 1.321(a) (2005) (a terminal disclaimer is used when an applicant has two or more applications pending wherein the subject matter is so closely related it appears that it is an attempt to get numerous patents on the single invention).

¹⁹⁸ See 37 C.F.R. § 1.321(a) (2005).

¹⁹⁹ See USPTO MANUAL, *supra* note 37, § 804.02

²⁰⁰ See 35 U.S.C. § 154(a)(2) (2002).

²⁰¹ See *id.*

commercial reality for another twenty years. So I just see that as kind of holding on to what you already have, rather than what you will have. I don't think it has a chilling effect on true innovation.

What does the panel think?

MR. RICHARDS: I think the problem in the pharmaceutical industry tends to be where you come up with a new formulation towards the end of the life of the basic patent. You decide that a particular polymorph, a particular form of the crystallized product, is the thing which is really the great thing rather than the sort of generic disclosure that you had twenty years ago.

There are arguments, pro and con, on that. There is no reason why—if it really is an invention—just because it is relatively minor as compared to the main one, that you shouldn't be entitled to a patent for it. The other question is, is it really an invention, and that's where the examination issue comes up again.

MR. BYE: The critical thing is the presence or absence of generic competition. Where you have this sort of patent life extension, you may be preventing generic companies from entering those markets, thereby denying consumers low-cost drug products.²⁰² Innovation is critical. Competition is also critical. You have to have both components and you have to have them working in some balance.

QUESTION: That was my only point. That is the competition. But I don't think it has any chilling effect on innovation or on new technologies that would spur our economy as a country in the future. That is my feeling.

MS. CRITHARIS: I would like to add that before the enactment of Hatch-Waxman,²⁰³ which was in 1984, the generic market was a very small component of the marketplace—I think it was less than 19 percent.²⁰⁴ Since Hatch-Waxman, it is now,

²⁰² See Chris Adams & Gardiner Harris, *Drug Makers Face Battle to Preserve Patent Extensions*, WALL ST. J., Mar. 19, 2002, at A24.

²⁰³ Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. §355 (2000); 35 U.S.C. §§ 156, 271, 282 (2000)).

²⁰⁴ See Merrill Matthews, *Patent Protection for Me, But Not For You*, June 14, 1002, at <http://www.cnehealth.org/pubs/IPI-PatentProtection.pdf> (noting that “the generic industry

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according to the FTC report, upwards of 45 or 50 percent.²⁰⁵ So the Hatch-Waxman Act did really spur generic competition, which is a great thing.²⁰⁶ I mean we are trying to find just the right balance, which is a difficult thing, especially in the pharmaceutical area. We are talking about access to medicines.

But I think it is important to point out that patents get a twenty-year term from filing.²⁰⁷ The problem in the pharmaceutical area is that even though you may get a patent, you might not get marketing approval from the FDA to enter the market until much later. That is why it is important to have some kind of patent term—we don't call it "extension"—restoration, because that patentee had no market exclusivity at all because he can't enter the market until he gets FDA approval.

Studies have indicated that the average life of a pharmaceutical patent is really only about ten or eleven years because they have lost all that time in regulatory approval.²⁰⁸ So there is just a mechanism to compensate the patent owner, to at least get some more exclusivity—not more than other patentees, but just to give him some, because in some cases they are left with five or seven years, and that is really just not enough.

MR. BALTO: Wait. I can't let you get away with that. They have a monopoly for the five-to-seven years, or three years, or whatever it is, and they will price at the monopoly price, and they will recover what they recover, whether you give them an

has also prospered under Hatch-Waxman. Its share of the prescription drug market has grown from 19 percent of the volume in 1984 to 47 percent in 2000, according to IMS Health).

²⁰⁵ See Ashoke Bhattacharjya, *FTC Health Care Workshop Panel on Branded and Generic Pharmaceuticals* (Sept. 10, 2002), at <http://www.ftc.gov/ogc/healthcare/bhatta.pdf> (Sept. 10, 2002).

²⁰⁶ See *id.*

²⁰⁷ 35 U.S.C. § 154(a)(2) (2002).

²⁰⁸ See The Biojudiciary Project, *Patent Life, Generic Drugs, and the Drug Approval Process*, at <http://www.biojudiciary.org/subpage1.asp?tid=110> (last visited May 9, 2005). ("the long FDA approval process strips a large fraction of the twenty-year patent term and decreases the patent life of a drug.").

eighteen-year patent or a three-year patent. That's what economics shows.²⁰⁹

But I want to go back to a point you made earlier about questionable patents. I don't want—well, actually, personally I do want—all of you to leave the room and think that there is no problem of questionable patents, because that means that Matthew and I will have enough work to do when you misinform your clients in the future about what they can and cannot do. That will result in substantial legal fees to my law firm.

It is very valuable to read the testimony of the FTC hearings.²¹⁰ You hear this over and over again in the testimony from business people in many different industries.²¹¹ The problem is that they are spending money to go and create patents and to do regulatory filings, so that they are in a bargaining position to enter into cross-licensing arrangements.

I have no qualms about protecting intellectual property rights when what is being protected is real invention, when what is happening is protecting the incentives to innovate. But when what you are doing is creating regulatory gauntlets, wars of mutual destruction, where people just try to overwhelm each other with patent filings and creating mutually adverse thickets, I don't think you are creating any kinds of incentives as to innovation.

One more point. The important empirical studies that are cited in the FTC report²¹²—you know, are patents questionable? What happens when patents are effectively litigated? They are oftentimes struck down. They are struck down a remarkably great amount of times.²¹³

²⁰⁹ See, e.g., generally *Grid Systems Corp. v. Texas Instruments Inc.*, 771 F. Supp. 1033, 1038 (N.D. Cal. 1991) (noting that a patent holder may charge the maximum price that the market can bear).

²¹⁰ *Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy*, at <http://www.ftc.gov/opp/intellect/index.htm> (last visited May 9, 2005) (listing the relevant hearings and providing links to speeches).

²¹¹ See FTC REPORT, *supra* note 2, at Executive Summary, 5–7 (summarizing the various testimony by industrial representatives on defensive patent practices and patent thickets).

²¹² See, e.g., FTC REPORT, *supra* note 2, at ch.2, p. 11.

²¹³ See, e.g., Univ. of Houston Law Center, *U.S. Patent Litigation Statistics*, at <http://www.patstats.org/> (last visited May 9, 2005). (illustrating the number of times a

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Now, you may say that is not a problem because there are plenty of avenues for people to challenge patents or bring antitrust suits to challenge anticompetitive activity.²¹⁴ The problem identified by the FTC report is that not everybody can sue, not everybody has the resources to go and sue and try to challenge an invalid patent, especially the way the patent litigation system is currently set up.²¹⁵

So the FTC report says, “Here are a few adjustments to the patent litigation system that will make it work more effectively.”²¹⁶ It doesn’t say, “Let’s go and cut back on these rights substantially” or anything like that. It is just saying, “Let’s overcome these barriers so people can truly vindicate their intellectual property rights or appropriately challenge them.”²¹⁷

MR. SCHWARTZ: I couldn’t disagree more. It just seems to me that’s simply not so. There are two pieces to the FTC report.²¹⁸ The piece about having an alternative mechanism for challenging patents is not new at the FTC.²¹⁹ They have just hopped on the bandwagon of lots of other people. There needs to be a way to challenge patents in the PTO. Everyone agrees with that.

The second piece of it, which David calls tinkering and the FTC calls tinkering, is a fundamental change in the law to make it easier to invalidate patents.²²⁰ That is really what is going on in the FTC report.

patent owner prevailed compared to the number of times an alleged infringer prevailed between the years of 2000 to 2004)

²¹⁴ See, e.g., United States Patent and Trademark Office, Report to Congress On Inter Partes Examination, at <http://www.uspto.gov/web/offices/dcom/olia/reports/reexamreport.pdf> (discussing the *inter partes* challenges to patents).

²¹⁵ See FTC REPORT, *supra* note 2, at Executive Summary, 6 (stating that existing avenues to challenging patent validity or assess potential infringement present prohibitive costs).

²¹⁶ See *generally id.* at Executive Summary, 7–17 (discussing the FTC’s proposed reforms).

²¹⁷ See, e.g., *id.* at ch. 5, 31–32.

²¹⁸ See *generally* FTC REPORT, *supra* note 2. (discussing FTC recommendations to allow post-grant review and to change the standard of review for evidence necessary to invalidate a patent)

²¹⁹ See FTC REPORT, *supra* note 2 at 7–9 (discussing new legislative recommendations).

²²⁰ See *id.* at Executive Summary, 8–11.

That is what is going on by changing the burden of proof from clear and convincing evidence, to a mere preponderance of the evidence standard.²²¹ As someone who has litigated patents, I know of no single change effected by the Federal Circuit that had more long-term effect in sustaining patents' validity. I think that this goes to the heart of the FTC's attempt and desire to, in effect, get rid of that and erode that and turn it back to the days when patents are, as a practical matter, presumed invalid.²²²

That's what this is all about, and I decry it as a terrible idea, not a little tinkering.

MR. BALTO: Herb, let's just stick with that last idea about the burdens of proof. I, as just a general litigator look at that and say, "I think the FTC's argument is sound about why it shouldn't be clear and convincing." You know, when you look at general litigation, this looks like the appropriate thing for a challenge under the preponderance of the evidence standard. Maybe Matthew knows more examples than I do. But clear and convincing just basically sets such a high bar that very few people are going to be able to effectively challenge the patents.²²³

MR. SCHWARTZ: That's contrary to what you said a few minutes ago, where 50 percent of patents are held invalid. That can't possibly be. The standard has allowed significant numbers of patents to be held invalid.

The previous standard of preponderance of the evidence was such that, ultimately it got to the point where the Supreme Court said, "No patent has been held to be valid that has ever come

²²¹ Brenda Sandburg, *FTC Floats Controversial Plan* (Oct. 29, 2003), at <http://www.law.com/jsp/article.jsp?id=1067350952811>; Anna Vishey, *Patent Industry Responds to FTC Recommendations* (Fall 2004), at <http://www.srz.com/PDF-files/ip-fa04-vishev.pdf>. (discussing the FTC's proposed reduction of the standard of "clear and convincing evidence" to a "Preponderance of evidence" for the invalidation of patents) to reduce litigation risk)

²²² David C. Bohrer, *Knocking the Eagle Off the Patent Owner's Shoulder: Chiron Holds that Jurors Don't Have to Be Told That a Patent is Presumed Valid*, 21 SANTA CLARA COMPUTER & HIGH TECH. L.J. 259, 271-72 (2004).

²²³ See Symposium, *Ideas Into Action: Implementing Reform of The Patent System: Reforming Patent Validity Litigation: The "Dubious Preponderance,"* 19 BERKELEY TECH. L.J. 923 (2004)

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before us.”²²⁴ The Federal Circuit was trying to put some balance into the enforcement of patents and to get rid of the notion that, at least in the Eighth Circuit, no patent was sustained for thirty years. That is what you got with the preponderance of the evidence standard.

I think clear and convincing was an attempt to remedy it. As far as I know, considering the numbers of patents that are held invalid, which I think is still very high²²⁵, it suggests that it is still working.

That doesn't go to the other point, which I agree with: that you need an additional way to deal with patents in the PTO. Simply going to litigation is not a sensible solution for an awful lot of controversies. To me, that is the most important thing. The FTC is certainly on the right bandwagon on that, but it is very different than to me changing the standard of proof.

MR. BYE: The number of patents that are invalidated, the statistic is not the critical thing. If you say, “Well, 50 percent are invalidated; therefore, that's a good amount,” that is essentially a meaningless number.

The critical question is: is the standard that we are applying appropriate for the examination that the patents get? The current standard is deemed too high for three main reasons.

One is that patent law and patent regulations favor the applicant. There are a number of presumptions that basically force examiners to issue things unless they can essentially produce a counter-argument.²²⁶ These examiners are operating under very tight time constraints, as I mentioned before, eight to twenty-five hours. So the burden is essentially put on them to rebut the application.

²²⁴ *Jungersen v. Ostby*, 335 U.S. 560, 572 (1949) (“[I] doubt that the remedy for such Patent Office passion for granting patents is an equally strong passion in this Court for striking them down so that the only patent that is valid is one which this Court has not been able to get its hands on.”) (Jackson, J. dissenting).

²²⁵ See Univ. of Houston Law Center, *supra* note 213.

²²⁶ See *Chester v. Miller*, 906 F.2d 1574, 1578 (1990) (describing how 35 U.S.C. 132 can be violated by an examiner for failing to provide adequate reasons for rejecting a patent application).

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Second, the whole examination process is *ex parte*,²²⁷ there is no one else involved, so the patent sort of slides through. And it is examined on a preponderance standard.²²⁸

Third, when the patent is issued and you take it to court, suddenly the standard to protect it is clear and convincing.²²⁹ There is an imbalance there. The treatment that it gets in the examination stage doesn't warrant that higher standard when it gets into court.

I will confess there have been quite strong reactions to this recommendation. Some patent litigators say it is the worst thing that could ever be done to the patent system. But there are also many other patent litigators who said, "Yes, actually we think that's a really sensible idea. We think that would be an improvement to the system." It is not clear what the correct view is, but I think this is an important issue and needs to be considered.

QUESTION: But, patents are not just granted without any foundation. I have been involved in litigation in getting patents. If you think it is that easy, it isn't. When you have an examiner who is really giving you a hard time on certain issues, those issues are thoroughly documented on the record.

I think what Herb is saying is that the standard that we currently face in litigation takes into account the fact that you have had this examination on the merits. If you find evidence that wasn't part of that record, then you can more easily meet the clear and convincing standard.

Do you disagree, Herb?

MR. SCHWARTZ: No, I don't disagree with that at all. To me, in practice the clear and convincing standard has been working well.

QUESTIONER: It makes sense.

²²⁷ 35 U.S.C. §§ 302, 307 (2002).

²²⁸ See USPTO MANUAL, *supra* note 37, § 2142.

²²⁹ See David W. Okey, *Issued Patents and the Standard of Proof: Evidence Clear and Convincing or Merely Ponderous*, 17 JOHN MARSHALL J. COMPUTER & INFO. L. 557 (Winter 1999), available at <http://www.jcil.org/journal/articles/206.html>.

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MR. SCHWARZ: There has been no hue and cry against it. In fact, the only organization that has really come out and tried to change it is the FTC, who fundamentally wants to get rid of patents anyway.

QUESTIONER: I mean we're not South Africa, which just issues patents without examination.

MR. BYE: Can I just say that's absolutely not true that we want to get rid of patents.

MR. SCHWARTZ: You certainly do.

MR. BYE: Throughout the entire report it discusses how important patents are to driving innovation. They are a critical aspect in many industries. We might not even have some industries without them.

Back in the 1960s and the 1970s, the patent and antitrust doctrines tended to butt a lot of heads, and many of the problems were due to antitrust enforcement,²³⁰ which wasn't really anchored in any conceptual framework. Since the early 1980s and moving forward, antitrust has incorporated economics into its analysis and its treatment of patents is quite different to what it used to be.²³¹ The FTC firmly acknowledges the importance of patents. So I think it is important to correct that misperception.

MR. SCHWARTZ: I would suggest you to read the report of the National Science Foundation, called "A Patent System for the 21st Century."²³² That was a group that does not have a particularly either pro-patent bias or anti-patent bias. They happen to be a group of people on all sides of this subject. They have written a very, I think, interesting and provocative report.

They agree on the basic notions of strengthening the patent system by having a post-application review system and strengthening the Patent Office.²³³ They do not, at all, get into what I would consider to be the more controversial patent-bashing

²³⁰ See Gary Stix, *IP Rights – And Wrongs*, SCI. AM., May 2002, at 38, available at <http://www-rcf.usc.edu/~engrtutr/IPRights.pdf>. (discussing the effect of aggressive antitrust enforcement on patent applications)

²³¹ See *id.* (noting the increase in the number of patents granted from 1980 to 2001)

²³² NAS REPORT, *supra* note 73.

²³³ See *id.*

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aspects of the FTC report, and that is really the startling difference between the two.

When you look at the people who put this together and you look at the FTC report, you are left with the conclusion that, no matter what the gentleman says here, the FTC is fundamentally looking for a mechanism to weaken patents.²³⁴

The National Science Foundation report is an attempt to look at both sides of this problem and see what can be done to strengthen innovation overall and look at the good, the bad, and the ugly and try to clean up the system.²³⁵ In other words, I think that it is a balanced and fair report and I don't believe that is true with the FTC report. I think if anyone would read the two, you would begin to understand why I say that.

MR. RICHARDS: Mary wants to say something.

MS. CRITHARIS: I have a question. I've pretty much only worked for the Patent Office. I worked in private practice before for a little while, and I did work at the Solicitor's Office in the Patent Office, which defends the cases.

My understanding has always been, from most litigators, that when you go to litigation, there is not an issue of whether there was a good examination or not. The issue is litigation usually involves the introduction of prior art that was not considered by the examiner doing the prosecution of the application.

But I think to make the implication that Matthew was making, that things slide by, I think that is a little incorrect.²³⁶ I was an examiner for five years. I issued about nine or ten patents a year. That's a very low percentage rate. Most of the people in our unit had a very low percentage rate. Because it was chemical arts, a lot of stuff was pretty much already known. It is different in some of the other areas.

²³⁴ See generally FTC REPORT, *supra* note 2, at ch. 1, pp. 18–23 (stating the patent protection was strengthened by the courts during the 1980s and implying a better balance must be reached to achieve proper competition).

²³⁵ See NAS REPORT, *supra* note 73. (suggesting reforms to the current system of patents)

²³⁶ See *supra* text accompanying note 227.

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But I don't know if it is fair to necessarily say that a poor-quality patent gets litigated. Some things go to litigation and I don't know if it has to do with whether the quality of the patent is poor.

So I guess I'd like to ask Herb, and the others what their experience is with that.

MR. SCHWARTZ: As I said, I have never heard of the concept, other than in the FTC report, of what they call "poor-quality patents."²³⁷ Usually when you litigate patents and you are litigating the issue of validity, it is about art that wasn't before the Patent Office. It is very rare in this day and age to re-litigate over art that was before the Office. When all is said and done, the art usually has been considered by the Office and it is very hard to persuade a hearing officer that it should come out differently.

I don't think that it matters whether the standard is clear and convincing or a preponderance of the evidence. The usual issues are new art or publications—a lot of times it's publications that the Office didn't see—and certainly if the art is a prior public use it raises issues of invalidity that most likely could not have been before the PTO office.

So I think a lot of the issues are ones that could never have arisen in the Patent Office. I've been involved on both sides of this argument: whether or not the arguments made in the Patent Office should have persuaded the Office differently. Ultimately, it is a very hard argument to make out either way.

MR. BALTO: Matthew, you would be doing a disservice to yourself to accept on face value what Herb tells you about the FTC report. It would be sort of like watching the American League Championship Series and turning off the TV after the third game.

If you look at the specific chapter that deals with the point that we are rigorously debating,²³⁸ you will see a very moderate, even-handed tone going to the burden of proof issue, and not using pejorative terms, as is suggested. Rather, this chapter looks very

²³⁷ See FTC REPORT, *supra* note 2 at Executive Summary, 5.

²³⁸ *Id.* at ch. 5.

carefully at what is being patented and the obstacles such patents create for innovation.²³⁹

That is the issue that we are faced with on this program today: is the intellectual property regulation working in such a fashion that it actually stifles innovation?

MR. RICHARDS: Matthew?

MR. BYE: I would commend the National Academy's report to people. I think it is a fabulous report. All the evidence that they used in that report is exactly the same evidence that we rely on in our report.²⁴⁰

I also want to point out one of the major recommendations they do make; they say there are problems with the obviousness standard, that too many obvious patents are being issued, the standards are not right, and they should be tightened up to prevent this happening.²⁴¹ That almost exactly overlaps with one of the recommendations we make.²⁴²

The other thing I want to get back to, which is the statement I began my presentation with, is that you have to be mindful of the two spheres we are dealing with here—the sphere of innovation that competition can promote and the sphere of innovation that the patent system can promote. If you increase one, you affect the other.

The critical thing is to put them in a proper balance and be mindful that if you adjust things in the patent system you might be displacing competition, and competition is the baseline, as the Supreme Court says, of the U.S. economy.²⁴³ This balance is a very important fact to be mindful of.

MR. RICHARDS: Anything more from the audience?

²³⁹ *Id.*

²⁴⁰ Compare NAS REPORT, *supra* note 73 with FTC REPORT, *supra* note 2.

²⁴¹ See FTC REPORT, *supra* note 7, at Executive Summary, 10–12 (discussing obviousness in “Recommendation #3”).

²⁴² See FTC REPORT, *supra* note 7, at Executive Summary, 9–11.

²⁴³ See *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989) (holding that “Federal patent laws embody ‘a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy.’”); FTC REPORT, *supra* note 2, at ch. 1, p. 3.

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David, maybe you would like to sum up.

QUESTION: One question. My name is Judy Bass. I am a media lawyer in private practice, but I don't do patents.

I actually found it somewhat interesting that there is this sort of tension going on within the government. I have never seen the government work so well to both safeguard competition and also to try to curb it in the right way.

I am wondering what happens with this report now, these recommendations. You mentioned these town hall meetings are going to happen. Ultimately is this a legislative matter? What would have to happen to get some of these innovations, either in an administrative proceeding or whatever, to take effect? What is the next step?

MR. BYE: There are a number of steps that could be taken. Many of the recommendations we make discuss legislative reform, like creating this post-grant review procedure or giving the PTO more funding.²⁴⁴ There are other recommendations we make that could be addressed through court decisions, and that is one of the things we note, that we are going to have an increasing role in filing amicus briefs. Then, the perspective we bring to bear on these issues can be delivered to courts at that sort of range.²⁴⁵ Those are two areas that things can happen.

Another great thing this report has done, it has spurred so much debate across the country. We even had a professor visit recently from Japan who said that she is discussing this report with her colleagues in Japan. It has a lot of academics talking. It has inspired people who work in law reform to start thinking about these ideas and incorporating them throughout the patent system.

MR. RICHARDS: David, would you like to make some closing remarks, then Herb, and then if either of the government speakers want to say anything more?

²⁴⁴ See FTC REPORT, *supra* note 2, Executive Summary, at 7–8, 12–13 (discussing post-grant review procedure in Recommendation #1 and adequate funding for the PTO in “Recommendation #4”).

²⁴⁵ See *id.* at Executive Summary, 17–18 (discussing the need to increase communication between antitrust agencies and patent institutions through the use of Amicus Briefs).

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MR. BALTO: No. Herb.

MR. SCHWARTZ: I really don't have much to say in closing. I think I've made my views fairly clear.

I would say, going back to your comment about the NSF report, yes they do discuss a non-obvious standard, but they discuss it in a couple of very specific areas where there have been some issues, in business method patents and gene sequence patents.²⁴⁶ They do not suggest changing the statutory framework. They suggest a reasoned approach to try to work it out.²⁴⁷

That is fundamentally different from what the FTC is doing in this area. The FTC is, in effect, suggesting very specific changes in the basic ground rule of how obviousness should be determined.²⁴⁸ Such a change would be effected by either legislation or court decision, and my guess is presumably legislation, since I doubt that they will persuade the Federal Circuit to put in the changes they are suggesting by court decision.²⁴⁹

Now, certainly they are entitled to take that position. I don't quarrel with their right to do it. But to suggest that they are on the same page as the National Science Foundation is not fair.

MR. RICHARDS: A note on obviousness. As a practical matter, I prosecuted applications before the U.S., European, and Japanese patent offices, and I don't find any glaring lack of rigor from the examiners I deal with in the U.S. Patent Office when raising issues of obviousness. They seem to raise very similar issues to the Europeans and the Japanese, so we seem to effectively have a sort of worldwide standard on obviousness at the moment. I wonder whether it is in anybody's interest for the United States to take a different view from the rest of the world.

MR. RICHARDS: David, do you want to say anything?

MR. BALTO: I think the important question is establishing this balance. It is important to recognize that protecting intellectual property rights to create an incentive to innovate is the primary

²⁴⁶ See NAS REPORT, *supra* note 73, at ch. 4, pp. 87, 91.

²⁴⁷ See *id.*

²⁴⁸ See FTC REPORT, *supra* note 7, at Executive Summary, 9–11.

²⁴⁹ See FTC REPORT, *supra* note 2, at Executive Summary, 10–12.

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concern. But when a process starts to morph into people seeking out regulatory rights to engage in bargaining, that balance is broken. That is what I think the FTC's report suggests. I think their suggestions are modest and appropriate.

And don't bet on the Federal Circuit not accepting the FTC's point of view. The FTC has a very effective amicus program in which they are often successful in convincing the appellate courts of the appropriate interpretation of both IP and antitrust law.²⁵⁰

In fact, the linchpin to the *Bristol-Myers* case,²⁵¹ where there were millions of dollars of consumer harm for every day that Bristol-Myers improperly extended its patent—for those people who think that there might not be some harm from the misuse of patents—the key to the *Bristol-Meyers* case being successfully litigated, was an amicus brief filed by the Federal Trade Commission before the district court.²⁵² So I wouldn't place any bets whatsoever that the FTC is going to be ineffective in convincing the Federal Circuit.

MR. RICHARDS: I want to thank everybody.

MR. BYE: One final word?

MR. RICHARDS: One final word.

MR. BYE: Just one quick final remark. I want to thank you all for listening today. I would encourage everyone to take the NSF report and take the FTC report and compare the two recommendations with respect to obviousness.²⁵³ You will see that we recommend that there should be no change in the statutory standard. We think the standard is good as it exists.

We do believe that, in certain contexts, the test has not been applied as well as it could, which is quite similar to what the

²⁵⁰ See generally R. Ted Cruz, *Remarks before the Antitrust Section American Bar Association* (Dec. 12, 2002), at <http://www.ftc.gov/speeches/other/tcamicus>.

²⁵¹ *In re Buspirone Patent and Antitrust Litig.*, 185 F. Supp. 2d 363 (S.D.N.Y. 2002).

²⁵² Brief of Amici Curiae The Federal Trade Commission, *In re Buspirone Patent and Antitrust Litig.*, 185 F. Supp. 2d 363 (S.D.N.Y. 2002) (No. 1410), available at <http://www.ftc.gov/ogc/briefs/buspirone.pdf> (last visited May 9, 2005).

²⁵³ Compare NAS REPORT, *supra* note 73, at 87–95 with FTC REPORT, *supra* note 2, at ch. 4, pp. 4–19.

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National Academies say. But I would just encourage you to go and compare them yourselves.

MR. RICHARDS: Thank you to all of you for your interesting contributions, and thank you to the panel. We are now adjourned.

MS. SYBBLIS: I'd like to thank our moderator and our panelists for their participation today and their insightful comments on this dynamic area.

We are now going to take a ten-minute coffee break. There are refreshments in the Atrium. Then we will return here for our second panel.

Thank you.