Precedential Patent Case Decisions During August 2019

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I. Introduction

This paper abstracts what I believe to be the significant new points of law from the precedential decisions in patent cases this month. Cases captions relating to the PTAB are in **red** text. Case captions of extraordinary importance are in **blue** text.

II. Abstracts and New Points of Law

Biodelivery Sciences International, Inc. v. Aquestive Therapeutics, Inc., 2019-1643, 2019-1644, 2019-1645 (Fed. Cir. 8/29/2019).

This is an order in appeals from PTAB cases IPR2015-00165, IPR2015-00168, and IPR2015-00169. In a prior appeal, the Federal Circuit had vacated and remanded in view of SAS. The PTAB then reconsidered, vacating the institution decisions and dismissing the petitions. Biodelivery appealed the dismissals. Aquestive moved to dismiss. The Federal Circuit majority, consisting of Judges Reyna and Lourie, granted the motion. Judge Newman dissented.

Legal issue: 35 USC 314(d), scope of bar to judicial review, remand resulting from *SAS*.

Here, the majority made it clear that the bar extends to PTAB vacatur pursuant to the discretionary authority in 314(a), after remand from the Federal Circuit resulting from *SAS*.

Section 314(a) of the Leahy-Smith America Invents Act *** "grants the Director discretion not to institute even when the threshold is met." *Wi-Fi One, LLC v. Broadcom Corp.*, 878 F.3d 1364, 1372 (Fed. Cir. 2018) (citing *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2140 (2016)). In other words, the Director is limited in his power to institute review but has discretion to not institute review even when the threshold showing is met. *See Saint Regis Mohawk Tribe v. Mylan Pharm. Inc.*, 896 F.3d 1322, 1327 (Fed. Cir. 2018) ("While he has the authority not to institute review on the merits of the petition, he could deny review for other reasons such as administrative efficiency"), *cert. denied*, 139 S. Ct. 1547 (2019). [Biodelivery Sciences International, Inc. v. Aquestive Therapeutics, Inc., 2019-1643, 2019-1644, 2019-1645 (Fed. Cir. 8/29/2019).]

Section 314(d) plainly states that the Patent Office's decision whether to institute IPR is not appealable. *See Cuozzo*, 136 S. Ct. at 2139. As the Board recognized, we have previously held that under § 314(d), "[t]he Board's vacatur of its institution decisions and termination of the proceedings constitute decisions whether to institute inter partes review and are therefore 'final and nonappealable." *Medtronic*, 839 F.3d at 1383 (quoting 35 U.S.C. § 314(d)); *see also GTNX*, 789 F.3d at 1313. [Biodelivery Sciences International, Inc. v.

<u>Aquestive Therapeutics, Inc.</u>, 2019-1643, 2019-1644, 2019-1645 (Fed. Cir. 8/29/2019).]

In this case, the Board initially erred under *SAS* by instituting partial review instead of making yes-or-no institution decisions. In following our Remand Order to "implement *SAS*," the Board corrected its partial institution errors by revisiting its institution decisions and properly exercising its discretion not to institute review at all. Nothing in our Remand Order divested the Board of that discretion. *** Here, the Board's orders on remand modifying its previous institution decisions constitute the Board's (1) determination of whether the information presented in the petitions shows that there is a reasonable likelihood of success with respect to at least 1 of the claims challenged, and (2) exercise of its discretion whether to institute IPR. Section 314(d) bars judicial review of both aspects of the Board's decisions. *Cuozzo*, 136 S. Ct. at 2142. [Biodelivery Sciences International, Inc. v. Aquestive Therapeutics, Inc., 2019-1643, 2019-1644, 2019-1645 (Fed. Cir. 8/29/2019).]

Arthrex, Inc., v. Smith & Nephew, Inc., 2018-1584 (Fed. Cir. 8/21/2019).

This is a decision on an appeal from PTAB case IPR2016-00918. The PTAB found claims unpatentable. Arthrex appealed. The Federal Circuit affirmed.

Legal issue: Retroactivity, Constitutionality (takings, due process) of IPR proceedings applied to patents issued after enactment of the AIA from applications filed prior to enactment of the AIA.

The Federal Circuit found no constitution question for a patent issued after enactment of the AIA.

Finally, we address Arthrex's challenge to the constitutionality of certain IPRs. Arthrex notes that the Supreme Court has not addressed the constitutionality of IPR as applied to patents issued prior to the America Invents Act (AIA), which created IPRs. *** We exercise our discretion and reach Arthrex's argument rather than finding that Arthrex waived this issue by failing to present it to the Board. See e.g., In re DBC, 545 F.3d 1373, 1378–79 (Fed. Cir. 2008) (noting "discretion to reach issues raised for the first time on appeal" but holding party waived constitutional challenge based on Appointments Clause by failing to raise it before the Board); Harris Corp. v. Ericsson Inc., 417 F.3d 1241, 1251 (Fed. Cir. 2005) ("An appellate court retains case-by-case discretion over whether to apply waiver."). We need not reach the merits of the issue, however, because the '541 patent issued on September 2, 2014, almost three years after passage of the AIA and almost two years after the first IPR proceedings began. See Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 6(c)(2)(A), 125 Stat. 284, 304 (2011) (providing that IPR "shall take effect upon the expiration of the 1-year period beginning on the date of the enactment of this Act [Sept. 16, 2011]"). That Arthrex filed its patent applications prior to passage of the AIA is immaterial. As

the Supreme Court has explained, "the legal regime governing a particular patent 'depend[s] on the law as it stood at the emanation of the patent, together with such changes as have since been made." *Eldred v. Ashcroft*, 537 U.S. 186, 203 (2003) (quoting *McClurg v. Kingsland*, 42 U.S. 202, 206 (1843)). Accordingly, application of IPR to Arthrex's patent cannot be characterized as retroactive. [Arthrex, Inc., v. Smith & Nephew, Inc., 2018-1584 (Fed. Cir. 8/21/2019).]

In any event, even if Arthrex's patent had issued prior to the passage of the AIA, our court recently rejected arguments similar to Arthrex's in Celgene Corp. v. Peter, No. 18-1167, 2019 WL 3418549, at *12-16 (Fed. Cir. July 30, 2019). As we explained, pre-AIA patents issued subject to both district court and Patent Office validity proceedings. Though IPR differs from these existing proceedings, we held that the differences between IPRs and the district court and Patent Office proceedings that existed prior to the AIA are not so significant as to "create a constitutional issue" when IPR is applied to pre-AIA patents. Id. at *15; see also id. at *12 & n.13 (affirming that our prior decisions ruling that retroactive application of reexamination does not violate the Fifth Amendment, the Seventh Amendment, or Article III "control the outcome" of similar challenges to IPR). When Arthrex's patent issued, it is beyond dispute that patent owners expected that "the [Patent Office] could reconsider the validity of issued patents on particular grounds, applying a preponderance of the evidence standard." Id. at *16. Consequently, even if Arthrex's patent pre-dated the AIA, application of IPR to the '541 patent would not create a constitutional challenge. [Arthrex, Inc., v. Smith & Nephew, Inc., 2018-1584 (Fed. Cir. 8/21/2019).]

Anza Technology, Inc., v. Mushkin, Inc., 2019-1045 (Fed. Cir. 8/16/2019).

This is a decision on an appeal from the D. Colo. district court case 1:17-cv-03135-MEH. The district court granted a motion to dismiss Anza's second amended complaint. Anza appealed. The Federal Circuit we reversed in part, vacated in part, and remanded. The Federal Circuit addressed choice of law, standard of review, and applicability of the relation back doctrine, to patent cases.

Legal issue: FCRCP 15(c) - Choice of law applicable to the relation back doctrine when amended complaint asserts new patent claims.

A preliminary question is whether Federal Circuit law, rather than regional circuit law, governs whether newly alleged claims in an amended complaint relate back to the date of the original complaint when the new claims are based on newly asserted patents. *** As in the case of motions to sever, the determination of whether newly alleged infringement claims relate back to the original complaint also turns on "an analysis of the accused acts of infringement." *Id.* Therefore, we hold that this determination is also governed by Federal Circuit law. [Anza Technology, Inc., v. Mushkin, Inc., 2019-1045 (Fed. Cir. 8/16/2019).]

Legal issue: FCRCP 15(c) - Standard of review for the relation back doctrine when amended complaint asserts new patent claims

The next question is what standard governs this court's review of a district court's application of the relation back doctrine.*** We adopt the majority rule. The rationale underlying that rule, when it has been expressed, is that the de novo standard of review applies because determining whether the amended claim "arose out of the conduct, transaction, or occurrence" set forth in the original complaint requires the reviewing court to apply the legal standard of Rule 15(c) "to a given set of facts," which is "a task we are no less suited to perform than the district court." Miller, 231 F.3d at 247; accord Percy, 841 F.2d at 978; Lundy v. Adamar of N.J., Inc., 34 F.3d 1173, 1177 (3d Cir. 1994). In some instances, however, factual issues may need to be addressed as part of the district court's analysis of the relation back issue. With respect to any disputed facts that are material to the relation back issue, we are not as well situated as the district court to make the appropriate findings. Therefore, in the event that such factual issues arise, we would review any findings by the district court on those issues for clear error, as we do in analogous circumstances. See, e.g., Presidio Components, Inc. v. Am. Tech. Ceramics Corp., 875 F.3d 1369, 1375 (Fed. Cir. 2017) (indefiniteness); Par Pharm., Inc. v. TWI Pharm., Inc., 773 F.3d 1186, 1194 (Fed. Cir. 2014) (obviousness); Alcon Research Ltd. v. Barr Labs., Inc., 745 F.3d 1180, 1188 (Fed. Cir. 2014) (enablement); SanDisk Corp. v. STMicroelectronics, Inc., 480 F.3d 1372, 1377 (Fed. Cir. 2007) (presence of a case or controversy); Rambus Inc. v. Infineon Techs. AG, 318 F.3d 1081, 1087-88 (Fed. Cir. 2003) (attorney fee award); In re Emert, 124 F.3d 1458, 1460 (Fed. Cir. 1997) (double patenting). [Anza Technology, Inc., v. Mushkin, Inc., 2019-1045 (Fed. Cir. 8/16/2019).]

Legal issue: FCRCP 15(c) - Substantive test for the relation back doctrine when amended complaint asserts new patent claims

The Supreme Court has interpreted the relation back doctrine liberally, to apply if an amended pleading "relate[s] to the same general conduct, transaction and occurrence" as the original pleading. *Tiller v. Atl. Coast Line R.R. Co.*, 323 U.S. 574, 580–81 (1945) (holding, in a rail-road negligence case that even though the amended complaint alleged a different theory of negligence, the new charge related back to the original complaint because "[t]he cause of action now, as it was in the beginning, is the same—it is a suit to recover damages for the alleged wrongful death of the deceased."). That liberal interpretation of the relation back rule reflects the rationale of Rule 15(c), which is that "a party who has been notified of litigation concerning a particular occurrence has been give all the notice that statutes of limitations were intended to provide." *Baldwin Cty. Welcome Ctr. v. Brown*, 466 U.S. 147, 149 n.3 (1984). [Anza Technology, Inc., v. Mushkin, Inc., 2019-1045 (Fed. Cir. 8/16/2019).]

Legal issue: FCRCP 15(c) - Substantive test for the relation back doctrine

Accordingly, in determining whether newly alleged claims, based on separate patents, relate back to the date of the original complaint, we will consider the overlap of parties, the overlap in the accused products, the underlying science and technology, time periods, and any additional factors that might suggest a commonality or lack of com-monality between the two sets of claims. At bottom, however, the question remains whether the general factual situation or the aggregate of operative facts underlying the original claim for relief gave notice to Mushkin of the nature of the allegations it was being called upon to answer. [Anza Technology, Inc., v. Mushkin, Inc., 2019-1045 (Fed. Cir. 8/16/2019).]

<u>Nalpropion Pharmaceuticals, Inc. v. Actavis Laboratories FL, Inc.</u>, 2018-1221 (Fed. Cir. 8/15/2019).

This is a decision on an appeal from the D. Del. district court caste 1:15-cv-00451-RGA. The district court inter alia found a would not have been obvious in view of the prior art. Actavis appealed. The Federal Circuit reversed on that issue.

Legal issue: 35 USC 103 motivation to combine, FDA approval factor.

The Federal Circuit concluded that denial of FDA approval of a drug due to lack of sufficient efficacy was not dispositive of obviousness of combination including that drug, for the same effect.

As for the combination of the two drugs, the district court concluded that Dante and O'Malley did not teach a person of ordinary skill that the combination was effective for weight loss. *** We are not persuaded. Nalpropion argues that bupropion does not possess sufficient weight loss efficacy to obtain FDA approval by itself. But, while bupropion alone may not have been entitled to FDA approval as a weight-loss treatment, "[t]here is no requirement in patent law that the person of ordinary skill be motivated to develop the claimed invention based on a rationale that forms the basis for FDA approval." Allergan, Inc. v. Sandoz Inc., 726 F.3d 1286, 1292 (Fed. Cir. 2013). "Motivation to combine may be found in many different places and forms; it cannot be limited to those reasons the FDA sees fit to consider in approving drug applications." Id. Instead, "[t]he court should consider a range of real-world facts to determine 'whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue."" Arctic Cat Inc. v. Bombardier Recreational Prods. Inc., 876 F.3d 1350, 1359 (Fed. Cir. 2017) (quoting Inter-continental Great Brands LLC v. Kellogg N. Am. Co., 869 F.3d 1336, 1344 (Fed. Cir. 2017), cert. denied, 139 S. Ct. 143 (2018)). The inescapable, real-world fact here is that people of skill in the art did combine bupropion and naltrexone for reductions in weight gain and reduced cravings—goals closely relevant to weight loss. Contrary to Nalpropion's view, persons of skill did combine the two drugs even without understanding bupropion's mechanism of action but with an understanding that bupropion was

well-tolerated and safe as an antidepressant. *See* J.A. 7165 ("The precise mechanism for bupropion SR that is responsible for effects on weight loss is unknown."); see also J.A. 7157 (same). Thus, we conclude that skilled artisans would have been motivated to combine the two drugs for weight loss with a reasonable expectation of success. [Nalpropion Pharmaceuticals, Inc. v. Actavis Laboratories FL, Inc., 2018-1221 (Fed. Cir. 8/15/2019).]

MTD Products Inc. v. Iancu, 2017-2292 (Fed. Cir. 8/12/2019).

This is a decision on appeal from PTAB case IPR2016-00194. The PTAB held MTD's claims unpatentable. MTD appealed. The Director intervened to defend the PTAB decision. The Federal Circuit vacated and remanded.

Legal issue: 35 USC 112, claim construction, whether a recitation invokes MPF construction.

The PTAB had concluded that the claim recitation "mechanical control assembly . . . configured to" was not a MPF recitation. Based upon the non-MPF construction, the PTAB held the claims obvious over prior art. The Federal Circuit held that the PTAB erred by relying upon the existence of corresponding structure in the specification to conclude that the claim recitation "mechanical control assembly" defined sufficiently definite structure to preclude MPF construction.

First, the Federal Circuit restated the process for determining if a recitation was a MPF recitation.

Interpretation of an asserted means-plus-function limitation involves two steps. First, we determine if the claim limitation is drafted in means-plus-function format. As part of this step, we consider whether the claim limitation connotes "sufficiently definite structure" to a person of ordinary skill in the art. If we conclude that the limitation is in means-plus-function format, the second step requires us to review the specification to identify the structure that performs the claimed function(s) and thus "corresponds to" the claimed means. While related, these two inquiries are distinct. In this case, however, the Board conflated these distinct inquiries, holding that the specification's disclosure of corresponding structure demonstrates that the alleged means-plus-function term is sufficiently definite so as to not invoke § 112, ¶ 6. The Board's analysis implies that so long as a claim term has corresponding structure in the specification, it is not a means-plus-function limitation. This is not consistent with our prior decisions. Indeed, this view would seem to leave 112, 6 without any application: any means-plus-function limitation that met the statutory requirements, i.e., which includes having corresponding structure in the specification, would end up not being a means-plus-function limitation at all. [MTD Products Inc. v. Iancu, 2017-2292 (Fed. Cir. 8/12/2019).]

While we agree with the Board that the specification plays a role in assessing whether particular claim language invokes § 112, \P 6, we do not agree

that the patent specification at issue here renders the nonce term "mechanical control assembly" sufficiently structural to a person of ordinary skill in the art. The specification does not demonstrate that the patentee intended to act as its own lexicographer and define the nonce term "mechanical control assembly" as the "ZTR control assembly" of the preferred embodiment. Indeed, the specification does not even refer to a "mechanical control assembly." Furthermore, the functional language in the claim limitation suggests a broader meaning of the generic term "mechanical control assembly," as it specifically adds to the "mechanical control assembly" limitation the ability to execute a zero radius turn. '458 patent col. 9 ll. 13–16. Interpreting the "mechanical control assembly" as the "ZTR"—or zero-turn-radius—control assembly would render this functional language superfluous. [MTD Products Inc. v. Iancu, 2017-2292 (Fed. Cir. 8/12/2019).]

The Federal Circuit also stated that the PTAB erred by relying upon prosecution history statements that were consistent with an MPF construction to preclude an MPF construction.

We are also not persuaded by the Board's interpretation of the prosecution history. While it would have avoided uncertainty and argument had MTD shared its current view that the claim limitation is written in means-plus-function format during the original prosecution, MTD's statements did not clearly disclaim such an interpretation. Rather, MTD's statements indicated that the phrase "mechanical control assembly configured to" perform certain functions must be given weight because it connotes structure and thus is not merely an intended use. These statements were not made within the context of § 112, ¶ 6. Moreover, stating that the limitation connotes structure and has weight is not inconsistent with claiming in means-plus-function format since means-plus-function limitations connote structure (i.e., corresponding structure and their equivalents) and have weight. Furthermore, as MTD explained, its interpretation of the claims as being in means-plus-function format during inter partes review was based on this court's intervening law in Williamson. J.A. 1204. Given the lack of any clear and undisputed statement foreclosing application of § 112, \P 6, we conclude that the Board erred in giving dispositive weight to the equivocal statements it cited in the prosecution history. [MTD Products Inc. v. Iancu, 2017-2292 (Fed. Cir. 8/12/2019).]

We conclude that the Board erred by using the existence of corresponding structure in the specification to conclude that "mechanical control assembly" has a sufficiently definite structure to evade § 112, ¶ 6. The Board also erred by giving improper weight to out-of-context statements in the prosecution history. We hold that the remaining evidence and the Board's factual findings demonstrate that the term "mechanical control assembly . . . configured to" perform certain functions in independent claims 1 and 9 of the '458 patent is governed by § 112, ¶ 6. We

therefore vacate the Board's decision and remand for further proceedings consistent with this opinion. [MTD Products Inc. v. Iancu, 2017-2292 (Fed. Cir. 8/12/2019).]

Virnetx Inc. v. Apple Inc., 2017-1591, 2017-1592, 2017-1593 (Fed. Cir. 8/1/2019).

This is a decision on appeals from PTAB cases 95/001,788; 95/001,789; and 95/001,856 (which were appeals from inter partes reexaminations). Apple had lost on its district court invalidity challenge on the subject claims. The PTAB concluded that Apple was not barred from maintaining its reexams, and affirmed the examiner's unpatentability determinations. Vernetx appealed. The Federal Circuit majority vacated-in-part and remanded, concluding that Apple was statutorily barred (by pre-AIA 35 USC 317(b)) from maintaining the reexams. The panel split on the estoppel issue. Chief Judge Prost joined by Judge Moore concluded that estoppel applied. Judge Reyna dissented from that conclusion.

Legal issue: Pre AIA 35 USC 317(b), preclusion and construction of "final decision."

In dissent, Judge Reyna stated:

This appeal involves the Supreme Court's authority to take appeals involving U.S. patents under Article III of the U.S. Constitution. The majority holds that Apple's petitions for inter partes reexaminations are barred under 35 U.S.C. § 317(b) (2006). Although I agree with the majority's disposition of this case in all other respects, I do not agree that reexamination is precluded. Because Apple may still appeal this court's affirmance of no invalidity, there is no "final decision" that triggers a bar under § 317(b). Accordingly, I concur-in-part and dissent-in-part. [Virnetx Inc. v. Apple Inc., 2017-1591, 2017-1592, 2017-1593 (Fed. Cir. 8/1/2019); Reyna dissenting.]

Chief Judge Prost, writing for the majority consisting of Chief Judge Prost and Judge Moore stated:

VirnetX contends that Apple's reexams were barred by § 317(b). The PTO refused to terminate Apple's reexams based on the conclusion that the provision did not apply. In VirnetX's view, the PTO's decision was inconsistent with controlling case law, the statutory text, and Congress's intent. We agree. [VirnetX Inc. v. Apple Inc., 2017-1591, 2017-1592, 2017-1593 (Fed. Cir. 8/1/2019).]

The Patent Act requires that the PTO terminate a reexamination once there has been a final decision on the patent challenger's invalidity case in federal court. 35 U.S.C. § 317(b) (2006). *** we affirmed the district court's decision on the issue of invalidity. *** The 90-day period to file a petition for certiorari expired. *** On appeal, the sole issue is whether there has been a "final decision" entered against Apple that it "has not sustained its burden of proving" invalidity, triggering estoppel of its parallel PTO reexam proceedings. *** Two reasons

compel the conclusion that there has been a final decision on validity in this case. First, our decision in *Fairchild (Taiwan) Corp. v. Power Integrations, Inc.*, 854 F.3d 1364 (Fed. Cir. 2017), controls and holds that there is a "final decision" under § 317(b) once the time to file a certiorari petition has passed. Second, even if *Fairchild* did not foreclose Apple's argument, the plain language of the statute and its purpose advise against Apple's definition of a "final decision" on the issue of invalidity. [Virnetx Inc. v. Apple Inc., 2017-1591, 2017-1592, 2017-1593 (Fed. Cir. 8/1/2019).]

Since the PTO's decision in 2016, we have ruled on this very issue. *Fairchild* directly addressed a situation in which validity was affirmed but other issues in the case were remanded. *Fairchild* holds that if a finding of no invalidity has been affirmed on appeal and remand of other issues will not "have any affect" on validity, the decision is "final" once the 90-day deadline for a certiorari petition on the validity determination has passed. *Id.* at 1366. *Fairchild* announced this holding despite the fact that there is always some "potential" for future Supreme Court review if the entire case is taken up. Accordingly, *Fairchild* requires we reject Apple's position. [Virnetx Inc. v. Apple Inc., 2017-1591, 2017-1592, 2017-1593 (Fed. Cir. 8/1/2019).]

Hylete LLC v. Hybrid Athletics, LLC, 2017-2057 (Fed. Cir. 8/1/2019).

This is a decision on appeal from TTAB case 91213057. The TTAB sustained Hybrid's opposition. Hylete appealed. The Federal Circuit affirmed.

Legal issue: Waiver of arguments not raised below.

The Federal Circuit found that Hylete waived arguments not raised below. I include this case because it summarizes exceptions to waiver of arguments not raised below.

We have articulated limited circumstances in which considering arguments made for the first time on appeal is appropriate: (1) "[w]hen new legislation is passed while an appeal is pending, courts have an obligation to apply the new law if Congress intended retroactive application even though the issue was not decided or raised below"; (2) "when there is a change in the jurisprudence of the review-ing court or the Supreme Court after consideration of the case by the lower court"; (3) "appellate courts may apply the correct law even if the parties did not argue it below and the court below did not decide it, but only if an issue is properly before the court"; and (4) "where a party appeared pro se before the lower court, a court of appeals may appropriately be less stringent in requiring that the issue have been raised explicitly below." *Golden Bridge*, 527 F.3d at 1322–23 (quoting *Forshey v. Principi*, 284 F.3d 1335, 1353–57 (Fed. Cir. 2002)). [Hylete LLC v. Hybrid Athletics, LLC, 2017-2057 (Fed. Cir. 8/1/2019).]