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Who Defines the Law? USPTO Rulemaking Authority

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NICHOLAS M. ZOVKO,^{***} & DONALD L. ZUHN, JR.,^{****}

¶1 MR. HOWARD: Ladies and gentlemen, my name is Damien Howard, and I am the Executive Articles Editor of the Northwestern Journal of Technology and Intellectual Property. It is my pleasure to introduce the members of our next panel, "Who Defines the Law?: USPTO Rulemaking Authority."

¶2 DR. ZUHN: I'll just put my business card out here and, hopefully, you've got good eyes. (Laughter.)

¶3 MR. HOWARD: That is Dr. Donald Zuhn, who is a partner at McDonnell Boehnen Hulbert & Berghoff. Dr. Zuhn has more than a decade of experience in all aspects of patent prosecution, litigation, counseling, and licensing. He is also the founding author and editor of the Patent Docs weblog, a site focusing on biotechnology and pharmaceutical patent law. Next to him is Professor Jim Speta, who has been a member of the Northwestern University School of Law faculty since 1999. He teaches a number of courses, including administrative law, antitrust law, and telecommunications and internet policy. Prior to joining Northwestern, he practiced appellate, telecommunications and antitrust law with the Chicago firm of Sidley & Austin. His research interests include telecommunications and Internet policy. Next to Professor Speta is Professor Masur, who is a professor at University of Chicago Law School. He currently teaches administrative law, patent law, behavioral law, and legal theory. Prior to joining the University of Chicago, Professor Masur clerked for Judge Posner of the Seventh Circuit and Chief Judge Patel of the U.S. District Court for the Northern District of California. Professor Masur is the author of the recent article, "The PTO's Future: Reform or Abolition?" which was published in the University of Pennsylvania Law Review. Next to Professor Masur is Nicholas Zovko, who is an associate at Knobbe Martens Olson & Bear. His practice includes several areas of intellectual property law, including patent litigation, trademark litigation, and patent prosecution. Mr. Zovko has both litigation and prosecution experience with a wide range of mechanical and electrical technologies. Mr. Zovko will now introduce the panel topic.

¶4 MR. ZOVKO: Thanks, Damien. I think we have a very interesting topic, an excellent panel. I know it's going to be a lively debate. The panel members met each

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other for a few minutes before the panel started, and there was already dissent and debate, so I think this is going to be an interesting one. But before we open it up to questions and a general discussion, I want to spend a few minutes going through a few recent Federal Circuit cases, providing a little history on the Patent Office rulemaking authority so everyone is on the same page and can more fully participate in the discussion. As most of you know, the patent laws generally derive from the Patent Act of 1952. Section 2 provides and outlines the powers and duties of the Patent Office, and Section 2 says that the Patent Office may establish regulations, consistent with the law, that govern the conduct of proceedings before the Office. The Federal Circuit, which was created in 1982, has consistently held that that provision does not give the Patent Office substantive rulemaking authority; rather, it merely gives the Patent Office procedural rulemaking authority to govern the conduct and proceedings in the office.

¶5 In the late '90s, around that time frame, there were some important developments in terms of giving more power to the Patent Office, in terms of the Patent Office asserting itself in trying to shape the policy. One of those was legislation in 1999 that gave the Patent Office more control over its operations, over financial operations in particular. But then, also, a U.S. Supreme Court case in 1999, *Dickinson v. Zurko*, was an important case. In that case, at issue was the standard of review that the Federal Circuit would apply when reviewing Patent Office factual findings. Up until this case, the Federal Circuit applied a clearly erroneous standard, which is a difficult standard an Appellate Court would apply to a District Court's factual findings. The PTO wanted more deference. They wanted the Federal Circuit to give the Patent Office more deference, and they argued for a slightly more deferential standard under the Administrative Procedures Act. The case ultimately went to the Supreme Court.

¶6 The Supreme Court ended up agreeing with the Patent Office, disagreed with the Federal Circuit, and afforded the Patent Office more deferential review upon appeal. The standards of review are similar. I don't know that the outcome of many cases changed after that; but it was an important step, and they showed the Patent Office was willing to take on a key issue, fight the Federal Circuit on it. And in this case, they won and set a precedent for where we moved on from then. It's also important to note that the Patent Office throughout the 20th century had not been that involved in creating and shaping patent policy. They left that to Congress, left that to the Supreme Court; more recently, the Federal Circuit. It's really been since the late '90s and now into the 2000s where the Patent Office has gotten much more involved with these issues. Next, I'm going to go through three Federal Circuit cases, try to go through them very briefly so everyone has some background.

¶7 The first case is *Cooper Technologies*, and the issue there was whether the phrase "original application" in the inter partes reexamination provision includes continuation applications or whether that term was restricted to first-filed applications in a series of continuation applications. The Patent Office had interpreted that phrase to include continuation applications, and why it's important is, this inter partes reexamination statute was passed in 1999 and said it only applies to original applications that are filed on or after November 29th, 1999. In this case, the patent issued from a patent application that was filed in 2003, but it was a continuation. It was the sixth in a series of continuation applications, and the first filed application in this chain was filed in 1993. Under the PTO's interpretation, inter partes would apply to this later-filed application. Under the

Cooper Technologies interpretation, it would not. The case went up to appeal to the Federal Circuit, and the Federal Circuit said this was an interpretive rule, it was not a substantive type of rule, and so they afforded Chevron deference to the PTO's interpretation.

¶8 Now, Chevron deference, I'm sure we will get into it a little more, and I'm sure the professors can explain and go into this in more detail. But just briefly, it derives from a Supreme Court case in 1984, and it's a two-step process. The first step is, you look to whether Congress has directly spoken to the issues. And if Congress has said what, in this case, "original application" means, that's the end of the analysis. You go with Congress. The PTO can't do something inconsistent with that. If, however, Congress has not spoken to it, there's some ambiguity, you would go on to the second step and ask whether the PTO's construction of that term "original application" here is a permissible construction under the statute.

¶9 Here, the Court looked to Congress, and they said "original application" had multiple meanings in patent law. There was no one single definition, and so they said Congress had not definitively spoken to it. Under the second prong of Chevron deference, they said yes, the PTO's construction is permissible, and the inter partes reexamination statutes term "original application" does apply to later-filed continuation applications and divisional CIPs. The next case is *Tafas v. Doll*, and this is probably the most publicized and discussed and debated case recently on this issue. The basic issue was whether the PTO rules relating to continuation and claim practice were proper and within the PTO's rulemaking authority; and very briefly, there were four rules at issue. The first rule said that an applicant can only file two continuations as a matter of right; and if the applicant wanted to file more, they would have to file a petition with the Patent Office explaining why they could not have submitted evidence, submitted that argument, submitted that earlier in the prosecution. The second rule related to RCEs or requests for continuing examination, is a similar type of rule. An applicant would be allowed one RCE per family of applications, and if they wanted to submit more, they would have to file a similar petition with the Patent Office.

¶10 The other two rules related to claims. They said that an applicant can only file five independent claims in a single application or 25 total claims in an application. If the applicant wanted to submit more claims in a single application, they would have to submit an examination support document which required the applicant to conduct a prior art search, to identify the most relevant references, and then to explain to the Patent Office why the applicant thought the claims would have been patentable in view of those references. As the practitioners know, this was a significant departure from current practice. There's no current duty on the behalf of an applicant to conduct a prior art search before filing a patent application. So there was a very divided opinion on this one.

¶11 Backing up a second, the District Court sided against the Patent Office. The District Court essentially held that these rules are substantive rules outside of the Patent Office's rulemaking authority. On appeal, the majority disagreed, in part, with the District Court. The majority started off by reaffirming prior case law and saying the Patent Office does not have general substantive rulemaking power, and then looked at the particular rules here, and the majority thought that the rules were procedural. They said that the rules merely governed the timing of applications, what the applicant had to submit, but they didn't change the duties and obligations of the applicant under the patent

laws. The majority applied Chevron deference, and the majority found one of the rules to be inconsistent with the current patent laws. That was the continuation rule. But the other three rules, the majority said did not conflict with current patent laws. Judge Rader disagreed in his dissent. He thought that all the rules were substantive, all the rules were outside of the PTO's rulemaking authority, and all of the rules conflicted with the Patent Act, and I'm sure we will get into the reasons why.

¶12 That's not the end of the story. After the three-panel decision, the Federal Circuit granted a petition for rehearing en banc, so the entire panel was going to decide the issue. But in the meantime, during briefing, the new Director Kappos rescinded the final rules, and the Federal Circuit—or the Federal Circuit ultimately granted the parties' joint motion to dismiss the appeal. At this point, what you have is, you have a District Court decision against the Patent Office which is still intact. It's not vacated. You have a Federal Circuit three-panel decision which has already been vacated. Thus, all you have is the District Court decision at this point on this issue.

¶13 The last case, quickly, is Wyeth v. Kappos. It came out a couple of months ago, and it dealt with a topic Ms. Barner was talking about earlier, patent term adjustment. The issue was whether the terms "period of delay" and "overlap" in these provisions support the PTO's interpretation that delays during prosecution overlap with delays for issuing a patent after a certain date. We talked about some of these delays this morning. Something called "A" delay or "A" guarantees are delays that occur during the prosecution of the patent. For example, the Patent Office has a deadline to examine or offer a first action within 14 months of filing. If they don't, every day after that 14th month can be added to the term of the patent if a patent is ultimately issued, and the patent will be extended. A "B" delay has to do with any patent that's issued after three years from filing. So the PTO's interpretation was that these entire periods of delay overlap, whereas Wyeth's interpretation was the "B" delay doesn't start until three years after issuance. For the first three years during prosecution, all you have is the "A" delay; and then, after three years, you have possible both delays. So the only overlap is three years and after.

¶14 On appeal, the Federal Circuit agreed with Wyeth and did not agree with the Patent Office. The Court said the Patent Office's interpretation was simply inconsistent with the statutory language and gave no deference to the interpretation. There was no Chevron deference analysis because it was simply an inconsistent interpretation of the statutory language. So that's the case law. As many of you know, there have been proposed patent reform bills the last few years. In 2007, there actually was a provision in the patent reform bill providing the Patent Office with substantive rulemaking authority. That bill never got passed. Here we are now in 2010. The current bills do not have that provision although recently the PTO has requested it to be included. It doesn't look like it's in there at this point, and it may not be in at all. That's all I have. I think at this point, we're going to open it up to questions or any comments the panel has.

¶15 DR. ZUHN: I'll just make a couple. So first off, just a minor correction. The House did pass that bill in 2007. The Senate did not pass its own bill, and there was no reconciliation. There was no law, obviously, enacted. Also last week, Senator Leahy announced that the Senate has come to a tentative agreement on the Senate patent reform bill—Senator Leahy is the Chairman of the Senate Judiciary Committee—and Senator Leahy has been working on patent reform for, I don't know, years; you know, 2005

maybe, going back to 2005. So he's very excited about this, has really been pushing hard to get a reform bill pushed through. And I think the provision that's in that bill is for the Patent Office to have fee-setting authority, and that's as far as—the Senate never, as far as I can recall, had a substantive rulemaking provision in the House bill. And then also related to the House bill, one other provision. The House bill that was passed in 2007, from this practitioner's perspective, was awful. It contains a lot of provisions that would make my job even more difficult than it currently is. In addition to the rulemaking authority provision, there was also a provision that was very similar to examination support documents. "AQS" was the acronym that was used, Application Quality Submissions. An AQS is a support document where you would have to do a search and provide an explanation of the references, and the Patent Office would get much authority in crafting exactly what needed to go into that document.

¶16 PROFESSOR MASUR: Go ahead.

¶17 PROFESSOR SPETA: Well, if I can take a few minutes, I want to sort of make a fundamental objection here, as it were. Nicholas is quite right that the Federal Circuit's opinions are consistent that there's no Chevron deference and no substantive rulemaking authority for the PTO, and I want to ask, why not. I do mostly administrative law and not patent law. To me, this is a great topic for the day that Tim Burton and Johnny Depp have come out with their latest interpretation of Alice in Wonderland. (Laughter.)

¶18 PROFESSOR SPETA: But starting from first principles of administrative law, I don't understand why this isn't a great case for Chevron deference. Here we have a statute that's ambiguous. We have an agency that administers the statute. We have an agency that has substantial expertise in the statutory subject matter, and deference would create uniformity, right? Substantial uniformity that the Federal Circuit itself cannot provide, at least on a case-by-case basis. Many people have criticized the patent litigation process as resulting in just far too many appeals to the Federal Circuit. Chevron deference would at least tip the balance in the other direction. And, in fact, there are deep reasons, from a public choice perspective, to be suspicious of the Federal Circuit interpreting the statute not to give Chevron deference to the administrative agency, because if the administrative agency doesn't have interpretive authority, it all ends up in the lap of the Federal Circuit. I'm not saying it's a conflict of interest, but one might be suspicious. So when at least this administrative law professor looks at Section 2(B) of the Patent Act, which says that the PTO "may establish regulations, not inconsistent with law, which shall govern the conduct of proceedings in the Office," that does not immediately say to me that that only includes procedural regulations.

¶19 Of course, the language "the conduct of proceedings in the Office" sounds like procedural rules, but I think a broader reading is possible when one considers the particular manner in which the PTO acts; that is, the PTO acts, of course, through the grant or denial of patent applications. In administrative law terms, it has consequences in the real world only through adjudications. There are no provisions of the Patent Act such as there are in the securities laws that state that certain behavior is illegal if it has been defined as illegal by the agency through a rulemaking. Thus, of course, a patent is issued through an adjudication, and such an adjudication is certainly, quote, "a proceeding" in the Office. So rules promulgated pursuant to 2(A) could do two things. They could, of course, just set procedural requirements in the classic description of procedural rules, how an applicant presents its case to the PTO. But rules that "govern the conduct of

¶20 If you take a step back from 2(A), one could ask the broader question which is informed by the Supreme Court's decision in *Meade v. United States*, whether the grant or denial of a patent application has the force and effect of law. Here again, there is evidence that it does although, perhaps, the matter is not one-sided. The grant of a patent undeniably has legal effect. It confers on the grantee certain exclusive rights, and the rest of the world is bound to respect those rights and bound by civil and criminal penalties in the statute. This goes beyond *Meade*. There, the Court said that the Customs Office letters at issue did not seem like law because they had, at most, effect between the Customs Service and the particular importer as to a particular shipment of goods. The grant of a patent, by contrast, has effects on third parties. It has effects on the entire world, backed up by legal sanctions, and that means that a Patent Office adjudication has the force and effect of law.

¶21 Of course, there could be other indications in the statute that the Patent Office issuance of a patent is merely provisional. Here again, *Meade* provides an interesting contrast. In *Meade*, the Supreme Court concluded that Custom Service ruling letters don't have legal effect, because the statute's judicial review provisions indicate that the Court of international trade made a *de novo* decision based on a record developed at the Court, instead of deciding deferentially based only on the record created at the administrative agency.

¶22 And now, it gets even uglier. Because the patent statute provides a presumption of validity in infringement litigation which, of course, has been interpreted to require clear and convincing evidence of invalidity, and that's a deferential standard to the agency's determination. But, on the other hand, it is also clear that a Court may build an independent record on the issue of invalidity in part because grant proceedings do not include the third parties on whom the grant has the legal effect. But on the whole, since Congress says the agency shall act through an adjudication and that adjudication has legal effect backed up by criminal and civil penalties, it seems to me, on the whole, the grant of a patent is a proceeding that has the force and effect of law. And so when the Patent Office decides how to interpret the Patent Act in granting a patent, it would seem to me that that should be an action which has the force and effect of law. I think the only way out of this predicament inside the statute is to widen the lens even further, to ask the even more basic question of what interpretive mode you are in when you are asking questions about what the ultimate authority of the administrative agency is.

¶23 Of course, again, if you believe in a broad version of the Chevron doctrine, if you are Justice Scalia, for example, the answer flows from the Patent Office's administration of the statute. If you are a believer in the broader version of the Chevron doctrine, you would give Chevron deference even to interpretative rules, and the PTO can, without doubt, issue interpretative rules that bind its own people even if it doesn't bind the rest of the world. And then, the issue of whether they have legal effect on third parties collapses together. On the other hand, if you think congressional delegations of law-making authority on administrative agencies are truly extraordinary matters that require a clear expression of Congress's intent to do so, then you are less deferential on matters of authority and more likely to attend to matters of history and consistency. And here, the

Courts have decided so many issues of the Patent Act, interpreting the Patent Act, without deferring to the PTO's interpretation that maximal deference on Chevron would seem to be a fundamental change in the rules of the game. For this administrative law professor, then, coming back to first principles, we have a Patent Act which is ambiguous in substantial regard. We have administration by an expert agency, and there would be substantial practical benefits in terms of uniformity from deferring to that administrative agency. So my bottom line is that the Federal Circuit's clear precedents saying that there's no substantive rulemaking authority for the PTO shouldn't be taken as quite so clear.

¶24 PROFESSOR MASUR: So I think I want to say something directly responsive to what you just said.

¶25 PROFESSOR SPETA: Good.

¶26 PROFESSOR MASUR: Although it's probably not going to be nearly as disagreeable as you might like. So I loved Jim's argument. I think it's terrific. I'm excited about it in the normative sense because I would like the PTO to have substantive rulemaking authority, and I think it's a really clever analysis of a very sticky administrative problem. But I do think it's still a sticky administrative problem, so I just want to raise two possible concerns with it that I think might be hard to overcome if this ever gets to the courts, and I hope that it does and it gets argued along the lines as Jim described it. So the first is that when we ask in administrative law whether an agency should get Chevron deference when it comes to the interpretation of its own statute, the thing we always look to in deciding that question is whether the agency has been given power to make rules with the force of law in carrying out the purposes of the statute that it's then trying to interpret. The reason for this is because the power to make rules with the force of law is given—is taken as a proxy for whether Congress meant the agency to be the primary policy-maker. So the EPA has the power to make rules with the force of law in carrying out the provisions of the Clean Air Act. We take this to mean that Congress meant the EPA to be a policy-maker when it came to the Clean Air Act; thus, the EPA gets Chevron deference.

¶27 I completely agree with Jim that patents are rules with the force of law sort of by a technical legal definition. I think the problem is that it will be pretty easy for a Court to say that patents don't involve policy-making in the same way. They are individualized, informal adjudications that just concern sort of the execution of a set of legal rules that have been laid down by other parties, not the actual making of legal rules by the Patent and Trademark Office and because of that, they don't answer the question of whether the PTO has the authority to make rules of law under this patent statute more generally. Now, you can easily argue it the other way. You could say, well, these patents, they could be appealed to the BPAI. They could become precedential. They tell us something about where the law stands. I think there are certainly arguments made in the other direction. My only point is that it's different to say that you have authority to make substantive rules under a statute as broad as, say, the EPA does in the Clean Air Act and to say that the Patent Office has the power to issue patents which themselves have legal force. So that's point one. And then,

¶28 Point two is to question whether the body has authority to make rules with the force of law, whether the body has been designated as the policy-maker. This is typically sort of antecedent to the question of Chevron deference. We don't usually—so we're not

necessarily in the habit of giving Chevron deference to agencies when deciding the question of whether they have substantive rulemaking authority in the first place. So I think what Jim is doing, very effectively, is using the patent-granting power to kind of leverage Chevron deference into substantive rulemaking power. It's a terrific argument. I just think it's one that will run into some opposition on the course. One other quick thing to say about that, I really like the way that Jim sort of finessed the use of the word "proceeding." I don't mean "finessed" in a negative way.

¶29 PROFESSOR SPETA: I didn't take it in a negative way.

¶30 PROFESSOR MASUR: Well, okay. Everyone else did. They dealt with the notion of the word "proceedings" in the phrase, power to make rules governing the conduct of proceedings in the Patent Office. So I think he's right that we think of the proceedings in the Patent Office as being the granting or denial of patents and, therefore, rules governing that, that could easily be substantive rules, et cetera. Just two small problems with that, also, that I think that Courts may seize upon. The first is that, generally speaking, when other agencies have the power to make substantive rules with the force of law in the course of a series of adjudications, we don't see language like that. So, for instance, the NLRB makes laws governing labor relations in the course of a whole series of adjudications, one adjudication after another, and they do it under a provision that doesn't say "power to make rules governing the conduct of proceedings before the NLRB." They do it under a provision that says "power to make rules to enforce the provisions of the Labor Relations Act." And so this language is different than we're seeing in other administrative contexts, where we found agencies to have some substantive rulemaking power.

¶31 The second issue is that even though Jim gets around the word "proceedings" very nicely, we've still got the word "conduct," so it's governing the conduct of proceedings. You might say "to make rules governing the outcome of proceedings, to make substantive rules that will be enacted or effectuated in proceedings," but this says "governing the conduct of proceedings." And when we think of the conduct of proceedings, we usually think of the actual process that will take place in the course of the hearing. Again, I think there are absolutely arguments to be made to contradict that. I'm sure Jim can offer them. And I think there are ways to try to say that the conduct really revolves around the substantive rule about whether a patent will be granted or denied. No question about it. This is just meant to say that I think that there are a lot of avenues for a Court to disagree and go the other direction on this and that it will be a difficult, tricky argument, although one that I hope will eventually will be made and I also hope we will win.

¶32 I'll just confine myself to one other quick point, also something that Jim raised to some degree, and this was about the political economy of Chevron deference in the Federal Circuit and the issue of who the primary rule-maker is in the world of patent law. It's really striking that at every juncture, the Federal Circuit has opposed the PTO's ability to gain more rulemaking power. They didn't want to give the PTO deference per the APA, didn't want to give the PTO Chevron deference, and so on and so forth, case after case after case. The quick answer, of course, is that the Federal Circuit doesn't want to do this because if the PTO doesn't get any deference, if the PTO doesn't really have these powers, then the Federal Circuit gets to make all of the key decisions. That's undoubtedly true. You might wonder, then, why do we see Chevron deference in the rest

of the world at large? Why is it that the Supreme Court and the Circuit Courts have been all too eager to grant Chevron deference left and right to other sorts of administrative agencies when you might think that they would be jealous guardians of their own power, much like the Federal Circuit.

¶33 The key point is that the Federal Circuit is a specialized court that really does one thing and one thing only. Obviously, it has a few other tasks, but the Federal Circuit is, first and foremost, a patent court, and it thinks of itself as a patent court. Whereas the First Circuit, the Seventh Circuit, the Ninth Circuit, they've got a lot going on, and they're more than happy to hand over some of the most technically difficult decisions to administrative agencies when they have the option to. It's not like their dockets are bereft of other interesting cases. So I think that in some sense, by creating the Federal Circuit as this particularized specialized court, Congress has created kind of an institutional rivalry within the patent law for control of the law because it's created this other body that has patent law to its name and not much else. And that's why any movement away from the Federal Circuit as the prime or even sole expositor of the patent law is going to have to be taken by someone else. It's going to have to be done by the Supreme Court or Congress. We can never, I think, count on the Federal Circuit to do it itself, and that has been borne out by the pattern of these cases in which the Federal Circuit will deny deference and then the Supreme Court will occasionally correct it. So I hope that there is movement on this. I think that the patent law would benefit from the input of the PTO. I suspect that we're not going to get that movement from the Federal Circuit itself. Should we open it up for questions?

¶34 PROFESSOR SPETA: Of course.

¶35 MR. NARAYEN: I was going to say that we talked earlier, but could you guys tell us the difference, what makes a rule substantive compared to procedural? Is it intent-based, or is it result-based?

¶36 PROFESSOR SPETA: So the classic definition—and, in fact, the Federal Circuit precedents do bar from the D.C. Circuit cases in this regard—say that a substantive rule is one that has an effect on primary conduct which, of course, doesn't adequately define it. But it either does one of two things. If we are talking about a penalty situation, then what the substantive rule does is, it defines the class of acts that are subject to penalties or not subject to penalties, whereas a procedural rule merely defines the manner in which parties make their case to the agency about whether they are in compliance with the law or not in compliance with the law.

¶37 The somewhat trickier set of cases is for statutes in which the government is granting a benefit, although I think, actually, it's a little clearer there and may actually apply in the patent context. And so what the cases say is, rules that define eligibility for the benefit are rules that are substantive while rules that, again, define how the parties may make their case as to their eligibility or how the agency processes cases about eligibility are procedural rules. Fair?

¶38 PROFESSOR MASUR: Yes.

¶39 PROFESSOR SPETA: Fair?

¶40 DR. ZUHN: I would add, it depends on which Federal Circuit Judge you talk to.

¶41 DR. ZUHN: So if you talk to Judge Rader—and that's who I like to talk to—you know, he said all four rules that were at issue in *Tafas* were substantive. And if you talk to Judge Prost, who wrote the majority opinion, she would tell you that all four were

procedural and, you know, you can't get a bigger difference of opinion than—those are the two extremes.

¶42 PROFESSOR SPETA: In the '80s, there was a huge difference of opinion, into the '90s on the D.C. Circuit, that reflect some of the disagreement on the Federal Circuit to the extent that the Federal Circuit cases are citing to principally this case in the D.C. Circuit called JEM Broadcasting.

¶43 DR. ZUHN: Judge Prost cited to that.

¶44 PROFESSOR SPETA: Yes.

¶45 DR. ZUHN: —and that was the basis for her decision.

¶46 PROFESSOR SPETA: Yes. I tried to summarize the law as it's stated in JEM Broadcasting, and that's all I tried to do. You're absolutely right.

¶47 DR. ZUHN: And I thought that Judge Prost's opinion was interesting in that that was the basis of her decision. She focused on that one FCC case involving whether you had a typographical error or some kind of error within the four corners of your application for a license. And the rule was, it gets bounced completely, no chance to fix it. And I think there's a big difference between—and my clients would agree—between patents and an FCC license. I suppose if you're running a radio station, you'd have a difference of opinion there, but I don't represent any of them, so I wanted to say a couple things.

¶48 I was talking to Hal Wegner, who is a professor at George Washington and an attorney at Foley & Lardner, and he also is a good acquaintance with Director Kappos. And he asked me before the rules were rescinded, "Well, you know, what would be the big deal with Director Kappos having rulemaking authority?" And I said, "Nothing." Director Kappos, interestingly enough, even though he was working at IBM, wrote—or signed a declaration that was filed with the AIPLA brief in support of Tafas and GSK in the District Court case. And so I have a pretty good idea I know where Director Kappos stands, and now we all do because the rules were rescinded, but I don't have a problem with him. I'm worried about the next director after him. If we get a Director like—no offense—Director Dudas and an administration like that, that wants to implement these significant rules, they would have grave impact—they would have had grave impact on my clients and on my practice. So I don't have a problem with Director Kappos having the rulemaking authority, but I do have a problem with maybe the next Director, and we don't even know who that is going to be.

¶49 The other thing is, you had mentioned, Professor, that the Federal Circuit isn't clear on the procedural substantive difference, and I think that that's pretty clear if you look at these three cases. And maybe before Tafas was decided, I had a feeling that the Federal Circuit was going to agree with the District Court, and they didn't. And that was a stunning—for me, at least, and maybe I'm the only one that was surprised and shocked by the decision, but that was a shocking decision. And then, when Wyeth comes around, I thought, well, they're going to go with the Patent Office on this because if you look at the District Court decision, Judge Robertson, in the District Court for the District of Columbia, said that—he kind of acknowledged or understood the Patent Office's argument that this is double-dipping because if you have an "A" delay in the first three years, that's probably going to bump into a "B" delay; and so now you get the "A" delay, it's not overlapping, and you get the "B" delay? That doesn't seem quite fair, so he did concede that. So the decisions have been the opposite of what I would have thought they

¶150 PROFESSOR SPETA: We're now usefully transitioning into sort of the broader question of should the PTO have this sort of substantive rulemaking authority, and I guess my interpretive project may fairly be said to be motivated by some of your same concerns. Flexibility is, of course, a downside where administrators have more range of action, and including the range of action to change their mind. On the other hand, in administrative law generally, we often think that flexibility for the administrator to change their mind is a good thing, especially in circumstances in which there's learning by doing.

¶151 So if you only want to take, one current example, say the question of business method patents or nonobviousness, one could say that the patent world has learned things by doing in these particular domains. When you have interpretations of the Patent Act made by courts, you freeze them in time. But if you put the fundamental interpretive authority in the agency, the agency can change its mind about what the statute means in response to its learning by doing. And, again, that may be an advantage, or it may be a disadvantage, but it's often thought of as being an advantage.

¶152 DR. ZUHN: Although there are consequences, too, then. Wyeth has shown us the same thing. Director Kappos was nice enough, and the Patent Office was nice enough to put in this interim procedure for getting back your "B" delay. But the policy, while it's nice, it's nice if you have a patent that was granted after the first week of August of last year. If it was granted before that, you know, you're past this—it's important to remember that the procedures that are in place for getting a correction, two are rule-based and one is statutory, and the statutory one is you filing a complaint against the Director in the District Court for the District of Columbia. You have 180 days after the patent issues to do that, and if you don't, you know it also calls into question the recalculation procedure because you can apply for recalculation on some things that you wouldn't be able to actually file suit. So I'm not saying the Patent Office, once they fix their algorithms—and I don't know, maybe they already are fixed—but once they get their algorithms fixed, maybe there is an error or mistake, you're not happy with the recalculation. What do you do? I mean, you've already passed your deadline.

¶153 PROFESSOR MASUR: So very quickly, we're transitioning into kind of a discussion of the normative values or the merits of giving substantive authority to the Patent Office. I guess the one thing I sort of want to say, from an administrative perspective, is that there are an enormous number of Federal administrative agencies, many of which do not do good things all the time or even a substantial portion of the time. But the vast majority of them, nearly all of them, have power to make substantive rules in their technical field of endeavor, the EPA, the SEC, et cetera, et cetera. The number of agencies that do not have substantive authority is really very small, vanishingly small, the PTO, the Federal Trade Commission and very few others.

¶154 So the question I think you would want to ask is: What exactly should separate the PTO from the rest of these agencies? What is the rationale for not granting substantive authority to the PTO to make substantive rules the way that the EPA has authority? Or if you think that there really is no division between the two, maybe you think that we should, in fact, dismantle the administrative state at large and take away substantive authority from the rest of these agencies, but I think that that's a much tougher argument.

So it's sort of easy to say that this particular rule will go badly or that particular rule will go badly. But it's a different question to ask why this administrative body shouldn't be in charge of making rules to govern the law that it is so intimately involved in when nearly every other similarly-situated administrative body does exactly that.

¶55 AN AUDIENCE MEMBER: Has anyone actually—since you're both kind of similarly aligned in terms of whether or not the PTO should have that authority, has anyone actually articulated why the PTO is different from all those other administrative bodies? I mean, they certainly have the technical expertise in those types of things. Why is it that they shouldn't have that substantive rulemaking authority?

¶56 PROFESSOR SPETA: Do you want to handle this?

¶57 PROFESSOR MASUR: Oh, sure, if you want me to.

¶58 PROFESSOR SPETA: Go ahead.

¶59 PROFESSOR MASUR: I mean, there are a lot of people who do not think that the PTO should be given this authority, but their arguments are almost always based on sort of the current state of the PTO and its current level of expertise. So the argument usually runs something like, "You can't give the PTO substantive rulemaking authority because they don't have any systematic knowledge about patent law. They have no economists on staff"—now, actually, they've hired one recently—"no economists on staff, no experts on staff," you know, et cetera, et cetera, "so they don't know how to make rules."

¶60 But, of course, the reason that the PTO doesn't have economists and policy experts on staff is because it doesn't have substantive rulemaking power, right? If the EPA didn't have substantive rulemaking power, it wouldn't have economists on staff, either. Form is going to follow function in these regards. So I have not seen a convincing argument that there is something different about the nature of patent law or about the relationship between the PTO and the Federal Circuit or some other institutional arrangement that would militate against giving the PTO rulemaking authority.

¶61 PROFESSOR SPETA: To my mind, there are two possible good arguments against more deference on substantive matters to the PTO. The first applies to more of a situation that we have now. That is, to the extent that interpretations are made in an individual grant proceeding, those interpretations are made without the kind of input that notice and comment rulemaking might call into question. They're made in a proceeding between an individual applicant and the Patent Office. And then, to use them to bind the world seems inconsistent and, in fact, the process of litigation gives the world the opportunity to contest it. But that's why I pointed at the presumption of validity. The presumption of validity seems to me to be inconsistent with that sort of view.

¶62 With the second argument, you have to ask the question, "Well, what if you gave them notice and substantive rulemaking authority?" Then they'd get due notice and comment. They'd get broader input on these big interpretive matters, which I think would be, unambiguously, a good thing. The downside to it can only be arguments made from capture. If you're concerned about administrative agency capture, you think that something about what the Patent Office does is particularly likely to lead to industry captures of some kind because applicants tend to be from concentrated industries and if you have broader concerns like a patent that hurts innovations, et cetera, then you may worry, okay, we want an institution like the courts, which are less subject to capture. As an empirical proposition, I don't know how happy I am with that argument. I don't know how happy I am with arguments that say, well, the Federal Circuit is less in favor of

patents than the PTO is. I just don't know. I'm not that empirical on this question. But I do think there's something to arguing that agencies get captured. We see it happen all the time.

¶63 PROFESSOR MASUR: Yes. Very quickly, I completely agree with all of that. Just two points. There's a lot of literature now that the Federal Circuit has been heavily captured by patenting interests, so it's not clear which way that cuts. And also, people have been worrying about agency capture, especially with regard to agencies like the EPA, for decades, for 40 years, basically; and there are a lot of people who suspect that the EPA is very heavily captured. And so you'd need an argument not just that the PTO is subject to capture but that it's subject to capture in a more dangerous, more extensive way than agencies like the EPA, which we have been worrying about in that vein for many, many years, and I don't think that argument has been made. I'm not sure that it can be made.

¶64 DR. ZUHN: I'm interested in your idea about capture. I'm wondering, could you explain what are the arguments that the Federal Circuit has been captured? I mean, this is a new concept for me, and maybe I'm just in my office too much and not getting out enough. I would say on this issue, Congress is way more captured. For example, the House vote in 2007, it was straight party line. And you look at where—the representatives, which side did they vote on, take a look at the big companies that were in their districts. If they were biotech/pharma, those are my clients. You know, they were not supporting the PED reform. You know, they don't—and biotech/pharma was not supporting the claims and continuation rules. I think it's no surprise that GSK and Dr. Tafas is kind of a biotech guy, not as much as GSK. GSK is definitely biopharm. So I don't think that's a surprise, but I'm interested in that, if you can elaborate a little bit, about the Federal Circuit capture.

¶65 PROFESSOR MASUR: Well, there's no doubt that Congress has been captured in a whole lot of dimensions

¶66 DR. ZUHN: I agree with that.

¶67 PROFESSOR MASUR: So that's beyond question. The definition of "agency capture" is when somebody has been unduly influenced by one set of interest groups or another and is, therefore, making decisions that are no longer in the public interest but too heavily in favor of one interest group. On the sort of results question—and there's a lot of evidence that the Federal Circuit is simply allowing too much patenting right now, so there's a lot of evidence that they have just gone too far in one direction. And on the question of influence, well, a lot of people have been led to believe—now, I can't vouch for all of this literature myself—but a lot of people have been led to believe that because of the interactions between the Federal Circuit and the Patent Bar and because of the constituency that the Federal Circuit believes it is satisfying. It is unduly under the influence of segments of the patenting industry and unduly desiring to help them, and that's what's resulting in this extensive patenting.

¶68 In some sense, it doesn't necessarily matter what the motives of the Federal Circuit are and how they got there, right? The question is just what kind of a job are they doing, and what kind of a job would some other organization do instead. And the Federal Circuit seems to be already moving too far in the direction of granting too many patents on too many things. So I, to some extent, reject criticisms of a hypothetical PTO on the

grounds that it will also go too far and grant too many patents on too many things since we're already there, and more.

¶169 DR. ZUHN: I would say a couple of the Federal Circuit decisions might run counter to that; KSR for one. Go ahead.

¶170 AN AUDIENCE MEMBER: Many of you guys spoke on ambiguity in the statute concerning "A" delays and "B" delays. But the text of the statute, I think, is a chronological definition of overlap, but if my reading is correct, the PTO interpretation is content-based overlap. So I guess the question is, if the text uses a chronological definition, where is that ambiguity?

¶171 PROFESSOR SPETA: I can't help you. Anyone?

¶172 MR. ZOVKO: In the opinion itself, they didn't provide that much analysis. They went through, and they simply said, "We believe this is inconsistent with what the statute says." And I guess if we have the statute itself, we could go through it, but—

¶173 DR. ZUHN: Actually, I brought a couple of posts for everyone, and I think I can probably dig that up if you wanted to take a look at it. Yes?

¶174 MR. NARAYEN: I've got a general question. Why is it that this question hasn't yet been settled to the extent it's settled with respect to other administrative agencies? The fact that it's still an open question, like how much rulemaking authority they have,, does seem a bit odd. The PTO didn't pop into existence five years ago. It's been around for a while—certainly, not as long as other agencies—but what's the explanation? Why has this question sort of not been settled?

¶175 PROFESSOR SPETA: I don't want to overstate matters. It's settled. Right? The Federal Circuit thinks it's settled. The PTO pretty much thinks it's settled because the Federal Circuit has told it enough times that it's settled unless the Supreme Court weighs in on it, and I don't see that they presented it to the Supreme Court in any fashion at the moment. The fact that I can construct an argument that says the Federal Circuit didn't get it quite right, I don't think should cause you to think it's not settled.

¶176 MR. NARAYEN: So the normative question is unsettled? Maybe I'm confusing the issue.

¶177 PROFESSOR MASUR: No. The question of whether the PTO has sort of substantive rulemaking authority, that's settled, by whatever definition of "settled" we want to use. The Federal Circuit has answered that question over and over again. So it's settled until the Supreme Court decides to unsettle it. The normative question of whether the PTO should have substantive rulemaking authority, well, that's a very, very difficult question that's very far from being resolved, and I don't know if it's resolved anywhere within the law. I will say, though, you are correct that the question of how broad the PTO's procedural rulemaking authority is remains unsettled, and the *Tafas* litigation was exactly on that point. So you might think that anything that governs how many times you get to come back with a continuing examination would automatically be considered a procedural rule, but the District Court didn't think so. And there's still a lot of debate about exactly what the conduct of proceedings in Section 2 of the Patent Act means there and how broad the PTO's procedural authority will be.

¶178 MR. ZOVKO: As we talked about earlier, it's still not settled within the Federal Circuit. You have Judge Rader who says that any rule that changes the obligations of a patent applicant under the patent laws.

¶179 DR. ZUHN: Or Wyeth.

¶80 MR. ZOVKO: —would be substantive, whereas the majority, they acknowledge that all these rules, they affect the ability to prosecute an application, but they don't foreclose that opportunity so.

¶81 DR. ZUHN: Yes. I think the issue is settled, but it has to—and this might be part of the problem. You almost have to take it to a Federal Circuit panel and see what that panel thinks. You know, can you get two votes on whether the rule is procedural or substantive; and then, if it's procedural, was it inconsistent or not. And so that might be part of the problem. I would rather not have this blanket authority to impose the claims and continuation rules, which there's a lot of aspects to that; that it's not just a limit on continuations and claims that practitioners were worried about. It was the fact that the only way to bypass these, at least with respect to the claims limitations, was to file an ESD. And I did not meet a practitioner during the entire time from August of 2007 when the rules were originally published until the rules were rescinded last fall that thought they were going to do that, that they would ever file an ESD. There's too much at stake. All these issues interconnect, and the issue that interconnects with ESD is this inequitable conduct. You do not want to expose yourself as a practitioner to that kind of charge.

¶82 MR. ZOVKO: That is true, and I think the counterpoint to that is now they have the accelerated examination procedure, and I think at first—and you have to submit similar—I don't know all the rules, but you have to do a search, you have to point out the most relevant references. And from my perspective it seems that for the first few years, no one was using it. But now, clients are interested with the backlog of the Patent Office we were talking about and this accelerated examination procedure. I think that the Patent Office will work with you to issue a patent within 14 months. That's their goal if you comply with these more rigorous procedures. It is actually starting to be used in certain cases if it's an important case and it's the right situation.

¶83 DR. ZUHN: And in my firm, we use that procedure, but almost exclusively for smaller clients.

¶84 MR. HOWARD: I'd like to thank our speakers for the interesting discussion. And in just a minute or two, we will be having our final panel of the day and then cocktail hour.