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The Impact of Recent SCOTUS and Federal Circuit Cases**

*Troy A. Groetken, Timothy R. Holbrook, Sean Seymore
and Donald L. Zuhn, Jr.*



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Troy A. Groetken,* Timothy R. Holbrook, Sean Seymore,**
and Donald L. Zuhn, Jr.******

¶1 MR. SCRUGGS: Well, welcome back to Rubloff 150, everybody. We are in here for the rest of the day. This panel is going to go until about 3:30. Then we are going to have kind of a cookie and coffee break. At 4:00 our last panel is going to kick off, and then at 5:30 we are going to have a little cocktail reception.

¶2 All of it, the rest of it, is in Rubloff 150. Hunker down, get comfortable. We will be here the rest of the day pretty much.

¶3 Quick housekeeping items. For any of the attorneys that are here for CLE credits, make sure you get these forms. They are out on the registration table in the atrium. If you don't want to go there, let me know and I can go get them for you real quick. Make sure you get them, and if you can fill them out and get payment to me before you go today. And if for some reason you were like, Oh, my gosh, I wanted to bring a check, forgot my checkbook, let me know that, too, and I can give you my business card and we can have you mail it in with the check and handle it that way.

¶4 Housekeeping items done, our next panel is a fun one. It is entitled, The Pendulum Swings Back: The Impact of Recent Supreme Court of the United States and Federal Circuit Cases specifically on patent law, but any other areas that it impacts, as well.

¶5 We have a very distinguished panel with us today. I would like to introduce them very briefly.

¶6 On my left and your far right is Troy Groetken. He is a partner over at McAndrews Held & Malloy here in Chicago. I'm not going to go into detailed into his biography, but let me assure you, if you go to his web page, you will find that he is every bit as esteemed and impressive member of this panel as anyone else.

¶7 Next we have Professor Sean Seymore, who is a visiting professor here with us at Northwestern University School of Law this year, but I believe next year he is going to William & Mary.

¶8 PROFESSOR SEYMORE: Washington & Lee.

¶9 MR. SCRUGGS: Washington & Lee. Sorry about that. So we will certainly miss him, but we appreciate his contributions here.

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** Timothy Holbrook is the associate director of the intellectual property law program at Chicago-Kent College of Law.

*** Sean Seymore is a visiting professor at Northwestern University School of Law.

**** Dr. Donald Zuhn, Jr. is a partner at McDonnell Boehnen Hulbert & Berghoff.

¶10 And at Washington & Lee he is going to be teaching courses in patent law and science and torts. He is obviously finishing his stint at Northwestern as a visiting assistant professor. His research focuses on the intersection of the patent laws with the norms of scientific research.

¶11 Now, before entering law teaching, Professor Seymore was an associate in the patent practice group at Foley Hoag in Boston, and before attending law school, he was actually a chemistry professor. He holds a B.S. in chemistry from the University of Tennessee, an M.S. in chemistry from Georgia Tech, and a Ph.D. in chemistry from the University of Notre Dame and a J.D. from the University of Notre Dame.

¶12 Next on the panel, we have Professor Tim Holbrook. He is a tenured associate professor of law and the associate director of the program in intellectual property law at the Chicago-Kent College of Law. He graduated summa cum laude from North Carolina State University with a B.S. in chemical engineering, where he was the valedictorian.

¶13 Professor Holbrook earned his J.D. from Yale Law School and then clerked for then Chief Judge Glenn L. Archer, Jr., of the Federal Circuit. He practiced in Budapest, Hungary, and Washington, D.C., before joining Chicago-Kent. His scholarship has appeared in a variety of legal and scientific journals, and he is the co-author of Patent Litigation and Strategy with Judge Kimberly A. Moore and Chief Judge Paul R. Michel of the Federal Circuit. Professor Holbrook was the Edwin A. Heafey Jr. Visiting Professor of Law at Stanford Law School in the fall of 2007.

¶14 And on your far left, my far right, we have Don Zuhn, who is a partner -- actually a named party at MBHB, McDonnell Boehnen Hulbert & Berghoff, where his practice focuses on biotech and pharmaceutical patent prosecution litigation.

¶15 He actually received his Ph.D. in mammalian genetics from the University of Illinois at Chicago, and graduated summa cum laude from the John Marshall Law School. Dr. Zuhn is also the founder and editor of the Patent Docs weblog, a site that focuses on developments in biotech and pharma patent law.

¶16 And so without further ado, I'm going to hand it off to our esteemed panelists.

¶17 DR. ZUHN: When you look at the topic, you will see that it's kind of broad, so a lot of cases have come down in the last three years in the Supreme Court alone that have had an enormous impact on patent practice: MedImmune, EBay, Merck, and about a year ago, KSR. So we were asked to do about 10 or 15 minutes on this broad subject but pick something that we wanted to talk about.

¶18 So I'm going to focus on KSR, since we are about two weeks away from the one-year anniversary. Also, as Brandon mentioned, my practice is biotech and pharmaceutical, so a little selfishly, I'm going to focus on the impact of KSR on my practice. Although, I think that some of the things that I will mention in my brief discussion would be applicable to, you know, other subject matter, as well.

¶19 And so about a month and a half ago, I was at a conference in New York, and the group director for The Technology Center 1600, Bruce Kisliuk gave a presentation. He had been invited to come in and talk about GSK, but at that time we did not have -- surprisingly did not have a decision in that case, so he had to fill his hour and a half with some other stuff.

¶20 He had a lot of interesting things to say, and the majority of his talk was about how examiners in his group were being taught to examine applications for obviousness, compliance with Section 103, and he mentioned that in October we had -- the Patent

Office had come out with guidelines for examiners to use in examining applications, and, of course, we had the KSR decision.

¶21 And it was his opinion that KSR didn't -- or the guidelines, neither represented a sea change in the way examiners are looking or supposed to be looking at applications. And, you know, it was his opinion that examiners were already using Graham, should be using Graham and that TSM, teaching, suggestion or motivation tests, should not be the focus of the analysis.

¶22 And so -- just as a reminder for the audience, the Graham factors, you have scope and content of the prior art, differences between the claimed invention and the prior art, level of ordinary skill in the art, and then the secondary considerations like commercial success, unexpected results, failure of others.

¶23 And so he has these guidelines and he has KSR, and instead of using that -- at the time they had just finished training all of the examiners in The Technology Center 1600, which by the way covers biotechnology and organic chemistry, and that is the focus of that particular group.

¶24 So instead of using the guidelines which he felt were more applicable to mechanical-type inventions and maybe not so applicable to the applications that his group is seeing, he decided to put together -- or the directors in the group decided to put together 11 cases, and they would teach the examiners how to examine for obviousness, based on these 11 cases, eight of which are Federal Circuit cases -- or seven of which are Federal Circuit cases, and there is one board decision and the rest are district court cases. Just as a plug, if you go to Patent Docs, you will see that we have covered all of these Federal Circuit cases, and if you do a search for Kisliuk, you will also see a list of the 11 cases and a little bit more detailed description.

¶25 We have summarized these cases, and I was just going to briefly touch on a few of them, the ones that I feel are maybe more interesting. So of the Federal Circuit cases, the seven, there is one that is pre-KSR, and all of the rest came out after KSR. And the one that is pre-KSR, to me, is maybe the most interesting, and I think it might be discussed a little bit more. This one came out about a month before the KSR decision came out. The case is Pfizer v. Apotex. Pfizer's patent is directed to a compound called amlodipine besylate, and this is the active ingredient in a drug Norvasc, which is for treating hypertension. And what Pfizer did is, they had a related compound, which was a maleate salt. Besylate is the salt version of this, and this is what you do to drugs to get them ready to make them more bioavailable to use them as therapeutics.

¶26 So Pfizer had a patent to a maleate form, and when they were making tablets, it was mucking up the tablet device and it was a very sticky composition and, also, it was not very stable. So they were looking for something that was better, something that was different, and what they had to pick from were 53 known anions that you could use to mix with the drug to get the salt form of this particular therapeutic.

¶27 And they even knew a little bit more of the prior art pointed towards certain anions, so the list was narrowed down to seven or nine different anions. What the district court had said was that Pfizer's compound was nonobvious, and the Federal Circuit reversed and said it was. And I think that this case is interesting because even though it is pre-KSR, it has a little bit of this, you know, known problem for which there is an obvious solution, and that is using these other anions to find something that is more stable and maybe less sticky.

¶28 There was also some obvious-to-try arguments that Pfizer used, but here again we have something that is related to KSR. In KSR you have this phrase of finite number of identified predictable solutions, so here we have that same kind of situation. We have at the most 53 anions, one of which they have already used for the maleate form, and at the least we have narrowed this down to seven or nine.

¶29 So I think that case, even though it is before KSR, it has some interesting KSR-like discussion in it.

¶30 And another case, Takeda Chemical Industries v. Alphapharm, this is kind of contrasted with Pfizer. In this case Takeda had a compound for treating Type 2 Diabetes, and the district court said that the compound was nonobvious and the Federal Circuit affirmed. And the difference between this case and Pfizer is here there were millions -- hundreds of millions of compounds in the prior art that you could pick from to find the compound that you would change to make into this patented therapeutic for treating Type 2 diabetes. So you can contrast that with Pfizer. Here we have not a finite number of predictable solutions.

¶31 One of the other cases, Pharmstem Therapeutics versus Viacell. In this case, you have a process for harvesting umbilical -- stem cells from umbilical cord blood and freezing them and then using them later to introduce them into the same person or someone who is a type match in order to reconstitute their blood and immune system.

¶32 And in this case, the prior art taught both, you know, freezing cord blood as well as -- there was a reference where cord blood was used to reconstitute. Although, the success was only like five weeks but to reconstitute a patient's immune system.

¶33 So this is akin in KSR to dissection -- in KSR the Supreme Court talks about these three cases, about combining prior known elements so it is old elements, you know, new combination. And this is akin to the one case that they talked about, which was the radiant heat burner and paving machine combination.

¶34 So here in this case, the process is obvious because these two major prongs are already in the prior art. You don't see a lot -- at least I don't see a lot of cases that address level of ordinary skill in the art. Remember, that is one of the Graham factors that I mentioned.

¶35 And one case that did, that came out July is Daiichi Sankyo versus Apotex. So this case deals with -- Daiichi had a method of treating ear infections using an antibiotic, and the district court had determined that the level of ordinary skill in the art was a pediatrician or a general practitioner. And Apotex disagreed and the Federal Circuit agreed with them, that the level of skill in the art was a drug researcher, somebody who is actually making ear therapeutics. And this is important because the district court had reached its decision that it was nonobvious, which the Federal Circuit reversed, because there was a piece of prior art that the district court said that the general practitioner/pediatrician would not be aware of. So by setting the bar low, you rope in a lot more people of ordinary skill in the art, and they would not be aware of this particular reference. As specious as the district court's argument was, that was how they actually reached that decision, and that is how the Federal Circuit reversed.

¶36 Another interesting case came out in August, In re Sullivan. This case involves an antibody fragment that you use to treat rattlesnake bites. It is an antivenom composition, and so the prior art teaches whole antibodies as an antivenom. It teaches the use of antibody fragments to detect but not treat, to detect snake toxin, and it also teaches that

antibody fragments are cleared from the body faster. This is important because venom hangs around the body for an extended period of time.

¶37 So in this case, the Federal Circuit -- this came from the board obviously, but the Federal Circuit vacated and remanded and said that the board needed to consider Sullivan's declarations -- he submitted, I think, three -- that suggested this was nonobvious because you would not use fragments to be cleared from the body fast to treat something that is going to stick around a long time. Also, Sullivan showed that there was some unexpected properties for the antibody fragments, and that is another important, you know, secondary consideration.

¶38 Then the last two cases that I wanted to talk about, you can compare them with each other also, and they are a little complex. I'm not going to go into too much detail about them. The first one is Forest Laboratories v. Ivas Pharmaceuticals, and the second is Aventis Pharma v. Lupin.

¶39 In Forest Laboratories, you have -- Forest Lab had a drug, Lexapro, it's an antidepressant, and the active ingredient in this drug is a plus enantiomer, and four groups in -- of researchers at the same time as Forest Labs had tried to separate -- and enantiomers are related compounds, but a plus enantiomer versus a minus enantiomer could have different properties. One could be more effective than the other.

¶40 In this case, that was the case. The plus enantiomer was much more potent than its related compound. The problem was that four groups in the prior art weren't able to actually separate this mixture, and the inventors were the first ones to be able to do that. Also, the prior art had a teaching that the other enantiomer, the wrong one, should be the more potent one, so the prediction was incorrect, so you have a teaching away.

¶41 In that case, the Federal Circuit affirmed a finding that the compound was -- Forest Labs' compound was not obvious. And, like I said, you could contrast that with Aventis, which involved ramipril, which is a blood pressure medicine. In this case, the district court had made one error, and that -- made a couple, but one of the errors that they made was that they had applied -- and this case is from September.

¶42 So they had applied TSM, teaching suggestion, or motivation, rigid application of that. They had required that you actually find a suggestion or motivation to use this particular compound to do this, and the difference between this case and Forest is that there were two stereoisomers, one was effective and one wasn't, but you could separate them. That was something that was easy to do, so in this case, the Federal Circuit reversed the district court's finding that the compound was obvious. I hope I did not go over.

¶43 MR. SCRUGGS: No, you are fine.

¶44 DR. ZUHN: Any questions? Or I'll just pass it on.

¶45 PROFESSOR HOLBROOK: Okay. I'm going to take a step back and do a little bit of why is all of this happening? Why on earth has the Supreme Court jumped back in, although they seem to have a little bit of patent indigestion right now? They only have one case currently pending on patent exhaustion, the first-sale doctrine.

¶46 But why on earth, if you have a Federal Circuit that takes all of the patent appeals from across the country, why would the Supreme Court step back in? To use a metaphor that has been grossly abused since George Clooney's movie, it's the perfect storm. Right? That what we have is, we have the FTC and the NRC giving these reports about something is wrong with the patent system.

¶47 What happens after these reports, you get Congress getting interest in making reform. You see the PTO start to issue new guidelines about obviousness, about subject matter, and, of course, you are going to see a reaction in the courts with perhaps one exception, the Federal Circuit. Right?

¶48 The Federal Circuit up until this point, I think, had been fairly insular. They think of themselves as "the patent court." We know what we are doing. No one else can tell us how to do our job. In fact, if you look at how much they cite any sort of literature, outside of their own opinions, it's almost nothing. Right? They look to their own law and no one else. You can't get much more insular than that, right?

¶49 You say, Well, what is wrong? Maybe we are going down the wrong path, there was no method to correct that path. So I think that is part of it, patent reform was just sort of in the air. And I also think the Supreme Court was interested in the institutional dynamic between it and the Federal Circuit. The Federal Circuit was created in 1982, right? It's a new court. It's fairly young. I think the Supreme Court was really letting the Federal Circuit get its wings. If you step in too much, too early in a young court, it loses its credibility, and this court really needed to assert itself.

¶50 And I think early on the Federal Circuit did a good job of sort of getting the law fairly harmonized compared to the patchwork in patent law that we had with the Regional Circuit deciding these issues. But after 20 years, a court grows up, and I think the Supreme Court was thinking maybe we should take a step back and see what is going on here, particularly when you see some of the decisions that were coming out of the Federal Circuit. The earlier cases the Supreme Court would take had a number of constitutional issues.

¶51 Markman was a right to a jury trial. Warner-Jenkinson was actually framed as whether or not there was a right to a jury trial. They ended up going towards prosecution history, estoppel instead, but then you started getting some odd cases. Like why on earth did they take that? Why does the Supreme Court care about the on-sale bar? But then I think what triggered their interest is Festo, where the Federal Circuit, in light of the Supreme Court decision, articulates this bright line rule out of left field, unprecedented, and I think the Supreme Court thought, something is going wrong at the court below us. They seem to think that they are the Supreme Court, and, remember, they are not. There is the U.S. Supreme Court. The Federal Circuit is not the Supreme Court of patent law.

¶52 So I do think they were concerned about this idea that the Federal Circuit had about certainty. The Federal Circuit loves these bright line rules. I have heard one of the judges express in public that their job is to put themselves out of a job, where they can make the law so certain, we would not have any litigation any more. And I don't think the Supreme Court shares that view. I think they believe certainty is important to a certain level, but not if you are going to operate at the expense of fairness in certain contexts.

¶53 So you see them taking what the Federal Circuit does and instead of using these harsh rules, they use these rebuttable presumptions. You see that with Festo, you see it with Warner-Jenkinson. I wish we would have seen it with KSR. Instead, they gave us, I think, some mush. You could see how they could have put presumptions in there. So I think there was an institutional dynamic at play as well. Right? We are the Supreme Court, not you. We are going to basically create what we think is, of course, correction and now I think what we are seeing is, we are going to step back a little bit and see what

happens. Right? Will this inferior court listen to us or not? So I think that is the question for the coming years.

¶154 Aside from congressional reform, I think it is going to see whether the Federal Circuit listens, and I think it is mixed signals so far of whether they are going to.

¶155 With respect to KSR, in particular, the Chief Judge of the Federal Circuit and Judge Rader have both said in public, KSR didn't change anything. That was our law beforehand. They changed nothing, so there it does not seem to be getting back to them.

¶156 Whereas, the PTO thinks the world has turned upside down. They think this important Federal Circuit case has been overturned by KSR, so there is completely a disconnect between what the PTO thinks the impact of KSR was and what the Federal Circuit thinks the impact of KSR is. The academics, if the Federal Circuit would ever listen or at least read one of our articles, when we think that we are writing to an audience, they think something happened. There was something taking place in KSR. You see them bringing back these cases post-Graham and giving teeth to this idea of obvious to try, which the Federal Circuit had expressly rejected.

¶157 The Federal Circuit has overruled Supreme Court precedent and just did not bother to tell them they were doing that. So I think in KSR more went on.

¶158 The other institutional dynamic about KSR that I think is interesting is, I have never seen a lower court lobby so hard in its opinions not to be reversed. If you read the opinion coming out of the Federal Circuit between the grant of cert in KSR and the actual decision, there is all this litany of language about, "We don't apply this rigidly, it is not a strict test." You even saw that dynamic at the oral argument in KSR. You want an interchange in colloquy, listen to this oral argument.

¶159 You have got Justice Scalia saying, "Isn't this just mush? And, what, now after 20 years when we finally grant cert, they try to make this clear what they actually mean?" Right? You saw that the Supreme Court heard it. They were not pleased with what the Federal Circuit was doing. In that way, I was a little bit disappointed that KSR did not speak up a little bit more strongly at that institutional level.

¶160 If you do have some passing time, it's an interesting argument to read because you see the odd dynamic of this specialized court guarding its turf a little bit, and you even see that now with the legislative defense coming before Congress. Other than the Chief Justice of the Supreme Court, I don't know that I have ever seen a federal judge write letters to congressmen suggesting that they like or dislike certain legislation.

¶161 You typically think courts are about, "Well, we will apply the law as Congress gives it to us," and the Chief Judge has actually sent letters to The Hill saying, "We don't like these provisions," which is a little bit different. Supreme Court, yeah, you get that on occasion, coming from the Judicial Conference, but the Federal Circuit is in a unique position.

¶162 I think some of the other interesting cases to watch to see if they get the message will be the Microsoft case. Now, Microsoft itself dealing with exportation of software is a fairly narrow issue, but when you read the Supreme Court's opinion, there is this ending paragraph about U.S. patent laws do not apply extraterritorially, and we create this presumption and reiterated the presumption that they had spoken in a case in 1972 Deep South.

¶163 Why I bring that up is increasingly there are these extraterritorial concerns in patent law. Most of you have probably heard of the Blackberry case, a little \$600 million

settlement. Unfortunately, I went into academia because that was my old law firm that got the settlement. I could have retired.

¶164 But part of the system there was in Canada, so we say there is infringement under a U.S. patent even though part of the system was in Canada. I think it will be interesting to see how that language in Microsoft will play out in some of these increasingly extraterritorial cases.

¶165 I mean, MedImmune dealing with the declaratory judgment jurisdiction is going to be tough for the courts. I think it is going to be harder for companies. They basically said, "If you have a disagreement over the license, you don't have to breach the license to get jurisdiction." Then you have the Federal Circuit saying, "Well, any license negotiation necessarily seems to suggest a conflict that gets you into court."

¶166 So what happens -- and any of you who did the Giles Richtown petition this year knows, they had a great problem. You have this license, it's about to end. The patent term is longer than the license. Let's say there is three years left on the term after the license ends. Can that license be just walk into court and challenge the validity of the patent? If I'm a patent holder, that is a little uncomfortable. Right? That my license now does not mean anything.

¶167 So I do think that the KSR side is suggesting, "All right, they are not getting the message." The Federal Circuit isn't getting the message, but there are some signals that they are getting the message. I think that *In re Seagate*, maybe the message was not coming from the Supreme Court, but it was coming -- that reform is coming, and we want to act first before Congress screws things up.

¶168 *In re Seagate* made it harder to prove willfulness, to get treble damages in patent cases, and it is an odd procedural case because they actually establish the standard for willfulness in a discovery dispute. So there is an argument whether that is even appropriate, so they do decide, they heighten the standards over this attorney-client privilege waiver.

¶169 But where you do, I think, see the Federal Circuit getting it is *In re Bilski*, which is the current en banc case to consider subject matter eligibility. Before you had *State Street*, anything under the sun that is made by man is patent eligible, business methods are great, tax methods are great, there is even applications to claim story themes as opposed to the actual copyright itself with the idea of, Oh, here is someone who witnesses a crime and must go into hiding to escape the mob. I just described every John Grisham novel, right?

¶170 They patent that. And so there have been applications in that regard, so many people who were frightened that subject matter eligibility was going awry, the Supreme Court was set to decide that. In the *Metabolite* case, they actually went out of their way to grant cert because the issue clearly was not before the lower court. The Supreme Court reaches, takes the case, grants cert, hears argument, and then dismisses its cert improvidently granted. So it was a little bit strange.

¶171 There was some changes of the court, but there was a descent from the dismissal that really suggested *State Street* is wrong. It is inconsistent with Supreme Court precedent, so I think that *Bilski* is the Federal Circuit, at least being beaten down enough to finally say, "Okay, we need to revisit subject matter eligibility." They did conclude earlier in the year that a patent claiming a signal or the signal itself is not eligible subject matter.

¶72 And, surprisingly, they let that one go. Even though *Bilski* is now en banc and it is dealing with a method of arbitration, they let -- no one knows how to pronounce it. That is why they did not take it en banc, *Knighton*. They let that one go. There is another one, *In re Comisky*, which is floating out there, and it seems that they are holding on to *Comiskey* until they decide *Bilski*, right?

¶73 But they clearly seem to be getting the message from the Supreme Court that we need to respond, we need to alter our standards for subject matter credibility. I think that is going to be argument May 7th?

¶74 MR. GROETKEN: Yeah.

¶75 MR. HOLBROOK: It is coming up in May. So at the end of the day, what is the current status? I think the Supreme Court is done for a little bit. I really don't think that we are going to see a lot of activity by the Supreme Court in patent law. I think they are going to wait and see what did the Federal Circuit do.

¶76 The Federal Circuit, I think, at this point is a little more concerned with what is Congress going to do. One, if the PTO gets substantive rule making authority, I think the Federal Circuit will openly weep because they really don't like that idea.

¶77 MR. KUHN: So will practitioners.

¶78 MR. HOLBROOK: So will practitioners. And I think the thought of interlocutory appeals -- automatic interlocutory appeals on claim construction really has the Federal Circuit crying.

¶79 DR. ZUHN: That was the Chief Judge's biggest criticism.

¶80 PROFESSOR HOLBROOK: Absolutely. And we will see what happens in that regard.

¶81 I think the other thing to watch is one where the Supreme Court might step in and one where the Federal Circuit might act on their own is *de novo* review claim construction. I really think that *de novo* review is on the way out the door. Whether it comes from the Supreme Court, whether it comes internally from the Federal Circuit, I'm not certain, but it is a question of who acts first because if you do the head counting, there are at least eight judges on the Federal Circuit out of 12 who are willing to reconsider *de novo* review. That is enough to get en banc consideration. It is just going to be which case provides the appropriate view. I will end with that.

¶82 PROFESSOR SEYMORE: All right. Well, to follow along with the current theme, I'm going to actually touch on the Federal Circuit's response to recent Supreme Court activity. So, specifically, I'm going to talk about the Federal Circuit's new enablement standard and explore its potential impact on patentees.

¶83 So, as most of you know, *KSR* was a very popular case. It seems like, at least in the headlines, whenever you hear about patent law, there are always these certain buzz words that always catch the public's attention. Obviousness, that is something that the public and ordinary people can grab onto. To me it seems that enablement is one of the issues that receives less attention, at least in the media and possibly among patent practitioners and academics.

¶84 For those of you that had me in class, you know that enablement is one of my favorite topics. And, in short, the requirement ensures that the patent discloses the claimed invention in sufficient detail so that a skilled artisan can make and use the invention without undue experimentation.

¶85 So I will give you a little road map of what I want to talk about today. The first thing I want to do is to set the stage and briefly explore the contours of enablement and the two lines of jurisprudence that have emerged within the Federal Circuit.

¶86 Then I will briefly explore the, I guess, impact of KSR on enablement, and within that, I'll touch on two specific cases. And then, finally, I will discuss the implications for patentees.

¶87 So the enablement requirement, one thing that it does do is, it places an outer limit on the scope of the claims. It is well settled in patent law that an applicant need not physically reduce an invention to practice before obtaining the patent.

¶88 So, for example, as a scientist working examples are ideal but they are not required. So sometimes you end up with these -- with a situation where an applicant will actually prophetically claim an invention or maybe only describe one or two embodiments in detail but they actually claim a very broad genus.

¶89 So the question is how has the court dealt with that in the past and how is the court dealing with that currently. Over the years, there are -- two strands of enablement jurisprudence have developed. One strand dealt with chemical types of inventions, and those inventions are known as the unpredictable arts. And they are called unpredictable because a skilled artisan in a field like chemistry, for example, can't really take the results from one experiment and actually extrapolate that across an entire genus with any reasonable expectation of success. So just because a certain scheme works for one particular compound, doesn't mean that it will work for a million others.

¶90 So in the unpredictable art realm, it seems that over the years, the courts have actually required that applicants come forward with a little bit more teaching. So maybe enable a multitude of embodiments to cover the full scope of the claimed invention. And fear -- and that was done because there was a fear that if the applicant discloses very little, there is a danger that the full scope of the invention could not be practiced. So that is the unpredictable realm.

¶91 On the flipside, we have the applied technologies, some electrical engineering, mechanical engineering, and what are known as the predictable arguments. And they are called predictable because usually in mechanical engineering, for example, you have these well-defined predictable factors, so if you build an engine of a certain size, you can predict how much power you would produce, for example.

¶92 So what is interesting about the predictable art realm is the courts adopted the view that a single embodiment was often sufficient to enable a broad claim. So as long as you provide a teaching for a single embodiment, oftentimes that was enough to enable a broad genus. And, in fact, the courts would even uphold a broad claim even if it encompassed other embodiments that were inactively disclosed.

¶93 So the assumption was that a skilled artisan in a predictable field could basically extrapolate across the breadth of the claimed invention, so as long as I know how to make and use one, I can extrapolate that over others. So that dichotomy between the predictable and unpredictable arts actually created a problem in at least two ways.

¶94 The first problem was that it oversimplified the enablement, at least with respect to the predictable arts. So as Judge Ridge said long ago, there are times when an engineering invention, for example, has unpredictable factors, so having an unpredictable dichotomy is not necessarily the best way to approach enablement. The best way to -- or

one way to do it is to actually look at the unpredictable factors within a given art field as opposed to just splitting the art units predictable/unpredictable.

¶95 The second problem with the dichotomy was that there was this assumption that, at least in the predictable art fields, that the skilled artisans could always fill in the gaps that the disclosure omitted. What you ended up with was a skilled artisan that had no identity, so since this person could fill in all of gaps, it did not matter who this skilled artisan actually was.

¶96 So as Professor Burke and those have pointed out long ago, at least in the predictable art realm, it was basically easy to satisfy enablement, and enablement basically played no role in limiting the scope of claims. So that is where we were, I guess, until fairly recently.

¶97 So we come down to KSR, and KSR has been discussed a lot today, so I'm not going to go into detail. I think that one lesson from the case was that the skilled artisan is a person of ordinary creativity, so instead of being some imbecile or plotter for a technology, this person is actually a creative individual. So I think it is fair to say that after KSR, the Federal Circuit has started to give the skilled artisan more attention explicitly within opinions, and we already talked about the Daiichi Sankyo case, which we discussed in class. And it's fair to say that at least after KSR, you do see some discussion of who this skilled artisan actually is.

¶98 In terms of enablement, I think that one thing that we have also seen since KSR is the emergence of something that has been called full scope enablement. So as I mentioned at the outset, for so long we always talk about obviousness as a lever to modulate claim scope and patent rights, but here recently, we were also seeing that enablement can be used to modulate patent rights, as well.

¶99 And so after KSR there have been three cases that basically have invalidated -- well, three major cases that have invalidated patents for nonenablement. I am not going to talk about all of them in detail, but I do want to touch on two briefly.

¶100 The first is the Liebel Florsheim case. In that case the invention was directed towards a high pressure medical injection system, and in Liebel's application, the -- Liebel explicitly recited an injector with a pressure jacket. So during prosecution, Liebel actually learned that its competitor actually had a product that did not have a pressure jacket on it, so what did Liebel decide to do? Liebel decided to actually modify its claim so that its claims could actually encompass its competitor's products. So the way that they did that, among other things, Liebel went through its patent application and actually deleted all references to the pressure jacket and amended the claim so that the competitor's injector would have come within the scope of Liebel's claims and that worked.

¶101 In a subsequent infringement suit, the Federal Circuit actually affirmed the district court's conclusion that Liebel's broad claim covered the competitor's injection. But the problem was the following. In spite of that, the district court actually found that Liebel's patent was not enabled, and there were at least two reasons.

¶102 The first was that -- so as I mentioned before, Liebel went through its own application and deleted all references to pressure jackets. So although Liebel provided an enabling disclosure for an injector with a pressure jacket, nowhere did the written description describe a pressure jacket.

¶103 So on appeal -- and really at trial and on appeal, Liebel actually argued, "Well, in predictable art fields, as long as you have a single embodiment, that is enough to enable a broad claim, so our single embodiment should be enough to enable both with the jacket and without," and the Judge Lourie said, "No, that is not the case."

¶104 But also, more interestingly, Liebel's written description actually includes statements which disparaged a jacketless injector. And I'm going to talk about disparagement in a minute or so. For at least those two reasons, the Federal Circuit actually affirmed the nonenablement.

¶105 The next case is Automotive Technologies versus BMW. In that case, the invention related to automotive side impact sensors, so the Federal Circuit actually adopted the district court's claim construction, that the broad claim covered both mechanical and electronic side impact sensors. The Federal Circuit also affirmed summary judgment of nonenablement because the written description only provided a detailed disclosure for a mechanical sensor.

¶106 So, again, the argument at trial and on appeal was that as long as I provide a detailed teaching for one, I'm entitled to the other because, again, it's a predictable art field so you only need one embodiment. And, again, Judge Lourie actually rejected that argument.

¶107 It seems there were two aspects of the invention that actually discouraged the panel. One was the actual content of the written description. So with respect to the mechanical side impact sensors, there were two columns and five figures devoted to teaching those. With respect to the electronic sensors, there was one short paragraph and one figure, and that one paragraph was basically a conceptual overview and not a specific and detailed teaching. So there was sort of an imbalance within the written description.

¶108 The second problem was that side impact sensing was a new field, and that was actually stated as such in the written description. And that signalled, at least to the Court, that a skilled artisan would have a problem filling in the gap submitted from the disclosure, so -- and also at the time of filing, there were no electronic sensors in existence, so Judge Lourie actually concluded that the mechanical and electronic sensors were distinctly different.

¶109 So the question is, so where does that leave us? And so those two cases and one other, the Citrix versus Dreamworks, which I'm not going to discuss. These three cases point to a few lessons for patentees. One is that if a claim covers a range of embodiments, the disclosure should contain specific written descriptions that adequately enable the scope of the range. And that is really nothing new because in the unpredictable realm, that you could argue that that has been the case for a while. But, again, in the predictable realm, there was this feeling that one embodiment was enough.

¶110 So patentees might actually consider instead of prosecuting one big patent application with all of these different embodiments that are arguably distinct and different, prosecuting smaller applications.

¶111 The second lesson is that a broadly construed claim coupled with a narrow disclosure creates a high risk of invalidation. Keep in mind that enablement or compliance with disclosure is as of the filing date. So if an applicant decides to broaden the claim during prosecution, then the applicant better make sure that the disclosure actually covers that new breadth basically.

¶112 The third lesson is that if the -- if statements in the written description which disparage an embodiment indicate that an embodiment is impractical or teach away from an embodiment may suggest that undue experimentation is required. Such statements tend to disavow claims or could be construed as disavowing claim scope and suggest that that embodiment was nonenabled at the time of filing.

¶113 So the lesson here is that patentees should carefully choose language when drafting. It is very tempting to say, "My invention is so much better than whatever" but, you know, down the road, you will want to, I guess, obtain scope over that whatever. So you just have to be very careful in how you actually word the written description.

¶114 So to conclude, I think, what do these cases do? I think one thing is that these recent cases actually fuel a debate over the generic claim. So as all of us know, generic claims can actually cover millions or billions of embodiments.

¶115 And the question is, after these cases, what is -- where do generic claims stand? Obviously, generic claims is the fourth broadest scope of protection under the patent laws. Some would argue that you need broad claims in order to encourage inventors to actually enter the field and state the invention, promote disclosure.

¶116 On the other hand, you have a chilling effect issue, so while it certainly remains the case that applicants need not provide a specific teaching for each and every embodiment, I do think it is fair to say that the quantity of exemplification required after these cases is actually higher now than it was before, so the end result might actually be a shift toward a narrower claim.

¶117 So there needs to be a closer correspondence between what is disclosed and what is actually claimed. So applicants may be less inclined to draft a claim that covers millions of embodiments because it's almost impossible for the state to provide enough written description to support a claim of that breadth.

¶118 DR. ZUHN: And, also, the Patent Office is trying to prevent us from doing that.

¶119 PROFESSOR SEYMORE: Yes.

¶120 DR. ZUHN: We are in limbo right now, and we will see what happens.

¶121 PROFESSOR SEYMORE: As a person who used to prosecute chemical patent applications, the Markush claim was a staple of my life, so I drafted claims that covered billions of embodiments, but the Patent Office --

¶122 DR. ZUHN: You unsolved the problem.

¶123 MR. GROETKEN: If you look at what is really going on with the Supreme Court and its current status and interaction with the Federal Circuit, you could say, "The Supreme Court wanted to knock the Federal Circuit back a little bit, wanted to create a situation of certainty, and even went so far as to put the term predictability in one case." So there was predictability or certainty for those who have to have the impact and the outcome, i.e., patentees or owners.

¶124 The problem that we would look at, though, is that if you look at all of the cases that are out there currently that have come down in the last, say, two to three years, Merck, Illinois Tool Works, EBay, MedImmune, Microsoft, and KSR, only one really, Illinois Tool Works, is dealing with the antitrust issue, which is kind of pro-patent. In other words, there is not a per se market power in having a patent, as far as antitrust is concerned.

¶125 But if you look at everything else, is it pro-patent? No, not at all. So really I would argue to you that the pendulum, as this has been kind of couched for today, has swung

back from the '80s and '90s where it was a situation of more pro-patent to a situation of non-pro-patent today.

¶126 Well, what are we going to do about it? That is always the outcome part of this. Well, I would argue to you that the outcome is not coming from the Federal Circuit and probably not coming from the Supreme Court. Neither one wants to really -- the Federal Circuit wanted to be the Supreme Court, got whacked back. The Supreme Court said, "No, you are not the Supreme Court, and here are some changes to the standards." Let's just look at the cases.

¶127 With Merck, the 271(e)(1) situation with respect to utilization of drugs, in essence, and preclinical and clinical trials, et cetera, anything related to the federal regulatory law, like the Food, Drug & Cosmetic Act. Guess what, you can go ahead and use that patented invention and the other side can't do that. Pro-patent? No. Change the standard? Yes. It gave quite a breadth for the use of these things, for testing purposes, experimentation, et cetera, as long as it related to something, say, for the submission to the FDA or the BFDC. Okay. Fine.

¶128 Well, what is the outcome of that? Well, I would argue that the outcome again now comes back to the patentees and the owners. What are you going to do about it? Well, somebody is going to be able to maybe use my materials, but let's look at it from another angle. Regulatory, from a biologics perspective, you still can't use my donor stem cell bank, right? I'm not going to give that to you.

¶129 What else am I going to do? Well, yes, you might be able to use my compound, but you can't use my methodology. You can't use my method, per se, in doing what I need to get where I get. So you infringe in that particular situation. Do we get help from the courts? No. We got the help from the patentees. They are looking at the statute, working with their counsels and saying, "What is my outcome?" My outcome is, I have to look at this in a new light. Does it create certainty? No. It created a situation where counsels and patentees and owners work together to address, how am I going to address this outcome now?

¶130 Then we look at the EBay case. Right? Here is a situation, Well, can I get a permanent injunction, or is it the first-sale rule? In a situation from the Federal Circuit, you infringe, permanent injunction will come forth. Now? No, now you have to meet the four factor test. Pro-patent? No. What is the outcome? Well, today I will argue to you that lots of patent plaintiffs anyway are considering, Well, I better argue irreparable harm as much as possible, upfront and throughout my case. Why? Because I know this factor, from the perspective of a lot of courts, at least in the district courts, when looking at this in an equity situation, are going to say, "Okay, you are so irreparably harmed, I can give you the permanent injunction." But, also, don't forget that we still have the ability for the preliminary injunction, we should utilize it to our advantage today.

¶131 So do we get certainty and predictability from the Supreme Court in the situation? No. But we can create the outcome, based upon what we do in reaction to it. Again, it's mostly an outcome basis for patentees and their counsel.

¶132 Then we look at MedImmune. This one for me is a major concern, but so as patent counsels we went ahead and wrote a license and now even though they are paying the royalties, guess what, I can go ahead and challenge you that I'm not infringing or your patent is invalid. Really not a great outcome. And a lot of people said, "Well, what is going to happen to me now? Are all of my licenses going to be troubling? Am I going to

have problems?” Yeah, potentially, we think that is true, but we think there is a way to deal with this as well. Did it create certainty again? No. The pendulum is swinging non-pro-patent, but we can address what we do at the time of renewal of old licenses and the new ones we create today. How do we do that?

¶133 Well, first of all, you have a pre-suit notification clause. Right? If you go ahead and want to challenge my patent, you have to challenge me four months ahead of time and, guess what, you should also give me all of the prior art that you are going to try and utilize, as well. Not so much of an advantages for a licensee now, is it? Because, guess what, you gave me everything that you want to argue.

¶134 You could also argue that if you go ahead and challenge my patent for a declaratory judgment action, I'm going to go ahead and say, “Fine, you are breaching, and you will agree to that in the license that we have.” You could also have a situation of differing royalty rates. If you challenge and I win, great, but the royalty rate goes up.

¶135 If I lose and I could still argue that you are taking no housing fees, et cetera, I will have a reduced royalty rate but any way I am getting a royalty rate.

¶136 So those are some examples in relation of how is the impact and outcome. Did we get certainty again? No. Because now you have these licensees that have the ability to challenge. I understand that a patent like personal property has aspects for principles of equity, like the Supreme Court said, but, unfortunately, it does not lead to uncertainty or predictability for those of us dealing with it. Everyone in this room, as future patent attorneys, counsels, inventor patentees, whatever it be, we still have to deal with the outcome. I would say again, the pendulum is swinging to a non-pro-patent basis.

¶137 Finally, I will just touch upon KSR. Guess what, we are going to tell you now the obvious standard is wider, a little more flexible. And we have even seen a response to that, the Patent Office coming up with new guidelines. They are called examination guidelines, and they have seven -- seven different tiers of this alone that examiners can use and try and fit things into to say, “You are obvious” but yet they themselves, pursuant to those guidelines, and with my interactions with the PTO and some of the administrative staff are not really sure how to apply that.

¶138 Again, what is the outcome? Unpredictability. How am I going to do this? There is two ways you are going to address it. As noted earlier on this panel, we are going to address it with drafting. You are going to try and link your claims so you don't have an elements analysis. You are going to address things in your background. You are not going to point out problems. You just don't have time, and USPTO, pursuant to the rules, you don't have to put in a background if you don't want to. It is not a requirement. I encourage you to be careful with that type of analysis, but you don't have to if you don't want to.

¶139 At the same time, you are going to be looking at how am I going to disclose things better and focus on comparative examples and things of this nature, if available. And I would argue that the change is in the various art. You have to look at it from that perspective, as well.

¶140 Then let's turn to the rejections themselves. You have a rejection and now this examiner is applying these standards. Well, first of all, did they? You still have teaching away.

¶141 They say, I can take things from different arts, so there was a need and, therefore, it was a predictable result. Is it? Maybe there is an unpredictable result. Maybe it was

very difficult to manufacture that particular outcome that you have for your composition in your claim. These things are all relevant points that need to be argued to the USPTO, and I would say that the outcome of predictability again is coming from the patentees and their counsels in addressing these issues, that we are now faced with the changing standards or flexible standards from our various court systems.

¶142 So the pendulum may swing, but it swung before in maybe a pro-patent fashion. And today it is swinging in a more non-pro-patent fashion, but in either situation, the outcomes are the same.

¶143 The people that have to address it, the inventors and corporate entities that own these IT assets are addressing it, and they need the assistance from everyone in this room to figure out the best appropriate way, since things keep changing all of the time.

¶144 MR. SCRUGGS: Okay. We are about to open up for Q&A. I want to congratulate our panelists on all doing a great on job.

¶145 (Applause.)

¶146 Okay. So now we will basically just open up the Q&A. If you have a general question, go for it. If you something specific for one of the speakers, make sure you let them know.

¶147 AUDIENCE MEMBER: I'll start. Footnote 11, from the MedImmune case, as I recall, the court really did not address specifically the Federal Circuit's standard. They just disparaged it in the footnote. Yet, the Federal Circuit has run with its tail between its legs to a certain extent. It says that they are listening very carefully to the Supreme Court and are very sensitive to what the Supreme Court has to say. Would you agree?

¶148 PROFESSOR HOLBROOK: I would say that is one signal that they are. I don't have enough faith -- and I'm hopeful that they will.

¶149 Given their past history of never finding a Supreme Court case they could not write themselves around, I'm not quite -- they are also afraid of the heightened level of review that they are getting. If the Supreme Court stays away for a while, I think we see the Federal Circuit start to assert its authority again.

¶150 You are absolutely right. Footnote 11 said reasonable apprehension of suit is arguably inconsistent with our precedent but it was not present in the case before. Right? That was not present.

¶151 So they did not answer the question, here comes SanDisk in the Federal Circuit, like, Oh, it is gone. You could say that reasonable apprehension of suits is sufficient. It may not be necessary, right, and that may have given us a little bit more guidance. Fine. We can still use that to get a good feel for whether there is a declaratory judgment action or not, but I think that was the Federal Circuit -- particularly, Judge Bryson's concurrence sort of saying, If there is a dispute of any sort -- and taking it to its extreme, that can't be the case. Right?

¶152 Article III cannot allow that type of dispute to actually go forward in every circumstance. My hope is what you will see is the district court's clamp down on the discretionary side. Right?

¶153 Even if there is an Article III case or controversy, they do have the discretion to not hear the case, particularly if they think it is simply being used for negotiation leverage. That is the other squeezing point. We blow this hole open, but we may tighten it up down there through discretion. I'm waiting to see if that happens. I'm waiting to see how

the Federal Circuit will react to district courts declining jurisdiction in that context. Will they accept it? Will they actually get imbibed by discretion standards or not?

¶154 AUDIENCE MEMBER: I bring it up particularly with regard to the Caraco case, where there was actually a covenant not to sue. They said that was not enough either and that was based on complex regulatory system. It just seemed to me that they went way past anything that the Supreme Court would have directed them to do in accommodating what they view as the Supreme Court's direction.

¶155 PROFESSOR HOLBROOK: I agree.

¶156 MR. GROETKEN: If I recall the name of case, it was Clausen where I believe the issue was inventorship, and they said even that would be enough, where you can go ahead and say that is a controversy and we will go ahead and address that, as well. So no one really knows, are you going this way or are you going this way with this kind of term of licensees saying, I can challenge where. Where is "where" for Article III?

¶157 PROFESSOR HOLBROOK: It is still a mess. Although, it does -- I know patent owners are not thrilled with this, but in the pharmaceutical context there was this added provision by Congress allowing a generic company who has applied to the FDA, there is a complex regime, where basically you send notice to the patent owner that you are going to get approval from the FDA. They have 45 days to respond. What happens if the patent owner does not respond within the 45 days?

¶158 Congress did create this mechanism that said, "Well, you as the generic can go seek a declaratory judgment action to get it clarified." Pre-MedImmune, it was not clear that that provision had any teeth under the reasonable apprehension of suit test. Now at least it does have some teeth, so I know patent holders may not like it. At least if you are looking institutionally, what did Congress attempt to create? At least that provision now has a meaning, which it may not have had before.

¶159 DR. ZUHN: I just want to say two things.

¶160 One, the Caraco case is very having interesting, and just a plug for Kevin Noonan. He wrote a summary. It's on the blog. He's a founding author on the blog, and it is a very interesting case. And I highly recommend that you go read it because I think it is very relevant in terms of this discussion.

¶161 And then I wanted to bring it back to obviousness. Maybe I'm just less skeptical about the Federal Circuit with regards to obviousness. I'm going to give them the benefit of the doubt on this one. There are cases out there, including one of the seven that I talked about, where a district court did require an explicit teaching, suggestion or motivation in a reference that was present, which is obviously as rigid an application as you can possibly get, and they reversed on that.

¶162 But if you look at the Pfizer case, that is pre-KSR. DyStar is pre-KSR, and those both have very strong -- they are very strong opinions, very strong statements about how this is not a requirement.

¶163 PROFESSOR HOLBROOK: I would say those are pre-KSR decisions. They are post-KSR cert grants, maybe it's going to be KSR -- the decision didn't change anything. I think that KSR did potentially change the law. It just was not the actual Supreme Court decision.

¶164 DR. ZUHN: It was the anticipation of it.

¶165 PROFESSOR HOLBROOK: Exactly.

- ¶166 The pro-patent pendulum, I do agree -- and I'm nervous that we are going too far to being opposed to patents. Although, I think the Federal Circuit really gets a bum wrap on this. I don't view them as pro-patent. If you are pro-patent, you should like the doctrine of equivalence, and they hate the doctrine of equivalence, right? If you are pro-patent, you should want broad generic claims. They don't like them. Right? Written description.
- ¶167 Their concern really is the certainty thing, so they are really happy to have lots of valid patents in lots of areas of subject matter that are that broad in scope. Right? They like really narrow patents that are very valid, but you are not going to get much protection with that patent, so it is sort of a mixed bag when it comes to whether the Federal Circuit itself is pro-patent. I think they get a bad wrap in that regard.
- ¶168 I really think it is a mixed bag because what they are worried about is certainty. They have this idea that uniformity and certainty is their mantra. That is why they exist. That is what our mission is, and I think that can go a little overboard. So if there's a reaction that the Federal Circuit takes from the Supreme Court in some regards, I feel that is part of it, right? And it actually may help patentees in that regard.
- ¶169 DR. ZUHN: I wanted to throw one thing out about EBay. That is that MJ Roche. Up until Roche appealed or filed notice of appeal, it has been an interesting case because this shows you exactly what EBay is going to probably do, and I think we are going to have the situation with almost every single therapeutic that you talk about, you know, the competitor comes in and they might have a product that works a little bit better.
- ¶170 It falls within the claims of the patentee's patent, and that is the situation here. You can't take that away -- you can't take this product away because it has a benefit, so you have all four factors and you are done. The district court judge on that case made it perfectly clear that the first two were boom, knock those factors right off. It is when you get done with the last one that you have a problem.
- ¶171 MR. GROETKEN: I would agree, and a lot of generics, I think, are looking in that direction. If I am going to come out with my generic formula or composition, one, I'm bioequivalent, right, to get out there. And now I can actually show that it's cheaper and it's going to be a situation where I have the benefit or a better benefit. It's a real concern by big pharma to say, "Well, wait a minute, this case has an impact upon me because that is exactly what is going to be argued."
- ¶172 How am I going to get my injunction? How am I going to be able to stop this? I would argue in response, "Yeah, you are going to have to use 271 in relation to those time frames and a lot of the regulatory issues to your advantage right now in light of this case."
- ¶173 DR. ZUHN: Wait until we get bylaws, which I think is just a matter of time.
- ¶174 MR. GROETKEN: They are addressing it in Europe, so I think you are going to see the U.S. dealing with biosimilars, in essence, soon.
- ¶175 MR. SCRUGGS: Any more questions? I thought I saw somebody here earlier?
- ¶176 DR. ZUHN: Nothing, Mike?
- ¶177 AUDIENCE MEMBER: You answered everything.
- ¶178 MR. SCRUGGS: I actually have a little bit of a question. How much do you attribute the recent Supreme Court interest -- I know Tim kind of mentioned The Perfect Storm.

- ¶179 How much do you attribute this to a dynamic that may be going on in the Supreme Court with kind of a constructionist wing like the John Roberts and Alito faction kind of combining with the Breyers and a couple of the other justices who just think patents got out of control base case?
- ¶180 Kind of combining and aligning and deciding, “Okay, patents have gotten out of control and we want this stuff grounded in the statute in Supreme Court precedent, not necessarily the Federal Circuit?”
- ¶181 DR. ZUHN: I suppose that has something to do with it, yeah.
- ¶182 PROFESSOR HOLBROOK: And the change of personnel is important. Although, the uptake of cases started happening before both of them came on, so I think that there was momentum beforehand. Whether that momentum is carried over and is now based on the concerns that you addressed, could very well be.
- ¶183 I really think what you had, cert grants take four and you have Stevens clearly curious about what patent system -- he made it clear, he thinks something is wrong. You have Breyer who has some exposure to it and some interest in it. I think -- the third descender Metabolite and then you throw Kennedy on board on occasion, right, his concurrence on EBay.
- ¶184 So you have those four that clearly were curious. So to the extent that they wanted to impact it, you had the block, you had the vote, so when I look at it from who seems to be pulling the strings of when we are going to take stuff, I did not see it so much as the Chief Justice or Alito being involved. Although, the Chief Justice, I think, is interested obviously from KSR and he litigated some IP cases in practice. So I think it may have been a tipping point for some of them.
- ¶185 DR. ZUHN: I think one thing that is interesting is last spring, California Health Care Industry is a collective of California biotech and pharma companies. It came out with this white paper, and their contention was that this is a three-pronged attack. Every single branch of the federal government is out to get patentees, so you have the Patent Office executive branch crafting all of these different rules packages, IDS rules, claims and continuation rules, which were knocked down in GSK. The alternative claiming rules, the appeal rules. I don't think that I missed anything.
- ¶186 PROFESSOR HOLBROOK: Subject matter guidelines, obviousness guidelines.
- ¶187 DR. ZUHN: Yeah. And new written description training materials that just came out last week. So you have the executive branch doing that.
- ¶188 You have Congress patent reform. The House bill is -- I don't even know where to begin. It's the one that is passed, and it got passed last September, I think. And it is atrocious. There is aspects of it that patentees and patent practitioners -- if you read it, it is going to make you sick. And the Senate bill is not that much better.
- ¶189 It's a little bit better because they have omitted some of the clauses, and we have seen some clauses fall off recently like the date of treasury issue, senator sessions, sticking some fork into the bill. So now he has agreed to pull that off the table. We will see if anything gets voted there.
- ¶190 And then you have the judicial branch. So we have got -- then you have the Supreme Court. And I think when you take that last spring, it looked really bad because you had all three branches. For patentees and patent practitioners, it looks a lot better right now because the Patent Office has been shot down, and GSK was an absolute

victory as it stands right now, not having been appealed yet, for the patent bar and for patentees.

¶191 And you are seeing the same thing with patent reform in Congress. It looks like it is stalling and not going anywhere.

¶192 So the Supreme Court is really the -- and the Federal Circuit's reaction to that and their fear of looking bad and, you know -- a piece about, you know, how long is the Supreme Court going to continue to flog the Federal Circuit. When is this going to stop?

¶193 Really, that is the branch of government that we really need to work with.

¶194 PROFESSOR HOLBROOK: If you look at the FTC and NRC reports, too, the things they flag as bad have all been corrected by the courts. Right? So even the impetus for patent reform, at least by Congress, has been undermined.

¶195 DR. ZUHN: What I would like to see the Patent Office and Congress do and they have not done, in my opinion, is listen to patentees and patent practitioners.

¶196 PROFESSOR HOLBROOK: I don't think that is --

¶197 MR. GROETKEN: I think he is somewhat right.

¶198 PROFESSOR HOLBROOK: I disagree.

¶199 DR. ZUHN: I'm not saying about your particular stance, but I take issue with a number of -- and I don't want to mention names -- academics who have led Congress and the Patent Office down this road.

¶200 And, thankfully, right now we are at a point where hopefully it looks like we are not going.

¶201 PROFESSOR HOLBROOK: My only counterpoint is -- I agree they should be listening, but I think the Patent Office needs to remember that its ultimate customer is the public, not the patent applicant. That is what I think it wants. They are there to represent the interest of the United States public, not the interest of an applicant before the PTO.

¶202 DR. ZUHN: I think the problem with the PTO right now is that the rules packages show clearly -- and I have spend countless hours researching -- and I'm sure you did, too.

¶203 MR. GROETKEN: Yeah.

¶204 DR. ZUHN: Last fall there are a lot of attorneys throughout the country that blew lots of billable hours learning about the rules. They are very complex.

¶205 PROFESSOR HOLBROOK: I agree with that.

¶206 DR. ZUHN: The problem is they were set up to address and benefit who? The Patent Office administrators, so I think that is the problem.

¶207 PROFESSOR HOLBROOK: I'm not saying that they are perfect.

¶208 DR. ZUHN: I agree they need to address the public interest, but I think if you listen to -- patent practitioners are not up there saying everything is perfect.

¶209 MR. GROETKEN: At least giving us an opportunity to have a voice and say, "That has some impact." If you think about it, we really are the customers. And if your customers are saying, "This is not working, this is not working the best way," even if it serves the public interest, at least try to work with that knowledge versus just ignore it.

¶210 PROFESSOR HOLBROOK: I agree with that knowledge. I bristle at the thought that you are the customers. I don't like that mentality for a public agency to think that you have a customer. That is troubling.

¶211 That is like the EPA saying that our customers are the air pollution, the people that pollute. No, it's not.

- ¶212 DR. ZUHN: I agree with you to a point, but up until five years ago, funding that went into the Patent Office which came from my clients actually got directed to the public.
- ¶213 PROFESSOR HOLBROOK: Absolutely.
- ¶214 DR. ZUHN: It was Bedemer. So for five years we have not had that situation, and the Patent Office is keeping the money that it is taking in as fees, and they are getting that money not from the federal government, they are getting the money from our clients.
- ¶215 MR. GROETKEN: Which are customers.
- ¶216 PROFESSOR HOLBROOK: And you are getting your patent, right? You guys get a patent and right to exclude. I'm not saying you should be shut out.
- ¶217 MR. GROETKEN: It's a poor exchange. I think it is even -- if we are going to have that bargain, at least give us some ability to have some say and to work with the Patent Office. I think right now they just said, "We don't want to hear from you at all."
- ¶218 PROFESSOR HOLBROOK: That is wrong. I'm not saying that you should not have a voice.
- ¶219 I'm just saying that saying this works like a company where we have to worry about our consumers takes a perspective that ignores the public's interest. It's a dangerous metaphor to use, in my opinion.
- ¶220 DR. ZUHN: The Patent Office needs to stop worrying about the administration. It needs to start worrying about -- I agree with you, the customer, the public interest, and its own examining court.
- ¶221 PROFESSOR HOLBROOK: The examining court's problem is retention.
- ¶222 MR. GROETKEN: They have lost, what, 50 percent of those that they already hired.
- ¶223 DR. ZUHN: They lose -- one of two examiners that walks in the door walks out within three years.
- ¶224 MR. GROETKEN: Or less.
- ¶225 DR. ZUHN: Or less. That is a significant problem, and the real problem with the Patent Office is production goals. So they are unreasonable, and the Patent Office refuses to look at it. There is no difference in time for examining based on the number of pages in an application, the number of claims in an application, the technologies. Let's face it, technologies are not all created equal. Some are a little bit more complex.
- ¶226 MR. GROETKEN: Well, based upon the ability of that technology coming into the Patent Office, I would argue there are certain technologies, nano, bio, et cetera, as they become the technology and emerging, et cetera, they have had to -- higher, higher, higher, and they can't because the industry, et cetera, is catching up here. Here is an example of when that problem occurs, but yet they use a formulaic approach to the whole situation of all units.
- ¶227 PROFESSOR HOLBROOK: There is a hand.
- ¶228 MR. SCRUGGS: I saw your hand come up a couple of times. I want to make sure you get in there.
- ¶229 AUDIENCE MEMBER: He actually answered my question, so there goes that.
- ¶230 MR. SCRUGGS: Any other questions?
- ¶231 AUDIENCE MEMBER: With respect to that case of the side impact air bags and enablement, wasn't that situation really a means-plus-function claim?

- ¶232 PROFESSOR HOLBROOK: No. Anybody who has curiosity about disclosure, Automotive is a very telling case in that if you think written description the doctrine is wrong, as announced in LizardTech. If you like it, that is fine. If you think it is wrong, Automotive is scary to you because it is the Federal Circuit making enablement exactly like written description. Right?
- ¶233 That it hears a claim limit, this does not exist in the specification. They don't ask whether one of in the art can actually understand that claim limitation. We simply say, "It is not present in the disclosure, therefore not enabled." So it is an expansion of enablement and makes it much, much more akin to written description. It sort of takes LizardTech Step 2, in my view.
- ¶234 MR. GROETKEN: Well, there it says that might be a situation of becoming more like the Europeans, you know, show me line, show me page.
- ¶235 PROFESSOR: Yes, exactly.
- ¶236 DR. ZUHN: And it will lose the comment that the requirements are separate.
- ¶237 PROFESSOR HOLBROOK: I'm one who thinks the distinction -- having two different doctrines does not make sense, that it is one. Unfortunately, the answer I may get from the court is, "You are right and it is written description, not the view of enablement that I like."
- ¶238 DR. ZUHN: I agree with you.
- ¶239 AUDIENCE MEMBER: A case I saw recently in the area of reasonable royalties, I think it is called Amato versus Microsoft. It dealt with pre-verdict damages versus post-verdict damages, when an injunction is not entered.
- ¶240 PROFESSOR HOLBROOK: I think it is the Z4, right? It's versus Microsoft. I know which case you are talking about.
- ¶241 AUDIENCE MEMBER: Something against Microsoft.
- ¶242 In that case the court made a comment that these pre-verdict damages have to -- in terms of the hypothetical negotiation, would have to take into account the legal uncertainty that surrounds negotiations prior to a resolution in court, which struck me as contrary to the general rule that most people have been following in these hypothetical negotiations. That if you are in that space, you are assuming that the patent is valid. That is what the jury is told. Assuming that the patent is valid, what would the reasonable royalty have been.
- ¶243 Does anybody have any thoughts about this particular -- it's a couple sentences in this opinion that sort of suggests that a jury ought to be considering the potential invalidity or the risk of invalidity in their determination, which would tend to result in lower royalty rates being granted as damages.
- ¶244 MR. GROETKEN: I mean, the only thing I can say on this is, I don't like that being included in the hypothetical. I don't see where it should be in the hypothetical. It has nothing to do with the royalty analysis.
- ¶245 The other thing is, I think it is a situation of how do you determine what the legal uncertainty is. If you say, what if I'm in a crowded bar or I'm not in a crowded bar. Is that how you should do the analysis?
- ¶246 There is really no way to legitimately say and have a jury consider, how do you know the legal uncertainty? It's not in its role. I think the sentences are just a very, very poor choice of words.

- ¶247 AUDIENCE MEMBER: There are cases where you can actually see in discovery that the parties, including the patentee had a discount internally?
- ¶248 MR. GROETKEN: Sure.
- ¶249 AUDIENCE MEMBER: So you are not sort of asking the jury to determine a discount based upon the evidence in the trial but rather to look at the evidence of their own mental state when they were taking to each other?
- ¶250 MR. GROETKEN: Fair enough. But how are they going to look at the idea of invalidity, et cetera? I just don't see that.
- ¶251 PROFESSOR HOLBROOK: Right. I mean, it is the ultimate hindsight problem. You are supposed to do that with a hypothetical negotiation, step back in time, but now you are really making it convoluted by, What would we think that validity is going to be, now that we now that the patent is valid. Right?
- ¶252 You really seem to be having a problem in that regard, but there must be -- you see that intuition in Justice Kennedy's concerns in EBay. Right? One reason he says we should deny an injunction is if it's a patent that we think is the suspect validity, which to me is a non sequitur. If we are at the injunction phase, it is not suspect validity. It is valid. It seems to be that same kind of intuition going on.
- ¶253 Maybe theoretically it makes sense. If we really were back in time negotiating, then one factor would be, well, what are my odds of winning? If I think that my odds of winning are really 60 percent, proving invalidity, then I'm going to want a lower rate. But to bring that in at the litigation phase, that just seems a nightmare. As if reasonable royalty was not bad enough as it is. Although, you are right, Congress will make it worse. That apportionment stuff disturbs me. But, yeah, that just seems a little bit bizarre.
- ¶254 Now, if you want to take that thought into the ongoing prospective royalty rate, there is no hindsight then. Right? It's a valid patent so that seems to be some unfortunate language.
- ¶255 MR. SCRUGGS: Any more questions?
- ¶256 AUDIENCE MEMBER: Do we have time for one more?
- ¶257 MR. SCRUGGS: Oh, yeah.
- ¶258 AUDIENCE MEMBER: We talked about -- or Professor Holbrook mentioned how the Federal Circuit kind of responds rather quickly to even minor suggestions by the Supreme Court when they granted cert. It was quite obvious that they backed out the motivation aspect rather significant and the statistics bear that out. I think that Professor Davis at DePaul has a new study out that is going to show that rather significantly.
- ¶259 So it seems that overall the Federal Circuit may be taking a lesson in backing off, making these pronouncements in general or trying to proceduralize certain aspects of the law. But there is one area of the law that really needs some clarification, which is claim construction.
- ¶260 And the most recent guidance that the Federal Circuit has put forth in Phillips, and people would go back and forth saying they went -- they did not go far enough, they should have gone further. In light of the Supreme Court, it's doubtful that they can go any further than that.
- ¶261 Now, we talked about the fact that courts are -- or the Federal Circuit is leaning on written description and maybe -- or blending it in written description, which may be their only recourse in trying to clarify claim construction at this point.

¶262 I'm just interested in what other ways you think that the Federal Circuit can clarify claim construction or maybe written description is the best way at this point.

¶263 PROFESSOR HOLBROOK: I don't like written description as the lever because then you have an invalid claim. I think most patentees would rather take a narrow claim construction and keep a valid patent claim, as opposed to lose the claim under written description, which that is some of the contention that is in LizardTech itself and Judge Rader's descent. We have got this doctrine where we are giving in -- supposedly giving expansive interpretation of these claims and then we knock them out as invalid under written description. That does not seem appropriate.

¶264 So I don't like written description because of the external consequences. Right? I would rather have some way to keep this within reasonable scope.

¶265 I think that Phillips is an utter disaster. It was the most disappointing opinion I think I have ever seen. It gives the litany of the questions and it looks like it is going to be everything that we ever wanted to know about claim construction but were afraid to ask and answered none of it. In fact, if you read it right, seemingly it resolved the question of dictionaries first versus specification first, seemingly.

¶266 But if you read Phillips, it expressly says, "We don't take into account any order of evidence we will consider, you are still free to think of this." I thought very tellingly, if you look at the Federal Circuit's web page yesterday, they issued an errata. Now, most times you don't look at erratas, right, but I'm like, What the heck.

¶267 They changed an opinion from last month where it said, "Phillips says that you consider the evidence in this order and we will consider it in that order." They delete that language and say, "Phillips doesn't tell us anything about what order to consider the evidence." So if you want to do Texas Digital, you still can. Technically, it didn't overturn Texas Digital. Phillips told us absolutely nothing, and some empirical work that has been going on by Professor Wagner at Penn and Pentherbridge down at Loyola LA says, in fact, everything is returned to the pre-Phillips state. If you believe there is a dichotomy, holistic versus procedural approach, it is now back to how it was.

¶268 I'm trying to go through some claim construction cases now to give examples of, well, when do they read limitations into the spec? I really can't find a justifiable basis other than which judge is deciding the opinion.

¶269 So, ultimately, what do I think? I wish the Federal Circuit -- I was actually a proponent of de novo review. I admit, I liked it. I thought it made sense. I thought it was a really integral document, the courts should be able to do it.

¶270 I now have to back off. Why? Because I think the Federal Circuit failed in providing strong legal rules to guide the courts. They are afraid for some reason to tell the district courts, This is how it is done, do it this way, use these steps. Don't know why they won't do it. And if they are not going to give that guidance, they need to give notice.

¶271 MR. SCRUGGS: Any more questions? Got a couple minutes. All right. Well, I want to -- little round of applause again. Thank you all for coming.

¶272 (Applause.)