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2C Patent Law Session. U.S. Patent Developments

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Session 2C

Emily C. & John E. Hansen Intellectual Property Institute

**TWENTY-NINTH ANNUAL CONFERENCE INTERNATIONAL
INTELLECTUAL PROPERTY LAW & POLICY**

Thursday, April 21, 2022 – 1:50 p.m.

SESSION 2: Patent Law
2C. U.S. Patent Developments

Moderator:

Martin J. Adelman

The George Washington University Law School, Washington, D.C.

Speakers:

Nicholas P. Groombridge

Paul, Weiss, Rifkind, Wharton & Garrison LLP, New York

U.S. Patent Developments Overview

Panelists:

Laura Sheridan

Google, New York

Carey R. Ramos

Quinn Emanuel Urquhart & Sullivan LLP, New York

Marjan Noor

Allen & Overy, London

Nahoko Ono

Lerner David, Cranford, New Jersey

* * *

Session 2C

MARTIN J. ADELMAN: This session is US Patent Development. Really, if we look at it, it's been 10 years since the America Invents Act was signed into law by President Obama. You can look at that act in various ways. I looked at it primarily as a mechanism for further reducing the role of juries in patent cases. There is a lot of other stuff to confuse people as to what was really going on, but, in fact, that was a primary function of the act. Now, since that time, there have been strong attacks on the PTAB, which is the primary organ for dealing with patent validity and taking cases away from the jury.

The jury, of course, already lost its small molecule litigation in the Hatch-Waxman Act which is now almost 40 years old. Since most of those cases don't involve damages, there's no right to a jury. Now, with the PTAB, there have been several major attacks in the Supreme Court. We will get into what I believe was the last major attack, and that's the Arthrex case. Now, we have to discuss all of these developments. A great panel. I found that not everybody on the panel, and let me just look at what I had to pull out. Not all the bios were actually in the material that I found that listed all of the participants.

I did look. All you have to do for anybody who's not there is to go on Google and you'll get the bio quickly. So I won't go through them, but we have a very good panel. We've got Laura from Google, Carey from Quinn Emanuel, Marjan from Allen & Overy and Nahoko from Lerner David. Nahoko, I think I've known forever. I think it's pretty much forever, way back more than 20 years which makes me feel old, but I'm delighted to see her on this panel. Now for our key speaker, who's going to go, I assume, up to 25 minutes, and there's plenty to cover, is Nicholas Groombridge. He's the gift, of course, from England to the American Bar. He's great, and he's great fun. He's got a huge team always working for him involved in all kinds of great patent litigation. I'm going to turn this over now to Nick.

NICHOLAS P. GROOMBRIDGE: Marty, thank you for the kind words. I'm conscious of the fact that I'm stepping into some big shoes here because Dimitrios Drivas has anchored this spot for a lot of years.

MARTIN J. ADELMAN: Forever.

NICHOLAS P. GROOMBRIDGE: Forever. Yes. Right.

MARTIN J. ADELMAN: Forever. I was wondering, so you're now stepping in. This is tough.

NICHOLAS P. GROOMBRIDGE: It is tough.

MARTIN J. ADELMAN: He always took 25 minutes, never 26.

NICHOLAS P. GROOMBRIDGE: Exactly.

MARTIN J. ADELMAN: Never 24. 25.

NICHOLAS P. GROOMBRIDGE: So here we go. Right. I certainly follow in Dimitrios' lead. I will talk about cases. Before we do that, I wanted to step back a little and look at the very big picture. We were very fortunate this morning to hear, as part of the conference, the first public speech by the new director, Director Vidal. It was in many ways fitting because we're, I think, at an inflection point. I'm sure we'll get into this.

But we are undoubtedly living in interesting times in the patent world. And we had something else that was touched on this morning, an editorial in the

New York Times. Just a few days ago, by the editorial board no less of the *New York Times*, articulating the premise that the US patent system is broken. I can't remember ever having seen such a thing. It, to me, was very interesting.

Let me throw out the idea that we may be at an inflection point in which the biggest single driver for changes in the patent system has been these many years the rise of the non-practicing entity, leading to, for example, the AIA, and that maybe we're now at a place where, if that's not being replaced, it's at least being overtaken as a driver by drug pricing as the major motive force that's going to affect the patent system.

MARTIN J. ADELMAN: Nick, I don't want to step on your thought, but I remember in 1964, Kefauver practically running for president on an extreme anti-patent platform. It may be that when I listen to you, I say, "Oh, boy, do I feel old," because this is really old. He thinks this is new. There isn't a new idea in this whole article. It is brainless, and I will go through it. It's exactly what you expect from the brainless *New York Times*.

NICHOLAS P. GROOMBRIDGE: I'm going to take issue with you a little bit on that, Marty, that some of the things that are in that article seem to me to make eminent good sense. One of the things they say is enforcing existing standards, giving the patent office more resources. They call out that statistic that we've heard that the average patent application gets a grand total of 19 hours of examiner time before it emerges as a patent. That is a very good point to me, right? There are many things in there that I would totally agree with you, make no sense.

The underlying premise seems to be driven by the idea that the patent system is the reason why drug prices are high. It talks about insulin, and there was a statement. I made a note of this. They're talking about what I take to be evergreening where they say that pharmaceutical companies may get a patent on quote, "making a tablet instead of a pill." I don't even know what that means. It talks certain things that, for example, capping the number of times a rejected application can be resubmitted, which I take to be a reference to some sort of limit on continuation practice.

That seems to be an idea that is gaining traction. Making it easier to challenge patents before they are granted. Marty, you will remember, decades past, how the US IP community was furious with countries that had pre-grant opposition, how that was a major bone of contention between the US and Japan. This seems like it's a suggestion, an idea that's gaining currency. Let's have what is in effect pre-grant opposition.

There's a lot of things in there that have history and also a lot of things where it seems like the patent system is being used as an object of blame for perceived social ills that really have much more complex causes. I'm sure we'll get into it. One of the things that I did want to flag is that they promote the legislation that Senator Leahy had introduced to restore the American Invents Act, which seems as though it was largely intended to undo many of the measures that the Director Iancu had put in place, for example, eliminating discretionary denials. Let's come back to that.

They talk about patents thicketing. One thing, I had thought there was a chance we might be speaking at this conference about the decision from the antitrust case that's pending in the Seventh Circuit, in which one of the two issues is whether amassing too many patents is in itself an antitrust violation, or it can be an antitrust violation. A case involving the biologic product HUMIRA, and that's been pending now. The oral argument was about 14 months ago and still pending.

But the idea, for example, that we've come to a place where simply having too many patents, even if you don't assert them, is some sort of violation of law is to me, also an indication of where we are. Director Vidal mentioned the FDA letter which was from last September, a letter from FDA to the USPTO, which takes issue with continuation practice, takes issue with patent thickets, so-called, takes issue with evergreening saying, and I was shocked to see this in that letter that, a change from a drug that has to be administered twice a day to make it administered only once a day is in some way inappropriate for patent protection.

Asking whether the PTAB could be made more effective as a means to support generic market entry. All of those things seem like they're driven-- They're all steps that would work directionally to weaken the patent system. I think that's in many ways where we are. There's a lot going on. It's all unidirectional. Our colleagues from other countries should probably be aware of that. But with that, I will talk now in the spirit of Dimitrios, let's turn to case law and go through some of other things that have happened, starting with the Supreme court and the *Minerva versus Hologic* decision on the doctrine of assignor estoppel, which is the idea in US law that someone who sells patent rights for valuable consideration cannot later be heard to challenge the validity of those patent rights.

This is a doctrine that has existed in US patent law for many decades. The Supreme Court took it up in a case in which they were asked to either abolish it or declare that it had been abolished long back. The court heard policy arguments saying that in the modern world, it was a bad idea to prohibit those who had invented something, sold it, and then moved on to their next gig from being able to challenge the validity of patents that they had sold or of arguments about serial innovation, the spirit of Silicon Valley, how common it was for people to start a company, sell it along with the IP, and then move on to do something similar but different and how that would spawn this type of situation.

The court in its decision, majority opinion by Justice Kagan declined to abolish the doctrine but did weaken it in some significant ways. Perhaps with a nod to the policy arguments that have been made, said that an employee agreement to assign inventions not yet made cannot be the basis of a subsequent assignor estoppel argument. Also carved out a couple of other exceptions, notably, where what has been sold is that, an application that is then subject to being broadened in later continuation practice. The court said that where the would-be patent challenger could show that the claims are materially broader than the doctrine prohibiting a validity challenge would not apply.

Let me move on to a perennial favorite, section 101, where what I see going on there is the judicial system still now several years into our 101

adventure. This is patent eligibility. What type of subject matter qualifies to be patented under US law?

The courts are still trying, perhaps struggling, to come up with a uniform set of rules about how we can apply, how we can know what is eligible for patenting and what is not eligible for patenting. I wanted to call out two cases, which to me, highlight the difficulty we face in this area of the law as it-- It does move forward, it does develop but fitfully and with a lot of challenges. These are both cases on patents that involved, broadly speaking, remote authentication techniques, technology for establishing that someone who was wanting to engage in a transaction, say from a mobile phone, was indeed a legitimate actor.

Both cases where the patent was held in the trial court to be invalid for lack of eligibility. Then when they went up to the Federal Circuit, in one case the Federal Circuit reversed that and upheld the patent. In the other case, it affirmed the district court and said, this patent is not eligible. The first case is CosmoKey solutions versus Duo Security. The issue was this idea of how to know whether someone who's attempting to make a transaction on a mobile phone is a legitimate actor.

The trial court, the District of Delaware, had invalidated the patent citing prior Federal Circuit decisions to the effect that this idea of authentication is an abstract idea and therefore fails step one of the so-called Alice test and particularly appointed to an earlier Federal Circuit case called Prism. Interestingly, I think here, the Federal Circuit in the CosmoKey case said, well, looking at prior cases is all well and good, but you shouldn't do it too much, and you have to be very careful with it.

That to me is important because if I'm a trial court judge and I'm trying to understand what I can and can't do, I would've thought that I could go to this now growing body of Federal Circuit cases and look at them for guidance. In CosmoKey, the court seems to be saying, you could do that at your peril. Here the court casts doubt on whether this idea of authentication is necessarily abstract but then jumps forward to step two and says "We don't need to answer the step one question because this is clearly an innovation at step two of the Alice test."

It, in some respects, sidesteps the potentially tricky problem of having to address their own prior precedent, upholds the patent, Judge Reyna dissents and says, the sidestep is not a good idea here and it makes the whole analysis questionable and it will inject doubt into the law here. Now, the second case I wanted to contrast is Personal Web versus Google, again, about essentially authentication technology. Here the court endorsed again, patent was struck down in the trial court, and got to the Federal Circuit. Federal circuit does exactly what in the CosmoKey case, it had called into doubt. It looks at its own prior cases and says, boy, this seems very similar to one of our prior cases. It's an abstract idea.

It also looks at real-world bricks and mortar examples and says that what you've got here is really just a computer-implemented method of doing something that, say, librarians have been doing since time immemorial, and there's really nothing more to this and strikes down the patent. I think if you look at these, it highlights the challenge that we've got taking these two together for predictability as we try to come to a place where practitioners can advise clients about what is

eligible and what's not and trial court judges can rule with some confidence that they know the principles that are to be followed. That's interesting. That's still moving along.

I'm going to move on now to written description and enablement. In enablement, the big news is that the Supreme Court, just on Monday, granted or issued a so-called CVSG order in a long-running case Amgen versus Sanofi, which has been the subject of this panel at this conference in prior years. Again, this is a situation where Amgen had a patent. It sued Sanofi. The case went to trial twice. Two separate juries' rule in Amgen's favor. Twice that was overturned by the Federal Circuit.

The question really here is in the context of biotechnology claims, and specifically monoclonal antibody claims, to what extent can broad functional claims be permitted? What are the rules that govern their enablement of those claims? Amgen, having lost in the Federal Circuit, filed a petition for certiorari on two questions. The first was whether enablement is a matter of law for a court, or a matter of fact to be decided by a jury. Going back to Marty's opening remarks, Amgen argues that the Federal Circuit has gone wrong by making it a matter of law.

Secondly, Amgen argues that the Federal Circuit has mis developed the law of enablement to say that in order to determine whether undue experimentation is required, Amgen's characterization of the Federal Circuit is that the circuit has focused on the cumulative effort that would be required to practice the entire scope of that which is claimed, in essence. The broader the claim, the more the cumulative effort is, and the less likely it is to be enabled. Amgen argues that's wrong. It is simply necessary that the patent applicant teach some ways to practice the invention.

Amgen argues that old Supreme Court cases, one from the 19th century and one from the early 20th century foreclosed the law as it's been articulated by the Federal Circuit.

The significance of the so-called CVSG is that statistically the chance of the Supreme Court taking a case is very low. Even in so-called represented cases, it's only about 3% of them that get granted, but where they call for the views of the government by this CVSG procedure, that percentage jumps to about 50%. Now it's a coin toss as to whether they will take this case, and if they do take it, presumably it's because they want to change the law of enablement.

Moving along, let me also talk about written descriptions. There is a, to me, significant case called Biogen versus Mylan that really, in some ways, is the capstone of a long-running change in the law of written description or series of changes going where it would have been decades ago. US law, that in order to determine whether it was written description or what would've been called in those days support for a claim, you look at the specification and see whether you can find in the specification that which was later on incorporated into the claim.

This is a case where the key question was whether it's a method of treatment. The question is whether the specification provides support for using about 480 milligrams or a dose of 480 milligrams of the drug in question where the specification includes an express disclosure that one of the effective ranges is

from about 480 milligrams to about 720 milligrams per day. We have that exact phraseology in the specification. Nonetheless, the Federal Circuit affirmed the district court decision saying that there was no written description of this invention because it was too speculative.

Notably, they pointed to the fact that there was only one place in the specification where this number, 480 milligrams, appeared and said that because it was one end of a range that detracted from subsequent claim limited to this dosage. I think what this is, it really is a convenient summary of how written description law has evolved to a point where even though everything that's recited in the claim is present *ipsisima verba* in the specification, the court is looking beyond that, including here looking to extrinsic evidence to say, "Yes, but we don't think that you had actually invented that with you later claimed."

I should say there was a vigorous dissent by Judge O'Malley in that case and remained to be seen whether there will be further proceedings there. I'm going to touch on another written description case, which is *Juno versus Kite*, also about a technology case involving the technology often referred to as CAR T a form of immuno-oncology in which the patient's T cells are extracted and then genetically reprogrammed to attack cancer using portions of antibodies, what's called a single chain of variable fragment, or scFv.

Again, in this case, there was a jury trial. There was a very large damages award, about \$780 million. Interestingly, a 27.6% running royalty awarded. All of that got overturned in the Federal Circuit on the basis that the two patents failed to provide written description because they did not spell out structurally what these antibody-like fragments would consist of and they provided no correlation between structure and function. Therefore, there was a failure of written description. Another case that illustrates the trend, I would say, towards making it very difficult to obtain broad generic coverage, particularly in the life sciences area.

I will move on touch just briefly on another case, an obviousness case about secondary considerations and specifically nexus. This is *Teva versus Eli Lilly*. Again, interesting in this case, Teva, which was the patent holder had sold products that embodied the claims. However, the patents in question were invalidated in an IPR proceeding, and that was subsequently affirmed by the Federal Circuit.

Addressing secondary considerations, the court again, it showed its distaste for broad structural claims, particularly in the life sciences area saying because the claims were broad and lacked structural elements, that meant that there was no nexus, that the effectiveness of these embodying products depended for example, on their binding affinity, their specific amino acid sequences, things of that nature, and because none of those specifics were in the claim, there was no nexus, even though the products were covered.

Again, I think, illustrative of an antipathy towards broad structural claims. We touched briefly on damages. You heard Paul Michelle this morning says that his view that the Federal Circuit had not done a good job in developing death damages law. I think that project is still ongoing and we call out a case, *Bayer versus Baxalta* about a hemophilia drug, but in that case, the damages issue on

appeal was whether it was proper for the plaintiff's expert to have provided a range of proposed royalties, in fact, from 5.1% to 42.4%. Whether that was legally operable to provide a basis for the jury's verdict, which came in at just under 18%. Having examined that issue, the court said, yes, that seems fine. Again, interestingly that a range, even a very broad range, could be blessed as the basis for a subsequent award.

I will move on through a couple of other things. I would like to get, I think, to post-grant, development in the post-grant area. I think as Marty mentioned, we should touch on Arthrex which was decided during the past year by the Supreme Court.

This is a case where the issue is whether under the AIA when in inter parts review proceedings, the so-called patent trial and appeal board are the judges of that, the administrative patent judges, whether their appointment violated the constitution, specifically the so-called appointments clause of the constitution, and whether the exercise of power by these administrative patent judges was unconstitutional because it was not reviewable by a government officer, in this case, the director of the patent trademark office appointed by the president subject to the confirmation by the Senate.

This case had made its way up through the courts. The Federal Circuit had found that the appointment of the APJs was unconstitutional and that the fix that the Federal Circuit came up with was to, in essence, make the APJs removable at will by the director, that in the words of the Supreme Court, specifically the Chief Justice, this satisfied no one and led to some unhappy APJs and a lot of unhappy patent applicants.

In the Supreme Court, the court did agree that the appointment of the APJs violated the constitution and that because their actions were not reviewable, and indeed, perhaps the structure had been put in place deliberately to make them not reviewable by the director, and thus struck down the relevant part of the patent law as unenforceable because it was in violation of the appointment's clause of the constitution.

I will look forward to Marty's remarks because I'm almost out of time on this, but my own sense is that Arthrex, while it has interesting constitutional implications, hasn't actually made a great deal of difference in patent practice. It is certainly true that the patent office has adopted procedures to make it possible for the director to exercise plenary review over our decisions of the patent trial and appeal board. As a practical matter, that review seems overwhelmingly likely to say that the director approves of what the board has done.

Ultimately, it's not clear to me that in the big scheme of things, this made a lot of difference to outcomes there. Maybe with that, Marty, I will finish my highlights.

MARTIN J. ADELMAN: You're right on. Perfect. Perfect. Right. On the timing, so that's perfect. I'm just wondering, Nick, if you thought institutional decisions also have to be reviewed?

NICHOLAS P. GROOMBRIDGE: I think I would say yes. I know that, that is a vexed question and that there are currently challenges underway that have not yet been decided on that.

MARTIN J. ADELMAN: Comments from the panelists on all of this? Nahoko?

NAHOKO ONO: Thank you, Nick, for a thorough presentation about US case law. You didn't touch much, but you put that on the slides. I also agreed that damaged cases like Omega or MLC are quite important as the Federal Circuit tries to tackle how to determine apportionment damage awards.

I'm not sure about 101. From me, I think, a truly international perspective, as well as in my real practice here in Cranford, although the Federal Circuit remains confused on this issue, Supreme Court Mayo/Alice two-steps test working clarified by the USPTO and then also its guideline, especially examples seem working well. Then I heard from my prosecution colleagues that they receive very few or fewer 101 rejections these days. I think this practice has happened maybe for the last several years.

Then the third point that I'd like to make, or you didn't select this case, but I thought that Caltech versus Broadcom case, that is very important that this is about IPR estoppel and then Federal Circuit clarify that IPR estoppel applies to the challenge claims and to all grounds that could have been asserted in an IPR petition.

MARTIN J. ADELMAN: Other panelists?

MARJAN NOOR: Maybe I can comment on the enablement and written description from the pharmaceutical field. That's a very, very hot topic in Europe and the UK as well. That's because we similarly have to grapple with the idea of patents that, for example, on antibodies are not sequences but are functionally defined. It's very interesting because a lot of the litigation involves US companies and the US patent counterpart, how the field views the way the world looks at these patents and sees the US as very much the most stringent of all because you have the written description on top of the other issues you mentioned.

I suppose I'd say that in Europe, that strictness gets less as you go through the UK and even less as you go into the rest of Europe. For the rest of Europe, you have the concept of whether you have serious doubts substantiated by verifiable facts as to the possibility of whether the skilled person can carry out the invention.

Then in the UK, you have the difficulties of knowing whether the idea is that you have to actually be able to identify all operative embodiments within the breadth of the claim or whether, actually, if the skilled person without undue efforts can actually identify with one compound, whether that does satisfy the feature, whether that's sufficiently enabled. We have those difficulties as well.

MARTIN J. ADELMAN: How would you like to practice before a jury that knows fundamentally nothing and is going to make a decision based on nothing? You have plausibility, and you have sufficiency, and you have judges who I find amazing.

MARJAN NOOR: Yes. Yes, they are. They have that. Yes. In fact, I remember even as a junior lawyer looking at some of the demonstratives that go before the jury, thinking you do have to start from the beginning. Whereas, our judges are technically qualified. Even if they're not technically qualified in the

pharma sector, they'll be able to understand it quicker than anyone else. Yes, we are privileged with that.

LAURA SHERIDAN: Marty, if I could jump in, and how's my sound by the way? Is it okay?

MARTIN J. ADELMAN: I hear you perfectly.

LAURA SHERIDAN: Okay, great. I'm sure we'll probably talk about this more, but I did want to just briefly touch upon what Nick brought up at the outset, which is the recent editorial. Actually, it mentioned something that I think had some similar themes to it but didn't get the coverage, of course, because it wasn't in the *New York Times* and that is rare for patent issues to be found there: that is, the Commerce Department's strategic plan for 2022 through 2026. That came out a few weeks ago. I think what you'll find in there are some of the things that maybe were not so controversial about that op-ed are also echoed in the strategic plan. It talks about the importance of reliability of patent rights. It talks about quality and patent processing and examination and access to prior art and making sure examiners have the time that they need to do their jobs.

I do think you're seeing the Commerce Department, just a few weeks back, recognizing already some of these important issues and setting out goals for the PTO, which I think, for those listening this morning, Director Vidal really welcomed that dialogue. I think she welcomed the conversation around some of these areas for improvement, that whatever you might think about the editorial from this week, I think we can all look to the Commerce Department's own strategic plan and say there's good things to work with that I expect a lot of folks will agree strongly with.

MARTIN J. ADELMAN: Understand that when I hear these ideas, I know they were old when I started to practice patent law and that's about 60 years. All those ideas are much older than my length of career. I hear them again. We should give time for examiners to examine and yes, of course, we should give them five years but practically, that won't work. In around 1900 people were saying, "If they stop issuing these crappy patents, you'll find it." I don't want to make fun of this.

But this is just very old and all the ideas in there were very old. They started out all these things that were patented. Yes, well, did they meet all of the tests? Well, sometimes they don't. Then they shouldn't be patented. That's why we have courts, et cetera, to throw them out. If you can come up with one idea that was new in that editorial, at least I will give you a hooray.

LAURA SHERIDAN: I will just say, Marty, I agree these are ideas that are not necessarily new but I think with the number of applications getting filed every year, the number of grants at the PTO, the complexity that's been introduced through artificial intelligence-based inventions. They may be old ideas, but they are long overdue because it's getting urgent to address some of these things. They are hard and I think with 9,000 examiners, it is a real challenge. I'm not intending to say this is something that would happen overnight, but it is getting to be urgent, given the complexity of technology and the importance of those technologies.

MARTIN J. ADELMAN: How would you correct it? We have patent offices all over the world. They're all looking at this stuff. The European Patent

Office spends an absolute fortune examining patents, and then they have other procedures. Tell me how you would fix the system.

LAURA SHERIDAN: I'll give one and then I'll let everybody else speak. This is something I'm passionate about.-

MARTIN J. ADELMAN: Maybe more, fix it right here.

LAURA SHERIDAN: We're going to fix it today, Marty. The first big change – and this is not an exciting one but it's critical – is moving the fee structure upfront, so that big companies who file patent applications, instead of paying all that money at the back end, after we've gotten a patent, we pay it at the front end. That gives the PTO the resources it needs so that examiners have better tools, but also more time because if we don't move that money upfront, it really comes down to a resourcing issue where the PTO can't give more time to patent examiners if they don't have money to do it.

What's critical here, though, is I'm not suggesting raising fees for everybody. It has to be those parties that can afford it and that then supports the rest of the system for those entrepreneurs and inventors who can't. There are plenty of large filers who have the means to take their maintenance fees and pay those upfront more like Europe. That's one idea.

MARTIN J. ADELMAN: That may well work. You'd have to program it out.

NICHOLAS P. GROOMBRIDGE: Marty, that is evocative of one of the things that's in the *New York Times* article which talks about a sliding scale in which wealthy applicants pay a lot more than small applicants. It's not just a binary system.

MARTIN J. ADELMAN: We have that but maybe not--

NICHOLAS P. GROOMBRIDGE: Well, you have a small entity system, but it's talking about a sliding scale, where that is where the fees are proportional to the resources of the applicant which I think, aligns with what Laura was just talking about.

MARTIN J. ADELMAN: Any other comment? Go ahead.

CAREY R. RAMOS: I agree with Marty, my personal recollection doesn't go back to the '60s but it goes back to the '70s. In the patent area, it's a pendulum, because it swings back and forth. Periodically, there's a call to adjust it one way or the other. The one thing that has changed, that I think the *New York Times* doesn't take account of and Marty touched on this, is that there now are international issues with regard to this.

If the US adjusts in one direction, and Europe moves in another direction, then you're going to have inconsistencies on a global scale. For many of these inventions, they are used worldwide. They're also considerations for US competitiveness in protecting inventions, by inventors in the United States and also promoting development of inventions and new discoveries. So it becomes an extraordinarily complex problem of trying to get the balance right.

Of course, here in the United States, you don't have a single person who's able to make up the rules. You have the patent trademark office. You have Congress. You have the Supreme Court. You have the judiciary trying to understand the Supreme Court. I tend to think that over time, we find our way

through these paths. No one could quarrel with additional resources for the patent office, upfront fees. I would agree with Laura. I think that makes an enormous amount of sense.

Just having the resources to do the thorough review of patents that they warrant particularly with some of the incredibly complicated technologies we're seeing both in the life sciences area and in the computer area. These are just incredibly complicated. Many of them are incredibly complicated and warrant more careful study. So I guess I also come out somewhere in the middle.

MARTIN J. ADELMAN: Well, the only thing I worry about with Laura's argument is there is no limit. We could have the perfect patent office, and we'd all be working there and we'd be studying each application in incredible details, that would be a couple of year's work and nobody else in Washington would be doing anything else, which might be a healthy thing for the rest of society. There has to be a balance.

I think everybody would agree with that, and may be shifting more fees up to filing rather than maintenance fees. Make sense. Giving examiners more time, but there's a limit. There's a limit to how much time you want to spend. That's the function of post-grant proceedings or in the pharmaceutical space they litigate them before judges without juries in Hatch Waxman proceed.

MARJAN NOOR: I think the same if you can have a perfect system, but for the biggest selling products and the most valuable ones, you're always going to have litigation of even a perfect system. Then the leveler is at the court's stage.

MARTIN J. ADELMAN: That's what you have to have.

MARJAN NOOR: Right now what you see when you were talking about global companies and for example, a wish to maybe have settlement, you have a very different approach for US settlement versus the rest of the world, or at least European settlement because the differences in the law that currently exists. The real leveler should be set at the court stage.

MARTIN J. ADELMAN: Is it the law or is it the use of juries so that you can get billion-dollar verdicts?

MARJAN NOOR: Well, I suppose in the pharmaceutical sector, it depends. You can have more predictability sometimes if you're a pharma company, for example, because if it's not a jury trial, then you're just dependent on the law and I suppose the judge rather than the unpredictability of where the jury is going to go.

NICHOLAS P. GROOMBRIDGE: I'm not so sure that I think that juries are such a terrible idea.

MARTIN J. ADELMAN: You see, he is a trial lawyer. The trial lawyer will always argue that he can confuse juries better than anybody else. That is in the tradition of great trial lawyers in the United States and Nick is one of them.

NICHOLAS P. GROOMBRIDGE: What you're saying is good for business, Marty. I was involved with a program, we would bring a bunch of lawyers from Europe and a bunch of lawyers from the US together and put them in a room and have them talk about one another's systems. I would always ask them who think it's a bad idea to have juries in all Europeans to raise their hands. Then I said now, of those ones who have your hands up, how many of you have

ever had a decision by a judge that you thought was completely wrong? All the same ones had their hands up. You got the reasoning with it. You don't like the reasoning but you got it. We've all been in that situation.

MARTIN J. ADELMAN: No, Nick. That's not right. I've been before juries in about 50 cases. The lawyers know this is a nutty system. Everybody knows it's a nutty system. Now, if you are better at convincing jurors, more power to you but don't tell me that our juries can equal Richard Arnold. You might not agree with his opinions but when you read his opinions, you know nobody's fooling him. You don't know that from a jury verdict.

NICHOLAS P. GROOMBRIDGE: I'm not going to quarrel with Lord Justice Arnold's powers of reasoning for political reasons.

MARTIN J. ADELMAN: You may be reading more than you want.

MARJAN NOOR: I think you might end up being frustrated. You might be frustrated by the end result, and even think the application of the law was wrong if you're on the losing side, especially, but you rarely think they misunderstood the science or the facts.

MARTIN J. ADELMAN: You may get more science from him that you want, but that's a different issue.

[laughter]

NICHOLAS P. GROOMBRIDGE: Let me throw out a question here, which we touched on a bit. Who thinks that there should be limits on continuation practice in the US?

MARTIN J. ADELMAN: It's a good question.

LAURA SHERIDAN: I can respond. I think the first limit I'd put into place is on just the request for continued examination, which isn't a true continuation. That's a separate--

MARTIN J. ADELMAN: It's the same thing, though?

LAURA SHERIDAN: It can be, but I think there's a distinction. I think what I'd like to see end is, frankly, just get rid of this ability to have a request to continue examination. It's just a fiction, you just pay money and then do the same thing.

MARTIN J. ADELMAN: You keep going.

LAURA SHERIDAN: Yes, and it's one of those things that I think if we just put a closing moment on prosecution, where at that point, you either appeal, you abandon, there's some finality to it. I think that's the low hanging fruit. I think the continuation question, I do think it's abused. If you look at the patent office's view of it, they think there's too much of it as well. Continuations are just a way to never let something die if you have the resources to do it, but the low hanging fruit, I think, is around the ability to just have an examination of one patent go on forever as long as you can afford to have it go on.

MARTIN J. ADELMAN: Of course, you're eating up your time?

NICHOLAS P. GROOMBRIDGE: You are, but--

LAURA SHERIDAN: That's fair.

NICHOLAS P. GROOMBRIDGE: What if we doubled the fees for each successive continuation?

MARJAN NOOR: I think the limitation on the period is the thing that's going to be the better check because in Europe, you have divisionals arising way down the line, you can revoke one patent, or you can have certainty, or a company can have certainty, and a divisional is raised against them. Especially, in the system like Germany, where you don't have your infringement and your revocation action at the same time, then you're at the mercy of the patentee if you're a defendant, so it causes that uncertainty.

MARTIN J. ADELMAN: Here, you do that, but your time limit is based on the original filing date. If you're filing a real continuation, then your 20 year period is being eaten up?

MARJAN NOOR: It's the same in Europe, but I thought Laura was mentioning that the filing of your divisional would stop at a certain point in time.

MARTIN J. ADELMAN: Yes.

MARJAN NOOR: In the Europe, you had a system where at one stage, you had to do it within 24 months, and so you have at least a certain amount of predictability as a third party as to when that divisional is going to go to grant, even though the end date will be the same.

MARTIN J. ADELMAN: Sure. That probably could be done. You could limit it in some way.

MARJAN NOOR: But on the antitrust side, the commission is now looking into divisional as a potential antitrust. Going back to Nick's comment on competition issues.

MARTIN J. ADELMAN: Now, why would it be an antitrust violation? I'm assuming I file a patent application, and these divisional or continuations, it's still just more prosecution. I'm still not able to get a different claim that I'm entitled to?

MARJAN NOOR: No, it's the use of them. The majority thinking is that no, divisional is a perfectly acceptable tool and patent filing practices, but the Commission's case against the Teva divisional is more concerned with whether you're using divisional in an anti competitive way, rather than just the mere fact that they exist and you've filed them. I think my understanding was, your patent thickets are just having those patents could be anti competitive.

MARTIN J. ADELMAN: So that would be the thicket theory?

MARJAN NOOR: Yes.

CAREY R. RAMOS: I must say, and then Nick had touched upon this, the argument that amassing too many patents could be an antitrust violation. That just seems to me to be truly perverse.

MARTIN J. ADELMAN: No, it's nuts. It's crazy.

CAREY R. RAMOS: To go back to what he was saying early this morning, that there has to be some constitutional limit on that. We do have a patent and copyright clause, and the idea that if you're really brilliant, and you get loads of patents, that you're going to be punished for that. Particularly, with the current antitrust division taking the view to section two monopolization can be the basis for a criminal case, I find it really distressing. The more the antitrust regulatory agencies get into these sorts of practices, the more troubling I find all of this. My take anyway.

MARJAN NOOR: Someone in the audience has just mentioned that, what about stopping drafting new claims that read on to existing products, and that's a typical thing that you could say. It starts bordering on to the anti-competitive, is when you take the benefit of your own earlier priority date, read on to a competitor's product with a new claim as part of a divisional.

MARTIN J. ADELMAN: That I'm entitled to? Or I'm not entitled to?
[crosstalk]

MARJAN NOOR: You're entitled—

MARTIN J. ADELMAN: I'm entitled to that? That I really made that invention, but I didn't claim it before, and then I see somebody using something, say, "I did that. I didn't claim it before." I haven't abandoned my case. I want those people to pay, I'm entitled to it. Perfectly legal, what's antitrust about that?

LAURA SHERIDAN: Marty, not from an antitrust perspective, but just from the way it plays out in the software industry, is you do have continuations that are filed to specifically cover things that come 15 years down the line on technologies that were never contemplated, and the issue is, again, going back to the patent office and why they need more money. It's 112. It's the claims that are being pursued in these continuations are often so far afield from what was originally filed, what was contemplated, and just stronger enforcement of the basics, which again, I think the statute exists. It just needs to be enforced so that the claims are actually about what was invented, not about gamesmanship 20 years later.

MARTIN J. ADELMAN: I think everybody would agree with that. How could you not agree with that? You laid in your claims 15 years later, to claim something you didn't invent, and to blow smoke and get something by the examiner is really bad. Marjan, I thought your hypo was, it was clearly disclosed. They didn't claim it, but it was clearly disclosed, boom, now they throw a claim in.

CAREY R. RAMOS: Marty, with respect to this particular issue, claiming something that you really didn't invent years later, I just don't think we need anti-trust law to accomplish that.

MARTIN J. ADELMAN: No.

CAREY R. RAMOS: Exactly.

MARTIN J. ADELMAN: The English will throw that out quickly.

NICHOLAS P. GROOMBRIDGE: As George mentioned in the chat, the late claiming doctrine used to serve that function. You had two years and then you couldn't write a broader claim, right?

MARTIN J. ADELMAN: Well, we could have that too.

NICHOLAS P. GROOMBRIDGE: Right.

MARTIN J. ADELMAN: Yes. You could say, fundamentally, figure out what you invented by a certain time, or a late claiming doctrine, yes. We don't have it. We could have something like that.

NICHOLAS P. GROOMBRIDGE: We used to.

MARTIN J. ADELMAN: Yes, we could have something like that, and that's not unreasonable. I don't know how often that happens. Now, this is a

question I was going to ask you on these antibodies. What was the invention in Amgen? Nobody talks about that. What the hell did they invent?

NICHOLAS P. GROOMBRIDGE: The invention is the use of an antibody to bind a protein called PCS K9 that--

MARTIN J. ADELMAN: Which was old.

NICHOLAS P. GROOMBRIDGE: Sorry?

MARTIN J. ADELMAN: Which the oldest idea, 2003, that invention was made much earlier.

NICHOLAS P. GROOMBRIDGE: I'm not so sure about that.

MARTIN J. ADELMAN: 2003.

NICHOLAS P. GROOMBRIDGE: If you look at the Amgen patents that are in that case, they're pretty extensive disclosures by the standards of their day. There's a lot in there, there's X-ray crystallography, there is at least some structure-function. To me, it was always hard. I think what it boils down to is to what extent do we permit functional claiming in the biotech area because it's hard to imagine a disclosure that would be qualitatively better than those but that still doesn't get you to the huge gulf of does that mean I'm entitled to a patent on any antibody that will perform the same biological function and that's ultimately what the fight is about.

MARTIN J. ADELMAN: The idea of using an antibody to manipulate PCS K9 certainly was older, obviously.

NICHOLAS P. GROOMBRIDGE: I don't know enough about the field to know that but-

MARTIN J. ADELMAN: Believe me.

NICHOLAS P. GROOMBRIDGE: These things, they go back fairly far toward the origin of that board.

MARTIN J. ADELMAN: Not that far. I looked at it, the earliest they could have was 2007 that was-

[crosstalk]

NICHOLAS P. GROOMBRIDGE: Yes, 2007.

[crosstalk]

MARTIN J. ADELMAN: Lots known by that time. I was trying to-- They came up with an antibody that works but how broad were they intact?

NICHOLAS P. GROOMBRIDGE: Well, that's the central question, that if you invent does the fact of showing that it's possible for an antibody to-

MARTIN J. ADELMAN: It was obviously possible. That's what they came up with.

NICHOLAS P. GROOMBRIDGE: That would be as you just said, obvious.

MARTIN J. ADELMAN: Obvious. That's what antibodies are for.

NICHOLAS P. GROOMBRIDGE: Note section 112, let me throw out this, what happens to the law when, thanks to Laura and her colleagues, the computing power advances to the point that we can predict structure-function relationships for antibodies? Does this entire body of law then collapse? Stumped everyone, see everyone is stunned into silence.

MARTIN J. ADELMAN: Let Laura answer that. She's going to wipe out all patenting in the biotech area, and you're going to retire. Fortunately, it won't happen for a while.

LAURA SHERIDAN: I have no opinion on antibody law, I'd turn to someone else for that, I'm a tech person.

MARJAN NOOR: I don't think computers structure-function, you can get to the point where like in a small molecule, a computer will be able to say if it's got a halogen on it or something, do X or it will have this function or if it's got something else, it'll have this function but a computer would never be able to well, [laughs] we hope, won't be able to get to the point where the underlying biological mechanisms all go.

MARTIN J. ADELMAN: All out of work and Nick will retire.

MARJAN NOOR: By the way, you don't put the computers as the inventor, you put the person who wrote the program and then you're all right in a lot of countries.

CAREY R. RAMOS: Nick and Marty just touched upon in obviousness. I don't think any of the cases, Nick, that you were viewed turned on obviousness? I suppose one way of addressing the *New York Times'* concerns is a more robust application of obviousness by the courts. Although it is one of those concepts that, in the eye of the beholder, but often I think for those of us who practice in this field we have this reaction. "Oh, come on, that's obvious but again, it's tricky when it's applied by the courts.

NICHOLAS P. GROOMBRIDGE: Carey, there's a policy issue which is how much money do I want to spend upfront on patents? When I understand that most of them will be economic dead ends that nothing will ever come with them so where do I turn the dial between spending the society's resources on making litigation give more reliable outcomes, as opposed to spending the resources on having high-quality patents, many of which are meaningless. I think there's no right answer to that. It's just a question that a lot of these issues are spawned by the fact that this, particularly in the US system has high transactional costs when you have to go to court. If you can take--

MARTIN J. ADELMAN: What if you didn't have juries?

NICHOLAS P. GROOMBRIDGE: [laughs] I'm sensing a theme here, Marty.

MARTIN J. ADELMAN: Well, there is a theme. It's nuts and the whole trend of modern developments, for example, Hatch Waxman litigation, is to get rid of juries. The irony is that is the effect of the America Invents Act, because the PTAB gets rid of juries, now we have a current fight, whether the director can have a discretionary denial.

NAHOKO ONO: Even if you remove jury system, there are many judges who make wrong decisions too.

MARTIN J. ADELMAN: Judges will make, even the brilliant English judges are occasionally wrong. They might be misled by brilliant lawyers.

LAURA SHERIDAN: I think this is why we may have different characterizations of the AIA, Marty. I view it as a chance for the PTO to correct

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its own errors. It's an agency function so that they can fix something that went wrong on the front end and I view it as--

MARTIN J. ADELMAN: We don't disagree. That's why you eliminate the jury.

LAURA SHERIDAN: I am not saying that. I think the issue-

MARTIN J. ADELMAN: Look at it, historically, once a patent was issued, I had a right to litigate that before a jury if I got a patent.

LAURA SHERIDAN: Well, I'm saying that I don't think post-grant review changes that. What it does-

[crosstalk]

MARTIN J. ADELMAN: It eliminates a lot of validity issues.

LAURA SHERIDAN: It does.

MARTIN J. ADELMAN: So that solves a lot of damages.

LAURA SHERIDAN: It streamlines a lot of issues in a way that's a lot more cost-effective. It can streamline things with respect to which claims might be ultimately asserted at trial.

MARTIN J. ADELMAN: I am with you.

LAURA SHERIDAN: It's not eliminating the proceeding, the jury trial itself.

MARTIN J. ADELMAN: It just did. Don't you know how litigation works? When I started practice, if you filed a case for patent infringement, there was validity and infringement and damages. Now, you might have infringement before the jury but validity is eliminated and that was part of--

LAURA SHERIDAN: To be quite honest validity is still happening when courts are refusing to stay litigation pending PTO review, which should be happening. That is something that the validity is proceeding apace.

MARTIN J. ADELMAN: I think that will go away. I will bet you that will go away.

LAURA SHERIDAN: I'll take that bet. I like that.

MARTIN J. ADELMAN: I'm almost certain it'll go away and in fact, if you look at the statistics, it almost has gone away. Recent statistics.

CAREY R. RAMOS: Further limitations on jury trials is going to butt up against the Constitution. However, and any effort to try to amend the Constitution, these days is tough.

MARTIN J. ADELMAN: No. You're not going to amend the Constitution. Stop, don't talk about it but where will there be jury trials if you have PTAB and real issues of validity, if you have Hatch Waxman and small molecule pharmaceutical patents, Juries will be for infringement which often is not the issue and damages. That may be okay. If you were designing a system, you might be okay with juries for damages. That's something they can understand.

CAREY R. RAMOS: Although, if you allow the experts to give the jury a broad range. [laughs]

MARTIN J. ADELMAN: That's a problem but judges can cut them out.

CAREY R. RAMOS: That's an invitation to steal. That's also an invitation to Waco, Texas.

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MARTIN J. ADELMAN: That's another issue. That could be worked on by the experts. They'd be around even for judges.

[silence]

MARTIN J. ADELMAN: So this has been a lot of fun. I think we're about at the end of the line. I don't see a clock anymore which might mean that we've overstayed our welcome. I want to thank everybody. This has been a lot of fun. I hope you all enjoyed it. Maybe we learned something. Nick, particularly, thanks for laying all of that stuff out. You did Dimitrios proud.

NICHOLAS P. GROOMBRIDGE: I'll join him in happy retirement. I'm taking your advice.

MARTIN J. ADELMAN: Bye, everyone.

NICHOLAS P. GROOMBRIDGE: So long. Bye.