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

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

Thursday, April 8, 2021 – 2:20 p.m.

**SESSION 2: PATENT LAW
2C. U.S. Patent Developments**

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U.S. Patent Developments Overview

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* * *

MARTIN ADELMAN: This is our last session of the day after the kind of hot session we just went through. This is going to be a little bit hot, I think. What we're going to do is a tradition at Fordham, because Dimitrios always delivers 25 minutes, exactly 25 minutes, not 24.5 minutes, not 25.5 minutes, but 25 minutes, where he summarizes everything that's happened in patent law in the US in that time.

We're going to get back into Section 101,¹ which incidentally, I might mention, that it actually goes back to 1948, in the *Funk Brothers*² case. If you read *Funk Brothers*, that was the beginning of this crazy nonsense. It was written by Mr. Justice Douglas, who may be one of the most brilliant justices to ever sit on the Supreme Court and was almost always wrong. A terrific instinct for error. He was badly wrong in this case. However, what you will find if you read the case, is that there were dissents. There was serious intellectual effort to point out that he was wrong.

However, the second thing you have to remember, and everybody should read and reread, *Kimble v. Marvel*³, where the Supreme Court says, "Once we decide a case of statutory interpretation, we stick with it no matter how stupid the case is, we will follow it." Justice Kagan explains that. It's a fascinating read. If you remember that that's what they do, the 101 jurisprudence is not all that surprising. You start with a very bad case, plainly wrong, and you follow it, and you follow it through. There's one possible exception, it is the *Deere*⁴ case, five to four, but that can easily be explained by the fact that the Supreme Court was extremely nervous around the time of the creation of the Federal Circuit. They've forgotten about the Federal Circuit and why they were nervous, but they were. Two justices jumped from *Parker v. Flook*,⁵ and they jumped on *Deere*, but that's the only deviation.

We're going to be back into 101 again. Everybody has their name on the screen. I have all of the bios, you have all the bios, so I'm not going to read their distinguished background. With that, 25 minutes but no more and no less, go to Dimitrios.

DIMITRIOS DRIVAS: Marty. Thank you.

MARTIN ADELMAN: I want to mention that you're for the first time, really going to discuss a constitutional law issue and we're going to act as administrative law lawyers for a few minutes. That's something we haven't ever done before, I don't believe.

DIMITRIOS DRIVAS: Great. There was an excellent panel earlier on patent eligibility. There are two cases pending certiorari petitions at the Supreme Court this term on 101 itself. As we all know, patent eligibility is a judicial doctrine. It's not in the statute. The exclusions are laws of nature, natural phenomenon, and abstract ideas.

The Supreme Court in *Mayo*⁶ set forth its Alice/Mayo two-step test. First step, you determine if the claims are directed to a patent-ineligible concept, and if so, then you determine, is there something in the claim that transforms it to a patentable eligible claim?

The first case we're going to discuss is *American Axle v. Neapco*.⁷ It is a patent to a method of manufacturing a drive shaft. The petition for certiorari is pending, but what I find interesting about the case is the questions presented and specifically the second question presented in the petition.

¹ 35 U.S.C. § 101 (2012).

² Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948).

³ Kimble v. Marvel Ent., LLC, 576 U.S. 446 (2015).

⁴ Graham v. John Deere Co. of Kansas City, 383 U.S. 1 (1966).

⁵ Parker v. Flook, 437 U.S. 584 (1978).

⁶ Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc., 566 U.S. 66 (2012).

⁷ Am. Axle & Mfg., Inc. v. Neapco Holdings LLC, 967 F.3d 1285 (Fed. Cir. 2020).

That really goes to, is it a question of law for the court based on the scope of the claims, or a question of fact for the jury based on the state of the art at the time of the patent, which to me seems to be obviousness, novelty, enablement, all the patentability issues that one routinely tries in a patent case, and going back to the earlier panel's discussion as to, are these really the threshold issues that should be addressed prior to patent eligibility? I think a lot of the case law, the Supreme Court and Federal Circuit case law, has conflated patent eligibility with obviousness and novelty.

On the next slide, we have a representative claim of the patent at issue, and that's Claim 22, which was the focus of both the district court and the Federal Circuit analysis. As you can see, it's a method claim. It's a simple claim, but it has some mechanical steps, providing a hollow shaft member, tuning a mass, and stiffness of at least one liner, and inserting the liner into the shaft member.

Now the District Court applying the Mayo test found that it was essentially the application of Hooke's law and friction damping.⁸ Now this is a result of evidence presented by experts on summary judgment. There's no mention of Hooke's law in the patent specification, but the court found that that is exactly what the claim is directed to and that the additional steps in the claim were just routine activity, for example, tuning, inserting, et cetera.

The Federal Circuit picked up on that and came up with its decision that the claim is essentially the application of the law of nature, Hooke's law, and is nothing more, and that the claim itself does not disclose how to accomplish the stated objectives of the methods. They found the claim to be invalid as directed to ineligible subject matter. Now, you'll see that there was a strong dissent by Judge Moore to the opinion written by Dyk and joined by Judge Taranto, and that after the case was denied an en banc hearing, the majority decision was modified to address some of the points made in the dissent.

It's clear from the dissent that Judge Moore thought, this is a totally new test that compresses the patent eligibility test of Mayo and Alice from a two-part test into a one-part test, and that if there is some abstract idea or natural phenomenon that the claim is addressing, if there is nothing more or know-how to, that this is really conflating enablement with patent eligibility. The court and Judge Moore addressed that as the new Nothing More test.⁹

In denying en banc, it was six, six. There were a number of dissents. One of the dissents pointed out that the case law on patent eligibility has become so unpredictable as to have a serious effect on innovation and incentive and criticized the Nothing More test and how the test itself is really conflating eligibility and enablement.

The next case that's up before the Supreme Court on petition for certiorari is *Ariosa v. Illumina*.¹⁰ Now, this is the result of really extensive litigation between these two parties, and a previous case, *Ariosa v. Sequenom*,¹¹ where a similar patent, not related to the patents here, was found to be invalid. Oh, not invalid, addressed to ineligible subject matter. The patents that are the

⁸ *Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, 309 F. Supp. 3d 218, 225 (D. Del. 2018).

⁹ *Am. Axle*, 967 F.3d at 1304 (Moore, J., dissenting).

¹⁰ *Illumina, Inc. v. Ariosa Diagnostics, Inc.* 967 F.3d 1319 (Fed. Cir. 2020), *cert. denied*, No. (R46-29), 2021 WL 2323012 (U.S. May 21, 2021).

¹¹ *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015).

subject of this case are to a method of preparing cfDNA, cell-free fetal DNA from parental source to identify which DNA was from the father and which from the mother in the mother's serum.

Now, the basis for the invention was the discovery that the paternal DNA was of a certain smaller size of 300 to 500 base pairs, whereas the maternal DNA was larger. As you can see from the representative claim from the '751 Patent, the claim addresses selectively removing DNA fragments that are greater than approximately 500 base pairs. That was the point of novelty and actually, the factor that the Federal Circuit found to take this out of the patent-ineligible sphere.¹²

The District Court found the claims addressed to a natural phenomenon and that the claim steps were well known and conventional, and specifically said that it was difficult to distinguish the claims from those found to be patent-ineligible in the previous case between the parties on the separate patent, which was for a method of detecting paternally inherited cfDNA by amplifying and detecting it.

The Federal Circuit in an opinion by Judge Lourie came up with a distinguishing factor that this is not a diagnostic case, it is not a method of treatment case; it is a method of preparation case. It found that Myriad, which found the Supreme Court decision in *Myriad*,¹³ which found that naturally occurring DNA sequences are a product of nature, specifically declined to extend its holding to methods resigning innovative processes to isolate DNA. Since it found this to be patent-eligible under step one, it found that it had no real need to reach step two of the Alice test.

In a strong dissent by Judge Reyna, he said that the claims in this case are directed to precisely the discovery of size discrepancy and nothing more and could not distinguish this case from *Myriad*.¹⁴ Both of these cases are pending petitions for certiorari, the question is whether the Supreme Court will take them up with two 101 cases in this term, and whether they believe they can actually fix the mess that has been created with either of these cases at this time or whether they should leave it to Congress.

There are a number of other cases coming out of the Federal Circuit, one recently, *In re Stanford*,¹⁵ where two different patents were found to be patent-ineligible by the PTAB for essentially a genomic analysis that was based on statistical procedures. The types of data used that were different from that was in the prior art, but they were couched in terms of a computer system. The Federal Circuit found that they did nothing to distinguish or transform the computer system to something new, and therefore, those were also patent-invalid.

Next, we'll discuss the enablement and written description issues. What we find is that the Federal Circuit is taking a hard line on claims that have functional limitations, and particularly those claims that have two or dual-functional limitations in the claim. They apply the *Wands* factors,¹⁶ of course,

¹² *Illumina, Inc.*, 967 F.3d at 1329.

¹³ *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013).

¹⁴ *Illumina, Inc.*, 967 F.3d at 1337 (Reyna, J., dissenting).

¹⁵ *In re Bd. Of Trustees of Leland Stanford Junior Univ.*, 991 F.3d 1245 (Fed. Cir. 2021).

¹⁶ “[Factors] include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the

which are the Federal Circuit's case law on the determination of undue experimentation.

In the *Idenix*¹⁷ case, here is the sample claim from the patent. It's a method of treating hepatitis C virus infection by administering an effective amount of a compound. The District Court had construed that as nucleosides that had a specific substitution. If you read the decision, it talks about 2' up and 2' down. The court construed the claims to be directed to a methyl group in the 2' down position and nonhydrogen functional groups in the 3' up and 2' up positions.

The patent disclosure and the drug that was brought by Idenix to market had a hydroxyl group in the 2' up and 3' up position, and the accused product had a fluorine in the 2' up position. However, the fluorine 2' up was not disclosed in the specification. Given the claim construction, Gilead stipulated to infringement, and the jury found that the asserted claims were valid and awarded damages of \$2.54 billion.

Gilead filed the judgment as a matter of law on non-enablement and lack of written description, and the District Court¹⁸ granted the motion on non-enablement but did not grant the motion for lack of written description, finding that there was no guidance within the specification for determining which molecules would meet the dual-functional limitations of the claim of treating hepatitis C infection with an effective amount of compound.

This was appealed, of course, at the Federal Circuit, a non de novo review. The court found that, not only was the patent invalid for non-enablement, but also reversed on written description grounds¹⁹ and found the patent was not meeting the written description requirements. I think the main takeaway from this case is that synthesizing and screening tens of thousands of compounds, even if the synthesis is routine and the screening methods are routine, can still amount to undue experimentation, even if that is routine, due to the amount of experimentation that has to be used in order to determine whether the compounds meet the limitations of the claims.

In a dissent, Judge Newman said it is improper for the court to rely on compounds disclosed in the specification but not claimed, in order to find non-enablement and lack of written description.²⁰ It's difficult to reconcile that with the claim construction.

It's a difficult case to determine what actually falls within the claim construction, but clearly, one of the issues that the majority focused on was that during the trial, there was testimony that a person of ordinary skill in the art would have relied on a test to a specific enzyme to see if the compounds activated that enzyme, which was NS5B. The court found that that was not part of the claim construction, there was no disclosure of that test in the specification, and therefore, it was improper for the court to rely on the knowledge of a person of skill in the art to supplement that which was not in the specification.

predictability of unpredictability of the art, and (8) the breadth of those claims." *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

¹⁷ *Idenix Pharms. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149 (Fed. Cir. 2019).

¹⁸ *Idenix Pharms, LLC v. Gilead Scis. Inc.*, No. CV 14-846-LPS, 2018 WL 1313973 (D.Del. Mar. 14, 2018).

¹⁹ *Idenix*, 941 F.3d at 1153.

²⁰ *Id.* at 1166 (Newman, J., dissenting).

The next case is a recent decision by the Federal Circuit in *Amgen v. Sanofi*.²¹ The claims, in this case, are to an isolated monoclonal antibody, which must react with or bind to one specific residue from an epitope on PCSK9, and also block PCSK9 from binding to the LDL receptor, in order to effectively treat levels of cholesterol. Again, this is a claim with two functional features, one binding to one amino acid residue in an epitope of more than one amino acid residue obviously, and also the ability to block the binding with PCSK9 to its receptor.

There's a long history to this case. The case was originally tried to a jury.²² The jury found that the patent was non-obvious and enabled. It went up to the Federal Circuit, which reversed on enablement and written description.²³ Petition for certiorari was denied. It was remanded for a new trial on enablement and a written description. The jury again found that the patent was valid and did not lack enablement, or it had an adequate written description. On a judgment as a matter of law, the court applying the *Wands* factors found that the patent claims were invalid for non-enablement.²⁴

It was appealed to the Federal Circuit, and the Federal Circuit took a hard line, finding that functional limitations, while they do not necessarily preclude claims that meet the enablement requirement, pose high hurdles in fulfilling the enablement requirement, and that whereas here, undue experimentation was involved in identifying from the many thousands of monoclonal antibodies that could have met the limitations of the claims, those which bound and specifically blocked the binding of PCSK9.²⁵ To make such a determination would require undue experimentation.

The message is: functional limitations and claims can be a minefield. Patent prosecutors often insert them in order to obtain allowance of claims and distinguish their claims and invention from the prior art, but as we now find, the Federal Circuit is taking a hard view on the scope of functional limitations.

There are two cases now that are being argued in the Supreme Court this term. The first one is on assignor estoppel. Assignor estoppel is a judicial doctrine that precludes one who has assigned their patent rights for good consideration, to later challenge that patent in court and claim that the patent is invalid. Now years ago, the Supreme Court rejected the doctrine of licensee estoppel in *Lear v. Adkins*,²⁶ which prohibited a licensee from challenging the validity of a patent that it had licensed, but that is a different doctrine from what we see in assign or estoppel, and assignor estoppel still is the law.

The case before the court is *Minerva Surgical v. Hologic*.²⁷ This is going to be argued on April 21st, in two weeks. In *Minerva*, the inventor had invented a medical device and methods for using the medical device and had assigned his rights to a company he had formed. The company was sold, and subsequently sold again to Hologic. The inventor went on to found Minerva Surgical, and came up with a new device that was arguably different from the device that he had assigned and the patents that he had assigned previously.

²¹ *Amgen Inc. v. Sanofi, Aventisub LLC*, 987 F.3d 1080 (Fed. Cir. 2021).

²² *Amgen Inc. v. Sanofi*, 227 F. Supp. 3d 333 (D. Del. 2017).

²³ *Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1381 (Fed. Cir. 2017).

²⁴ *Amgen Inc. v. Sanofi*, No. CV 14-1317-RGA, 2019 WL 4058927, at *13 (D. Del. Aug. 28, 2019).

²⁵ *Amgen Inc.*, 987 F.3d at 1087.

²⁶ *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969).

²⁷ *Hologic, Inc. v. Minerva Surgical, Inc.*, 957 F.3d 1256 (Fed. Cir. 2020).

Hologic in continuation applications of the original patents, sought and obtained broader claims and asserted them against Minerva. Minerva filed two IPRs,²⁸ one of which was granted on the methods patent, and the other which was not instituted on the apparatus patent, and the case went on in District Court. In District Court, the court found that assignor estoppel was a viable doctrine, and that Minerva could not assert that the patents were valid, and found that the patents were infringed.²⁹ The jury on a trial of willful infringement and damages, awarded damages to Hologic.

Subsequently, the PTAB³⁰ invalidated the method patent, and even though the decision, the jury award of damages did not apportion between the two patents, so the jury award of damages was upheld. However, an injunction did not issue because the PTAB had invalidated the patent, and therefore, it was invalid ab initio, from the beginning.

That was appealed to the Federal Circuit. The Federal Circuit found that the assignor estoppel did not apply in the IPR PTAB decision, since any one statute provides that a person can bring an IPR except the patent holder itself, but that assignor estoppel did apply to the district court proceeding. Judge Stoll who wrote the opinion stated that it was time to reexamine whether this doctrine should apply going forward. Critically, in an instance whereas here whatever the inventor assigned was not exactly what was asserted against them.

Another interesting point is that in oral argument, the Supreme Court has asked the Solicitor General also to present the argument. The US' position is that the assignor estoppel doctrine should not be jettisoned, but its contour should be clarified so that in an instance such as this where the patent has been expanded beyond that which the inventor assigned, the investor should be allowed to challenge it on those grounds.

Finally, probably the most important case before the Supreme Court, this term has to do with the constitutionality of the appointments clause³¹ in the appointment of the administrative patent judges in the PTAB. This case arises from a number of cases with a complicated history of *Smith & Nephew v. Arthrex*,³² Arthrex being the patent holder. The patents were challenged in IPR proceedings and invalidated. The question was raised at the Federal Circuit appeal level whether the appointment of the administrative patent judges under the America Invents Act violated the appointments clause of the constitution and therefore, whether the decision should be vacated.

What it turns on is whether the administrative patent judges are principal officers or inferior officers under the appointments clause. This is the appointments clause of the constitution. I'm not going to go into it because we're running out of time, and I've already probably broken my pledge to Marty.

MARTIN ADELMAN: Not yet.

DIMITRIOS DRIVAS: Oh, okay. Well, I'm close.

MARTIN ADELMAN: I'm going to give you your two minutes.

²⁸ Inter partes review.

²⁹ *Hologic, Inc. v. Minerva Surgical, Inc.* 325 F. Supp. 3d 507 (D. Del. 2018).

³⁰ Patent Trial and Appeal Board.

³¹ U.S. CONST. art. II, § 2, cl.2.

³² *Arthrex, Inc. v. Smith & Nephew, Inc.*, 941 F.3d 1320 (Fed. Cir. 2019), *cert. granted sub nom.*

DIMITRIOS DRIVAS: Let's skip the appointments clause and go right to it. The Federal Circuit relied on Supreme Court precedent in the *Edmond*³³ case, which was the case that dealt with a military tribunal of the Coast Guard, and the judges on that tribunal and whether they were appointed principal officers or inferior officers. There were three factors: whether an appointed official with a principal officer has the power to review the officer's decision; the level of supervision; and the appointed officer's official power to remove the officer.

The Federal Circuit found that the first and second factors weighed in favor of finding that the APJs³⁴ were principal officers, that there was some supervision over the APJs by the Director of Patents and the Secretary of Commerce. That weighed against it, but overall, that given the fact that they decide the validity of patents and that their decision cannot be overturned or reheard by the director himself or a principal officer, that they were, in fact, principal officers.

These are some of the factors listed on this slide that the Federal Circuit found convincing as to designating them as principal officers. The remedy was to sever from the statute the tenure positions of the termination provision under Title 5³⁵ of the APJs as federal employees and to make them terminable at will by the director or the Secretary of Commerce.

Under Title 5, they may only be removed for cause to promote the efficiency of the service. The Federal Circuit opined that that would be the most restrictive revision of the statute in order to preserve its constitutionality and remanded the case to be tried by a new panel, for rehearing by a new panel appointed of APJs appointed under the new revised statute as severed by the Federal Circuit.

There were some very strong dissents that this was not the correct remedy, that the Federal Circuit went too far. There were other dissents if you see the next slides, that the APJs are actually inferior officers because there was sufficient policymaking authority and review of their decisions by a board appointed by the director and by the Federal Circuit, so that they were, in fact, operating as inferior officers.

There were over 30 amicus briefs filed in support of both parties on either side. In addition to Smith & Nephew, Arthrex, and the US Solicitor General, there were at least 10 different proposed remedies to the statute and what the court should do. If we go to the last slide here, I leave it to the panel to discuss the possible outcomes and their consequences. I'll stop there, Marty.

MARTIN ADELMAN: Thank you, Dimitrios. I think you were one minute over, but given that this is an unusual situation, we'll waive it this year. Also, that *Arthrex* case is really complicated because you have to keep in mind that the real function of the PTAB is to eliminate the jury trial, and the jury trial is required because in 1791, Americans didn't want to pay their British creditors. This is American history, and this is the way to get rid of the jury in a key case. Hatch-Waxman³⁶ also gets rid of juries because, in my view, it's nonsense to have a jury trial in patent cases. Nobody in the world does it. If anybody even suggested it, I think they would be treated to a trip to the insane asylum.

³³ *Edmond v. United States*, 520 U.S. 651 (1997).

³⁴ Administrative patent judges.

³⁵ 5 C.F.R. § 300.707.

³⁶ 21 U.S.C. § 355.

Anyhow, it's something the Supreme Court has to deal with. It's up there. That's what they get paid the big bucks for so we can discuss that. Hopefully, next year, this will be decided one way or another. I wonder if we could turn for a moment to the key money case here, which I find fascinating, is *Idenix*. Maybe \$2 billion in the modern world is nothing anymore, but it still sounds like a lot of money to me, and it got overturned. Maybe, Ari, do you know what actually happened in Europe with respect to the corresponding patents?

ARI LAAKKONEN: I don't know about the corresponding patent, but I can talk about the corresponding doctrine, if that's of any use.

MARTIN ADELMAN: That's of use, but there actually were corresponding— The corresponding patent to *Idenix* was litigated in England, in Germany, in the European Patent Office, and ultimately, it went down. I've got all the cases here, but nobody gave it a broad interpretation that would actually cover the products made by Gilead, Sofosbuvir, something like that. Extremely important drug, multi-billion dollar drug for hepatitis C. The key was the argument that the fluorine had to be in a particular position. The question is, well, you had the methyl group in a different position, was that good enough to justify a generic invention? Nobody read it that broadly, but an American jury did and that was overturned. [crosstalk]

ARI LAAKKONEN: The underpinning doctrine here is that if you have overbroad claiming, you end up essentially losing a part of your patent. I do think it's interesting the way that you can diverge an outcome. One way of looking at it here is that, because, in the UK, you can amend a pattern down during litigation. If you have an overbroad claim, the answer to it can be you amend down to what's actually protectable. What is the core of what you really invented? If at that stage, you end up amending down to something where you don't actually have support for what you're trying to amend down to, then you know that the patent was insufficient to begin with.

MARTIN ADELMAN: That wasn't the problem. The problem is very simple. What they had was a lot of work and the potential for writing a generic claim, which would cover the specific invention made by Gilead, which was the big money. They didn't have a drug that was covered by their patent, so amending down wouldn't really help them. What they wanted, understandably, is a very broad claim saying that they were entitled to a generic claim. It was the same argument they made in the United States and got a jury to give them \$2 billion.

NICHOLAS GROOMBRIDGE: Marty, can I chime in on this? First of all, let me say I'm all in favor of having Americans pay their British creditors, on your jumping-off point.

MARTIN ADELMAN: Eliminate the [unintelligible] and we won't have this problem.

NICHOLAS GROOMBRIDGE: Exactly. To me, in *Idenix*, there are some unusual factual considerations, if I remember the disclosure rightly.

STEVEN LIEBERMAN: Marty, this is Steve. Can I pivot to a slightly different area?

MARTIN ADELMAN: Yes, we might as well move in because I think Nick had some interesting comments.

STEVEN LIEBERMAN: I just wanted to mention a couple of very practical patent developments that have taken place in the last year or so. I think these are trends that most people who litigate have seen. One is the tremendous

influence that litigation funders have had in patent litigation in a way that they've never had before. You have tons of money and smart money behind patent litigation.

They're investing in multi-patent lawsuits, often lawsuits that come from individuals who have bought patent portfolios from operating entities that have gone out of business, like Maxell buying the Hitachi portfolio, et cetera. In fact, if you like big money cases, one of the biggest patent judgments this last year was *VLSI vs. Intel*.³⁷ VLSI was not only funded by a litigation funder, but VLSI was also created by a litigation funder, Fortress Investments.

That's had a huge impact. It's had a huge impact, because these guys are very, very careful in their due diligence process. They've been picking out strong patents and it's driving a lot of big money cases. Number two, discretionary denials by the PTAB using *Fintiv*³⁸ factors and for other reasons, that's also having an enormous impact. There have been so many discretionary denials, that it's driving all sorts of litigation decisions, for example, patent plaintiffs are now thinking about filing lawsuits and choosing to file lawsuits, in rocket docket jurisdictions because they know that as a practical matter, applying the *Fintiv* factors, that it's highly likely that PTAB will never institute an IPR if you get a case scheduled for trial within 12 months of filing the complaint.

It's driving litigation to faster jurisdictions. It's increasing the trend of cases going to places like Western District of Texas, the Eastern District of Texas. The last point I wanted to make was one practical aspect of 101 jurisprudence. I think one of the things we've started to see in the last year is that defendants are starting to figure out the right procedural stage to raise 101 issues.

It's not always 12(b)(6),³⁹ sometimes it's a motion for judgment on the pleadings. Sometimes it's summary judgment. I think we're going to see more and more these issues going to the jury with special questions for the jury, so that the patent can be reversed on appeal if the jury handles the special questions in a particular way. Those were some practical developments I've seen that have considerable significance this last year.

MARTIN ADELMAN: That's fascinating. Anybody want to comment?

ADAM MOSSOFF: I'll just comment very briefly. Marty, is it okay if I—

MARTIN ADELMAN: Yes, go ahead.

ADAM MOSSOFF: On the *Fintiv* discretionary denial issue. Yes, this has impacted the PTAB decision-making process at the institution stage in the past year, but one can argue that the PTAB decision-making process before *Fintiv* was fundamentally broken, because it did not reflect the original intent of the America Invents Act⁴⁰ in creating the PTAB. I was on the Hill during the legislative debates over the PTAB and the AIA, and it was repeatedly stated at that time that the PTAB was not supposed to create a two-track litigation system.

³⁷ *VLSI Tech., LLC v. Intel Corp.*, No. 6:19-CV-000254-ADA, 2019 WL 4254065 (W.D. Tex. Aug. 6, 2019).

³⁸ *Apple, Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 15 (P.T.A.B. May 13, 2020).

³⁹ FED. R. CIV. P. 12(b)(6).

⁴⁰ America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2012).

The PTAB was not to be a secondary litigation process that would run concurrently along with an Article III⁴¹ court case. It was supposed to be only an efficient, easy, and quick way to resolve the legitimacy and validity of patents at the early stages of litigation, just as they do in Germany, where first you have the validity issue decided before you have the infringement issue decided.

As the rules at the PTAB were put into effect, however, because the AIA imposed no substantive or procedural restrictions on it from the get-go other than essentially that it must decide its cases within a year, it very quickly turned into a two-track litigation system. Empirical studies have shown that 60% to 70% of PTAB petitioners are defendants in Article III cases.

MARTIN ADELMAN: Let me stop you there Adam, you're saying that the intent was to file the IPR before there's litigation.

ADAM MOSSOFF: That was the original argument. People would receive the demand letter, such as mom-and-pop stores and small businesses, and the PTAB would provide an easy and inexpensive way for them to have the patent invalidated—

MARTIN ADELMAN: The real function of the PTAB is to get rid of the jury trial because we shouldn't have jury trials.

ADAM MOSSOFF: That was resolved by *Oil States* which said that the Seventh Amendment doesn't apply to the PTAB.⁴² But the concerns about the PTAB go way beyond jury trials, such as serial petitioning with sometimes 30 to 40 IPR petitions filed against the same patent. We can't drop that context in talking about the situation of the *Fintiv* discretionary denials, and what impact that those denials are having because it always must be compared to the empirical baseline of what came before.

MARTIN ADELMAN: Got it, did you have a comment because Nick now is back?

NICHOLAS GROOMBRIDGE: Let me see if I can do any better this time, Marty, but on Adam's point. I think maybe I'm seeing this in the chat that I think there was certainly a viewpoint that what would happen was the district courts would stay cases when there was an IPR, and perhaps more broadly, whether one likes it or not, isn't this an example of competition between tribunals in which the timeline of the PTAB is now motivating certain district courts to go more quickly? I've always thought we saw a similar thing in Europe in which competition between national court systems motivated the English court system to do patent cases much more quickly in the 1990s than they had before that. Is this a good thing where we see different tribunals, responding to what others do in order to try to be more efficient?

LAURA SHERIDAN: Marty, could I jump in on this issue?

MARTIN ADELMAN: Yes.

LAURA SHERIDAN: The purpose and the debate, as I remember it, around IPR and post-grant more broadly, was favoring PTAB proceedings. Favoring the agency correcting its own errors because it's cost-effective, and because it's efficient and it's time-bound. It's the place where these decisions should be made. The function of IPR has really been to improve quality by creating this incentive upfront.

⁴¹ U.S. CONST. art. III.

⁴² *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1369 (2018).

I think what you're seeing a lot now is people understand if you want your patent to be strong, you will do a prior art search and you will craft claims that are IPR proof because now you're understanding there is this error correction mechanism at the backend, and you'd like your patent to withstand that. With IPR, I think the debate understood that this was almost always going to be in the context of litigation, which is why they did come up with the one-year window, but it was also understood that it would have this tremendous effect on incentivizing the right behavior in the first place, which ex parte re-exam certainly wasn't doing, and IPR was designed to replace that.

MARTIN ADELMAN: Got that. Nick, you want to comment?

NICHOLAS GROOMBRIDGE: I'll try, Marty. I was just saying in response to what Adam said that, isn't this an example of competition between different tribunals? What is happening is the court system is actually trying to go faster because of the timeline of PTAB proceedings. Maybe that's a good thing.

STEVEN LIEBERMAN: Except that it's not all the courts, it's a very small number of courts are going faster, because for whatever reason, they want to have the patent cases in that jurisdiction. One of the things that almost always comes along with that speed, at least in several of those jurisdictions, is that they have jettisoned many of the rules of federal civil procedure. Rule 56⁴³ does not exist as a practical matter in the Eastern District of Texas because that would interfere with getting a case to trial in 12 to 14 months. I'm not sure that's a good thing.

MARTIN ADELMAN: So, you're essentially arguing, Steve, that the speed which we think would be a good thing is a competitive technique to grab cases, and what they're really saying is, "We'll give you, not necessarily a fair trial, but one biased towards the person who's filing the case."

ADAM MOSSOFF: I appreciate and applaud Steve's appeal that there should be due process and that we should follow civil rules of procedure and other laws. Therefore, I fully expect Steve to come out against serial petitions, panel stacking, the denial of the right to amend patents in the IPR process, and all the other PTAB practices that the Supreme Court has identified as "shenanigans."

MARTIN ADELMAN: Adam is with you on all that.
[crosstalk]

ADAM MOSSOFF: Join me to support the STRONGER Patent Act.
[laughter]

MARTIN ADELMAN: I'm against all shenanigans.
[laughter]

LAURA SHERIDAN: Marty, can I just point out, to Steve's point though, I think the trials aren't even happening. The trial dates, largely, they're just set, and then the PTAB can make decisions based on those dates, but those dates are not chiseled in stone. They're barely written in pencil. Those dates will move, and more likely than not, validity will never be decided. This idea that the PTAB is punting the validity question to district court – district court is not deciding validity. That patent continues to be asserted and enforced and the validity assessment isn't even done because these trial dates are simply not being met.

⁴³ FED. R. CIV. P. 56.

MARTIN ADELMAN: You would argue that the discretionary denials are really a bad thing?

LAURA SHERIDAN: Yes. What it's ended up doing is driving litigants to use ex parte re-exam⁴⁴ again, which I thought the whole point of IPR was to replace that.

MARTIN ADELMAN: It's fascinating. Adam has a strong patent focus which I understand. I have the focus that anything that gets rid of a jury trial makes it a more sensible system. Since we can't amend the Constitution, even Adam can't do that, that this is the next best thing, and we should craft proper rules to make it as effective a tribunal as possible. I do want to at least get back.

If we set aside for the moment these litigation funders, because the argument is they're only going to fund strong cases. I don't see any point in funding a cheap case, unless you're a holdup artist, and you're just going to file cases, then say, "Look, it's a million dollars for you to defend, and I'll settle for 50,000." If you're talking about big cases like the ones against Intel, I took a look at those patents. I'll make you a bet, Steve, they'll never hold up on appeal. They'll never get \$2 billion from Intel.

STEVEN LIEBERMAN: In general, the big litigation funders, by and large, are doing pretty serious due diligence. In my experience, their due diligence is weighted more towards the damages model than it is to issues of [unintelligible] infringement.

MARTIN ADELMAN: Yes, they said we've done everything.

STEVEN LIEBERMAN: Well, because that's where they have their expertise. They have financial analysis expertise. They look at the damages model, and when you're evaluating a patent case and you're doing it before it's even been filed, how well can you estimate the likelihood of success of a plaintiff unless it's dead on 101 grounds? What's the difference between 40% and 60%? It's really hard to do in advance like that. They're looking at the damage models, but they are looking seriously, I think.

MARTIN ADELMAN: That's logical, you'd look at how much you could collect. They got over \$2 billion. I didn't study the patents in great detail, but I'm just willing to bet we'll get nowhere near that amount. The *Idenix* patent was actually a better patent. Anyhow, Nick, you had a comment on the *Idenix* litigation that got cut off and you got frozen. I thought that was something bad.

NICHOLAS GROOMBRIDGE: Let me try again. I found one of the things about *Idenix*, about the decision, which is troublesome. It seems to suggest that for purposes of enablement it's relevant, how long it would take to create all of the compounds within the scope of the genus. It seems like if you're claiming a large genus, then as Dimitrios pointed out, that the rationale there was even if testing one compound is routine, you have to test thousands or tens of thousands or hundreds of thousands, then that's undue experimentation and it seems like it convert— There's a risk that the courts go in the direction of making enablement purely a quantitative exercise.

MARTIN ADELMAN: Well, do you think that there was a broad invention there? I don't care what the jury said.

NICHOLAS GROOMBRIDGE: I think I'm not the best person to answer that.

⁴⁴ 35 U.S.C. § 302.

MARTIN ADELMAN: Well, there, the methyl without the critical thing, which was the fluorine the bottom at the two position.

NICHOLAS GROOMBRIDGE: My recollection, Marty, and I could be wrong on this, is that in the spec, they disclosed all of the halogens except for fluorine.

MARTIN ADELMAN: Yes.

NICHOLAS GROOMBRIDGE: They then were trying to get claims to a molecule using fluorine.

MARTIN ADELMAN: Well, because generically, they were talking about methyl then the opposition [unintelligible] the opposition. Generically, it covers fluorine.

NICHOLAS GROOMBRIDGE: Oh, correct. I think there was certainly an invention there, but whether there was a sufficient basis to cover what Gilead was doing, I'm not sure.

DIMITRIOS DRIVAS: I agree with Nicholas. I think the caution is if you're going to claim broadly, be careful about putting a functional limitation in that claim, especially in the chemical sense. Judge Newman's dissent, she would have found that the claims are enabled, but not infringed.

MARTIN ADELMAN: Well, so far, I can't find any place in the world that found liability. It was litigated all over the world.

ARI LAAKKONEN: Well, that's reassuring because there's some consistency there, but I think that one of the themes that comes out of this case for me is that in the US, it's an enablement issue. When you look at an overbroad claim for that in the UK and Europe, generally, it's an insufficiency point, but from a prosecution perspective, it just shows that maybe ambitious claiming may not be so rewarding after all, because if you get nothing from your plane then why bother with the patent in the first place?

In the UK, those patterns didn't work. I think the general objection is that there may be an example of armchair claiming or armchair patenting, where people, instead of disclosing what the invention is, they say, "Well, what is it that they would like to achieve?"

You do experimentation in order to find out whether you've actually got there, you do a certain amount of experimentation to actually make the invention. Then once you've made it, you look at the claim to figure out does it fall within the claim itself? The problem there is that the invention itself hasn't been disclosed and it hasn't been taught, which is part of the fundamental patent bargain, because the idea of the patent, of course, as everyone knows, is that you give that invention to the public domain. In exchange, you get your time-limited monopoly.

STEVEN LIEBERMAN: Having represented pharmaceutical companies for many years, as a practical matter, they try to file patent applications as early in the drug development process as possible. Very often, they don't know exactly what the drug is going to be. Once they figure it out, sometimes it's too late to go back and it takes care of the problem. I don't think – [crosstalk]

MARTIN ADELMAN: It's a generic invention in the first place. You read this patent specification, and they knew they were close. They were trying to modify a particular nucleoside and they wanted to find one that would work and maybe having a methyl in the up position gave them some advantage, but that's all they came up with. The thing that really worked, which they didn't

have, was to also have a fluorine in the down position, which was very difficult to do, and they didn't do it. Why should they get anything for it?

STEVEN LIEBERMAN: Marty, I think you've got to look at it in the context of both economics and the morality issues that Joshua was talking about in the last panel.

MARTIN ADELMAN: Oh, no.

STEVEN LIEBERMAN: Let me just [unintelligible] for a second. Look, I mostly represent generic companies, but I also represent brands from time to time. They're spending hundreds of millions of dollars on research. Often, they think they have something, but the process takes a year, two years, three years – [crosstalk].

MARTIN ADELMAN: They generate hundreds of millions.

STEVEN LIEBERMAN: [unintelligible] going ahead turns out to be toxic. By the time you realize what the real drug target is, it's too late. You try to get protection early because, frankly, you don't have patent protection. There were very few, and Nick, I think, will confirm this, there are very few companies out there that will bring a drug to market if they don't have patent protection.

MARTIN ADELMAN: Gilead brought it to market, made \$60 billion. They had patent protection on what the invention really was.

STEVEN LIEBERMAN: I'm just trying to explain how this happens.

MARTIN ADELMAN: I know.

NICHOLAS GROOMBRIDGE: I think we could easily get drawn into a discussion with Josh who isn't even here.

MARTIN ADELMAN: But he is in spirit. He is in spirit because every time I think of his arguments, I oppose them.

NICHOLAS GROOMBRIDGE: Let me throw out a question. Is the Supreme Court going to abolish assignor estoppel?

MARTIN ADELMAN: Who cares? This is the most ridiculous case that they're taking. The guys don't have enough to do? I'm selling something, and then they say it's a piece of shit, but everybody should have freedom, *Lear v. Adkins*, to do this kind of stuff. I just can't believe they'd take a case like this.

DIMITRIOS DRIVAS: I think to your point, Nick, the fact that they asked the Solicitor General to present oral argument and the position that the US has taken, that the doctrine should be maintained, but its contours should be defined, may be signaling where they might go.

MARTIN ADELMAN: That's what they're spending their time doing when we have serious problems, like 101.

DIMITRIOS DRIVAS: I don't know if they could fix that one. Might be too late for them.

MARTIN ADELMAN: Oh, I could fix it in a minute. Overturn *Funk Brothers*. Overturn the idea that something that you discovered can be treated as prior art. *Funk Brothers* is the first case that brought that up. It's Douglas, he's always wrong. The Supreme Court just mindlessly follows it. That's what they do. They make up something and they call it a discovery, or they give it a name and they say, "You came up with it, but it's prior art."

DIMITRIOS DRIVAS: I agree. Marty. I don't think there should be any judicial exception to patentability.

MARTIN ADELMAN: Clearly neither does Congress. They never enacted one.

DIMITRIOS DRIVAS: Yes, but will they go there? I doubt it.

MARTIN ADELMAN: I doubt it. They're too busy screwing the country up to do that.

STEVEN LIEBERMAN: Please don't be so ambiguous. Tell us what you really think about the Supreme Court.

MARTIN ADELMAN: All right, Nick, you're [unintelligible].

NICHOLAS GROOMBRIDGE: I don't think they will take a 101 case. Even though the problem is of their creation.

MARTIN ADELMAN: I kind of agree with you, so we have to live with it.