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2019 Patent Law Decisions of the Federal Circuit

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2019 Patent Law Decisions of the Federal Circuit

AREA SUMMARIES

2019 PATENT LAW DECISIONS OF THE FEDERAL CIRCUIT

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TABLE OF CONTENTS

Introduction 1164
I. Claim Construction 1165
II. Validity 1169
A. Patent-Eligible Subject Matter 1169
B. Anticipation 1178
C. Obviousness 1181
D. Indefiniteness 1189
E. Written Description and Enablement 1192
F. Statutory Bars 1200
1. Ready for patenting 1200
2. Public use 1201
3. Experimental use 1202
4. On-sale bar 1202
G. Utility 1203
III. Infringement 1204
A. Doctrine of Equivalents 1204
B. Literal Infringement 1208

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C. Indirect Infringement 1209
IV. Equitable Defenses 1210
A. Licensing 1210
V. Patent Office Appeals 1211
A. PTAB Procedures 1211
B. Anticipation 1225
C. Obviousness 1229
D. Inventorship 1239
E. Patent Term Adjustment 1240
F. Federal Circuit Procedures 1242
VI. Remedies 1243
A. Attorney Fees 1243
B. Willful Infringement 1247
VII. District Court 1248
A. Procedural 1248
B. Motion to Amend Complaint 1250
C. Declaratory Judgment Jurisdiction 1252
D. Venue 1253
E. Subject Matter Jurisdiction 1255
F. Personal Jurisdiction and Sovereign Immunity 1256
G. Appellate Jurisdiction 1258
H. Standing 1259
I. Ethical Representation 1260
J. Inventorship 1261
VIII. Design Patents 1261
IX. Reissue Patents 1263

INTRODUCTION

In 2019, the Supreme Court was largely quiet in the realm of patent law, issuing only two rulings on the topic. In *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.*,[1] the Supreme Court decided that new wording in the America Invents Act's (AIA) on-sale bar did not overturn the Court's precedent regarding the applicability of the on-sale bar to secret sales of patents.[2] The Court also determined, in *Return Mail, Inc. v. United States Postal Service*,[3] that a federal agency of the

1. 139 S. Ct. 628 (2019).
2. *Id.* at 634.
3. 139 S. Ct. 1853 (2019).

United States was not a "person" and is thus not able to petition for post grant review under the AIA.[4]

The upcoming Supreme Court term, however, looks to be much more exciting. The Court has granted certiorari for cases arguing a variety of patent issues, including whether the U.S. Patent and Trademark Office (PTO) can move for attorney fees when it defends its decisions to deny patent applications in district court,[5] whether institution decisions for inter partes reviews are appealable,[6] and whether patent eligibility is a question of both fact and law.

The U.S. Court of Appeals for the Federal Circuit was, as always, busy in the patent field. With about half of its appeals originating from the PTO, it is unsurprising that many of its cases dealt with procedures of the Patent Trial and Appeal Board (PTAB or "the Board"). Indeed, the constitutionality of the PTAB itself was successfully challenged before the Federal Circuit this year. Of course, the Federal Circuit also issued many opinions regarding novel issues arising in the district courts, such as state sovereign immunity. This Article collects and summarizes many of the Federal Circuit's 2019 patent decisions and analyzes their effect on the practice of patent law.

I. CLAIM CONSTRUCTION

While many of the Federal Circuit's claim construction decisions were made in accordance with *Phillips v. AWH Corp.*,[7] several discussed discrete issues within that framework. For example, *Forest Laboratories, LLC v. Sigmapharm Laboratories, LLC*[8] analyzed the use of the word "and" in a claimed list.[9] The patent-at-issue claimed "[a] method for treating tension, excitation, anxiety, *and* psychotic *and* schizophrenic disorders."[10] The district court construed the claim to exclude the treatment of bipolar disorders.[11] After reading the claim and specification, the Federal Circuit disagreed, stating that "[t]he use of the conjunction 'and' before 'psychotic and schizophrenic disorders' indicates that 'psychotic and schizophrenic disorders' is a distinct item

4. *Id.* at 1867–68.
5. *Iancu v. NantKwest, Inc.*, 139 S. Ct. 1292 (2019).
6. Dex Media, Inc. v. Click-To-Call Techs., LP, 139 S. Ct. 2742 (2019).
7. 415 F.3d 1303 (Fed. Cir. 2005).
8. 918 F.3d 928 (Fed. Cir. 2019).
9. *Id.* at 938.
10. *Id.* at 932 (emphasis added).
11. *Id.* at 938.

on the list."[12] The naming of these specific types of disorders stood—in the court's mind—in stark contrast with the rest of the list, the elements of which were used in the specification as describing covered symptoms.[13] Because bipolar I disorder may include the symptom of "excitation," the Federal Circuit vacated the claim construction and remanded the infringement issue back to the district court.[14]

Similarly, the Federal Circuit decided the limiting effect of a "wherein" clause in *Allergan Sales, LLC v. Sandoz, Inc.*[15] The claim language at issue there had two separate "wherein" clauses: an efficacy "wherein" clause and a safety "wherein" clause.[16] The appellant argued that the "wherein" clauses only stated intended results and that they were not material to patentability.[17] The court disagreed.[18] The specification and prosecution history showed that the patent owner conveyed to a person of skill in the art and the patent office that the efficacy and safety of the claimed method were material to patentability; thus, the Federal Circuit determined that the clauses were limiting.[19]

Two cases also discussed means-plus-function constructions. First, in *MTD Products Inc. v. Iancu*,[20] the Federal Circuit reviewed the USPTO's claim construction of a potential means-plus-function claim.[21] Specifically, the Board held that the claim term "mechanical control assembly . . . configured to" perform some function was not a mean-plus-function claim subject to 35 U.S.C. § 112, ¶ 6.[22] The Board reasoned that the specification provided structural definition to the term such that a person of ordinary skill in the art would understand that the term "denote[s] structure."[23]

The Federal Circuit vacated the Board's decision, ultimately holding that the specification at issue did not provide enough corresponding

12. *Id.*
13. *Id.* (noting, also, that the parties agreed that there was "no such thing as an 'excitation disorder'").
14. *Id.*
15. 935 F.3d 1370 (Fed. Cir. 2019).
16. *Id.* at 1374.
17. *Id.*
18. *Id.* at 1374–75.
19. *Id.* at 1375–76.
20. 933 F.3d 1336 (Fed. Cir. 2019).
21. *Id.* at 1338.
22. *Id.*
23. *Id.* at 1340.

structure to remove the claim term from a means-plus-function term.[24] The court stated that the Board "erred by using the existence of corresponding structure in the specification to conclude that [the claim term] has a sufficiently definite structure to evade § 112, ¶ 6."[25] The Board also erred in giving improper weight to statements taken out of context in the prosecution history when defining structure.[26] Vacating and remanding, the court noted that the Board could reach a different conclusion on obviousness in light of this holding.[27]

The court also discussed the effect of nonce words on means-plus-function claims in *TEK Global, S.R.L. v. Sealant Systems International, Inc.*[28] Nonce words are generic terms such as "mechanism," "device," or "element" that "reflect nothing more than verbal constructs that may be used in a claim in a manner that is tantamount to using the word 'means' because they 'typically do not connote sufficiently definite structure' and therefore may invoke § 112, para. 6."[29] In *TEK*, the appellee Sealant Systems International ("SSI") argued that "'conduits connecting the container' and 'container connecting conduit' should be construed as means-plus-function limitations under 35 U.S.C. § 112, ¶ 6 because the term 'conduit' is a nonce word."[30] The Federal Circuit disagreed, and upheld the lower court's decision that "conduit" recites a definite, physical structure that is known to those skilled in the mechanical arts.[31] When read in light of the claim language, the dependent claims, and the specification, "conduit" in the patent in question in *TEK* refers to a physical structure used to connect other elements of the device.[32] The court also gave credence to the prosecution history because it clearly documented the applicant's intention to use "conduit" to avoid § 112, ¶ 6 issues.[33]

Finally, the court also addressed disavowal in two cases. At issue in *Continental Circuits LLC v. Intel Corp.*[34] was whether the district court

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24. *Id.* at 1344–45.
25. *Id.* at 1345.
26. *Id.*
27. *Id.* at 1338, 1345.
28. 920 F.3d 777 (Fed. Cir. 2019).
29. *Id.* at 785 (quoting Williamson v. Citrix Online, LLC, 792 F.3d 1339, 1350 (Fed. Cir. 2015)).
30. *Id.* (quoting *Williamson*, 792 F.3d at 1350).
31. *Id.* at 785–86.
32. *Id.* at 786.
33. *Id.*
34. 915 F.3d 788 (Fed. Cir. 2019).

erred in limiting the claims to require a repeated desmear process.[35] The Federal Circuit determined that statements in the specification did not rise to the level of a "clear and unmistakable disclaimer" or disavowal of claim scope but were merely a description of a preferred method.[36] Similarly, with respect to the prosecution history, the Federal Circuit held that an expert's declaration responding to indefiniteness and written description rejections was also not a clear disavowal.[37]

The Federal Circuit also noted that because it was not clear that the repeated etching process is "an essential part of the claimed invention," it was improper to read the process limitation into the product claims.[38] The Federal Circuit remanded for further proceedings.[39]

In *Iridescent Networks, Inc. v. AT&T Mobility, LLC*,[40] the court decided that it was proper for a district court to look to the prosecution history for guidance without having to first find a clear disavowal.[41] The claim term at issue was "high quality of service connection."[42] The court determined that this was a "coined term"; thus, it was acceptable to look to the prosecution history to construe the claim.[43]

The Federal Circuit addressed whether a preamble was limiting in *In re Fought*.[44] The patent application at issue related to the construction of the preamble term "travel trailer."[45] The examiner initially rejected the application as anticipated by prior art related to a "conventional truck trailer" and "a bulkhead for shipping compartments."[46] Despite the applicant's argument that a travel trailer is a recreational vehicle, the examiner maintained the rejection.[47] The Board affirmed the examiner's rejection, stating that the preamble term was "a mere statement of intended use that does not limit the claim."[48]

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35. *Id.* at 794–95.
36. *Id.* at 797 (internal quotations omitted).
37. *Id.* at 798–99.
38. *Id.* at 799.
39. *Id.* at 800.
40. 933 F.3d 1345 (Fed. Cir. 2019).
41. *Id.* at 1352–53.
42. *Id.* at 1348–49.
43. *Id.* at 1350–51.
44. 941 F.3d 1175 (Fed. Cir. 2019).
45. *Id.* at 1177.
46. *Id.*
47. *Id.*
48. *Id.*

Noting that the body of the claim recited the term "travel trailer" in a manner that relied on the preamble for its antecedent basis, the Federal Circuit ruled that the term was a substantive limitation.[49] The court directly addressed the issue stating that "[w]e have repeatedly held a preamble limiting when it serves as antecedent basis for a term appearing in the body of a claim" as it did in this case.[50]

II. VALIDITY

A. Patent-Eligible Subject Matter

The Federal Circuit continued to expand on its patentable subject matter jurisprudence under 35 U.S.C. § 101 in 2019. In *Athena Diagnostics, Inc. v. Mayo Collaborative Services, LLC*,[51] Athena Diagnostics ("Athena") sued Mayo Collaborative Services ("Mayo") alleging infringement of a patent covering methods for diagnosing neurological disorders by detecting antibodies to MuSK, a membrane protein.[52] Mayo moved to dismiss the complaint, arguing the asserted claims of the patent are invalid under § 101.[53] The district court granted Mayo's motion, concluding that the claims were invalid under § 101 for claiming ineligible subject matter.[54] The Federal Circuit affirmed and reiterated that claims reciting only conventional steps to detect a natural law are patent ineligible under § 101.[55]

The Federal Circuit followed the two-part test set forth in *Alice Corp. Pty. Ltd. v. CLS Bank International*[56] and *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*[57] to determine if the claimed matter was patent-eligible.[58] First, it held that the claims were directed to a law of nature, namely, the correlation between the presence of naturally occurring MuSK autoantibodies in bodily fluid and MuSK-related neurological diseases.[59] The court stated that the claimed advance was only in the discovery of a natural law and that the additional claim steps

49. *Id.* at 1178–79.
50. *Id.* at 1178.
51. 915 F.3d 743 (Fed. Cir. 2019).
52. *Id.* at 746–47.
53. *Id.* at 746.
54. *Id.* at 746–47.
55. *Id.*
56. 573 U.S. 208 (2014).
57. 566 U.S. 66 (2012).
58. *Athena Diagniostics, Inc.*, 915 F.3d at 749.
59. *Id.* at 750.

only apply conventional techniques to observe that natural law.[60] At the second step of the *Alice/Mayo* inquiry, the court held that the claims did not recite an inventive concept sufficient to transform the law of nature into a patent-eligible application of the natural law.[61] The court stated that the claim steps not drawn to the law of nature only required standard techniques applied in a conventional way, e.g., a conventional radioimmunoassay.[62] The court accordingly held that the challenged claims were ineligible for patent protection.[63]

Then, in *Natural Alternatives International, Inc. v. Creative Compounds, LLC*,[64] Natural Alternatives International ("Natural Alternatives") asserted patents directed to using a natural substance to "increas[e] the anaerobic working capacity of muscle and other tissues."[65] Some contained method claims and others contained product and manufacturing claims.[66] At the district court, Creative Compounds LLC ("Creative Compounds") moved for judgment on the pleadings, alleging that the asserted claims were directed to a natural law or product of nature, lacked any inventive concept, and, therefore, were ineligible for patenting under § 101.[67] The district court granted the motion.[68]

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60. *Id.* at 751.

61. *Id.* at 753–54.

62. *Id.* Athena argued the district court needed to consider an expert declaration and conduct fact-finding before it could resolve whether the claims covered more than conventional techniques. *Id.* at 755. The Court rejected this argument, finding that the district court did not abuse its discretion by declining to convert a 12(b)(6) motion into a summary judgment motion. *Id.* The Court explained that the "declaration does not 'merge into the pleadings' as the complaint does not reference it or otherwise depend on it." *Id.* Moreover, the Court explained the district court did not have to consider the declaration because it was "not consistent with the complaint read in light of the [challenged] patent." *Id.*

63. *Id.* at 757. Judge Newman dissented. *See generally id.* at 757 (Newman, J., dissenting). In her opinion, the claims covered a multi-step method of diagnosis for "a previously undiagnosable neurological condition," not a law of nature. *Id.* at 757, 759. According to Judge Newman, "[t]he reaction between the antibody and the MuSK protein was not previously known, nor was it known to form a labeled MuSK or its epitope, nor to form the antibody/MuSK complex, immunoprecipitate the complex, and monitor for radioactivity, thereby diagnosing these previously undiagnosable neurotransmission disorders." *Id.* at 758. In her opinion, this "man-made chemical biomedical procedure" should have been patent eligible, consistent with the otherwise broad prescription of § 101. *Id.* at 762–64.

64. 918 F.3d 1338 (Fed. Cir. 2019).

65. *Id.* at 1341–42.

66. *Id.* at 1341, 1343, 1347, 1349.

67. *Id.* at 1341–42, 1344, 1350.

68. *Id.* at 1341–42.

On appeal, the Federal Circuit reversed and remanded.[69] For the method claims, the court held, under Natural Alternatives' proposed constructions, the claims were directed to more than a natural law.[70] In the court's view, the claims embodied the benefit of natural substances *and* the administration of those substances according to a specific dosage and manner.[71] The court found persuasive that the claims "specify particular results to be obtained by practicing the method," "specify a compound to be administered to achieve the claimed result," and also "contain a dosage limitation."[72] As such, the claims were deemed patent-eligible "method of treatment" claims.[73]

For the product claims, the court held they were also eligible for patent protection.[74] The court explained that although beta-alanine was a natural product, the claims were not directed to beta-alanine.[75] In the court's view, the claims were "directed to specific treatment formulations that incorporate[ed] natural products, but they ha[d] different characteristics and [could] be used in a manner that beta-alanine as it appear[ed] in nature [could not]."[76] As such, the claims were deemed patent eligible.[77]

And, for the manufacturing claims, the court held they were "even further removed from the natural law and product of nature at issue" in the other claims.[78] In the court's view, the claims covered the manufacture of a human dietary supplement with certain characteristics; the supplement was not a product of nature, nor was its use to achieve a specific result directed to a law of nature.[79] As such, these claims were also deemed patent eligible.[80]

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69. *Id.* at 1350.
70. *Id.* at 1345.
71. *Id.* at 1345–47.
72. *Id.* at 1345–46.
73. *Id.* In dictum, the Court explained that factual impediments exist with regard to step two of the *Alice/Mayo* framework that would have also precluded judgment on the pleadings. *Id.* at 1349.
74. *Id.* at 1348–49.
75. *Id.* at 1348.
76. *Id.*
77. *Id.* at 1348–49.
78. *Id.* at 1350.
79. *Id.*
80. *Id.* Judge Reyna concurred in part and dissented in part based on his disagreement with the panel majority's reliance on what he considered erroneous claim constructions. *See generally id.* at 1351 (Reyna, J., concurring in part and dissenting in part).

In *SRI International, Inc. v. Cisco Systems, Inc.*,[81] SRI International, Inc. ("SRI") sued Cisco Systems, Inc. ("Cisco") alleging infringement of two of its network surveillance patents.[82] Cisco moved for summary judgment on several issues, including that the claims were patent ineligible under § 101.[83] The district court denied Cisco's motion for summary judgment of ineligibility, and Cisco appealed from that denial.[84]

The Federal Circuit affirmed that the claims were subject matter eligible under step one of the *Alice/Mayo* framework because they were not directed to an abstract idea, but rather to an improvement in existing computer network technology.[85] In the court's view, the claims were directed to using a specific technique to solve a technological problem that arises in computer networks, that is, identifying hackers or potential intruders into a network by using a plurality of network monitors to analyze data on that network and integrate reports using one or more hierarchical monitors.[86] This understanding was also confirmed by the patent's specification, which, the court noted, explained the claims were directed to solving "weakness in conventional networks."[87]

Cisco had argued these claims were analogous to claims found ineligible in *Electric Power Group, LLC v. Alstom S.A.*,[88] as being directed to generic steps required to collect and analyze data.[89] The court rejected this contention, distinguishing *Electric Power* because the claims there "were drawn to using computers as tools to solve a power grid problem," whereas the claims here were drawn to "improving the functionality of computers and computer networks themselves."[90]

In *Solutran, Inc. v. Elavon, Inc.*,[91] the Federal Circuit reversed the district court's determination that the challenged claims were valid under § 101.[92] The asserted patent described its invention as a system

81. 930 F.3d 1295 (Fed. Cir. 2019).
82. *Id.* at 1301.
83. *Id.*
84. *Id.* at 1301–02.
85. *Id.* at 1303.
86. *Id.* at 1303–04.
87. *Id.*
88. 830 F.3d 1350 (Fed. Cir. 2016).
89. *SRI Int'l, Inc.*, 930 F.3d at 1304 (citing *Elec. Power Grp.*, 830 F.3d 1350 (Fed. Cir. 2016)).
90. *Id.*
91. 931 F.3d 1161 (Fed. Cir. 2019).
92. *Id.* at 1163. The district court based its determination in part on the USPTO PTAB's denial of a CBM petition, wherein the PTAB concluded that the challenged claim was not directed to any abstract idea, but rather to a physical process, e.g., processing paper checks. *See id.* at 1165. The district court further concluded, in the

and a method for processing paper checks wherein "(1) 'data from checks is captured at the point of purchase,' (2) 'this data is used to promptly process a deposit to the merchant's account,' (3) the paper checks are moved elsewhere 'for scanning and image capture,' and (4) 'the image of the check is matched up to the data file.'"[93]

Applying the two-step *Alice/Mayo* framework, the Federal Circuit first held the claims were directed to an abstract idea, i.e., "crediting a merchant's account as early as possible while electronically processing a check."[94] According to the court, the "basic steps of electronic check processing" were well known and fall under the rubric of the court's prior decisions that find certain "transaction claims" performed in a particular order or sequence are directed to an abstract idea.[95] The court explained this was not a situation where the claims were directed to a specific improvement in the way computers operate, noting counsel at oral argument agreed that the patent's invention "did not improve the technical capture of information from a check to create a digital file or the technical step of electronically crediting a bank account."[96]

Holding that the claims directed to an abstract idea, the court turned to step two of the *Alice/Mayo* inquiry. There, the court concluded the claims did not contain an inventive concept to make them patent eligible.[97] In the court's view, the claims instructed a user to practice the abstract idea of electronic check processing in a routine and conventional way.[98]

In *Chamberlain Group, Inc. v. Techtronic Industries Co.*,[99] the Federal Circuit reversed the district court's decision finding the challenged claims patent eligible under § 101.[100] The claims recited a method for wirelessly communicating information about the status of a movable barrier, like a garage door.[101] Applying the two-step framework of *Alice/Mayo*, the Federal Circuit first held the claims covered

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alternative, that even if directed to an abstract idea, the claims nevertheless recite an inventive concept under step two of *Alice*. *See id.*

93. *Id.* at 1164.
94. *Id.* at 1166.
95. *Id.* at 1166–67 (highlighting Ultramercial, Inc. v. Hulu, LLC, 772 F.3d 709 (Fed. Cir. 2014), among others).
96. *Id.* at 1167.
97. *Id.* at 1168–69.
98. *Id.* at 1169.
99. 935 F.3d 1341 (Fed. Cir. 2019).
100. *Id.* at 1344–45.
101. *Id.* at 1345.

"communicating information wirelessly," which, "without more, is [only] an abstract idea."[102] The court analogized these claims to those found directed to a patent-ineligible abstract idea, e.g., those that cover wirelessly communicating regional broadcast content or delivering user-content to a device.[103] And the court distinguished the claims from claims that recite a specific manner of performing the abstract idea.[104] Because the claims covered an abstract idea, the Federal Circuit addressed the second step. At step two, the court held the claims did not recite an inventive concept to render them patent eligible.[105] The court reasoned that the claims only covered conventional components, for example, a controller, interface, and wireless data transmitter, recited in a generic way, to achieve the abstract idea of wirelessly communicating information.[106] Without more, the claims were held ineligible for patent protection.[107]

In *Endo Pharmaceuticals Inc. v. Teva Pharmaceuticals USA, Inc.*,[108] the Federal Circuit reversed a district court's holding that a patent claiming a method of using oxymorphone to treat pain in patients with renal impairment was patent ineligible under § 101.[109] According to the district court, the claims were directed to an abstract idea—that is, "the bioavailability of oxymorphone is increased in people with severe renal impairment."[110] The district court then concluded that the "providing," "measuring," and "administering" steps recited in the claims were insufficient to provide an inventive concept and save the claims.[111]

On appeal, the Federal Circuit reversed.[112] Applying step one of the *Alice/Mayo* inquiry, the court concluded that the claims were not directed to an abstract idea.[113] Contrary to the district court's characterization of the claims, the Federal Circuit reasoned they did

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102. *Id.* at 1347.
103. *Id.* (comparing to Affinity Labs of Tex., LLC v. DIRECTV, LLC, 838 F.3d 1253 (Fed. Cir. 2016), and Affinity Labs of Tex., LLC v. Amazon.com Inc., 838 F.3d 1266 (Fed. Cir. 2016)).
104. *Id.* at 1347–48.
105. *Id.* at 1348–49.
106. *Id.* at 1348.
107. *Id.* at 1349.
108. 919 F.3d 1347 (Fed. Cir. 2019).
109. *Id.*
110. *Id.* at 1351.
111. *Id.*
112. *Id.* at 1357.
113. *Id.* at 1353.

not only disclose the natural relationship between oxymorphone and patients with renal impairment, but rather they specifically captured a new application of that relationship for treatment, including with specific steps to adjust dosages.[114] In the court's view, the claims were directed to the "patent-eligible method of using oxymorphone or a pharmaceutically acceptable salt thereof to treat pain in a renally impaired patient."[115] The court reasoned that these claims were indistinguishable from the "method of treatment" claims held patent eligible in *Vanda Pharmaceuticals*, which covered a "specific method of treatment for specific patients using a specific compound at specific doses to achieve a specific outcome."[116] As the claims were not directed to an abstract idea (and thus patent eligible), the court did not address step two of the *Alice/Mayo* inquiry.

In *American Axle & Manufacturing, Inc. v. Neapco Holdings LLC*,[117] the Federal Circuit affirmed the district court's decision that claims directed to a method for manufacturing driveline propeller shafts were patent ineligible under 35 U.S.C. § 101.[118] Specifically, the patent claimed a method of manufacturing with liners that were designed to "attenuate vibrations transmitted through a shaft assembly."[119] There were three types of vibrations—bending mode, torsion mode, and shell mode—that operated at different frequencies.[120] The prior art already disclosed that altering the mass and stiffness of liners would attenuate these vibrations, but the prior art methods were not suitable for attenuating two vibration modes at the same time.[121] American Axle purported to invent a method for tuning liners that would attenuate two modes of vibration simultaneously; however, the claims and specification did not describe how to achieve such tuning.[122] Instead, the patent described the structure of a "tuned" liner and described the tuned liner in terms of the type or degree of attenuation achieved with different vibration modes.[123]

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114. *Id.* at 1353–54.
115. *Id.* at 1353.
116. *Id.* at 1355 (quoting Vanda Pharm. Inc. v. West-Ward Pharm. Int'l Ltd., 887 F.3d 1117, 1136 (Fed. Cir. 2018)).
117. 939 F.3d 1355 (Fed. Cir. 2019).
118. *Id.* at 1357–58.
119. *Id.* at 1358 (internal quotations omitted).
120. *Id.*
121. *Id.* at 1359.
122. *Id.* at 1359–60.
123. *Id.* at 1360.

The district court and Federal Circuit agreed that the claims were directed to laws of nature, Hooke's law[124] and friction damping[125] and that they only encouraged one skilled in the art to take routine, conventional steps to apply Hooke's law to achieve the desired results of attenuating vibration modes, therefore lacking an inventive step.[126] Judge Dyk, writing for the majority, explained that even though "the system involved in the '911 patent is more complex than just a bare application of Hooke's law," it was not patent eligible because "[w]hat is missing is any physical structure or steps for achieving the claimed result . . . [and] [t]he focus of the claimed advance here is simply the concept of achieving that result, by whatever structures or steps happen to work."[127]

Judge Moore dissented, opining that "[t]he majority's decision expands § 101 well beyond its statutory gate-keeping function."[128] Her view was that the majority did not properly apply Step 2 of the *Alice/Mayo* test and rejected the patent's many potential "inventive concepts" in its analysis.[129] She opined that issues concerning the patent's description of the claimed process were issues of enablement, not patent eligibility.[130] Judge Moore found the majority's result-oriented "validity goulash" concerning and stressed that § 101 should not be so "sweeping and manipulatable" as to invalidate claims under similar statutory standards and "convert traditional questions of fact (like undue experimentation) into legal ones."[131]

Finally, in *ChargePoint, Inc. v. SemaConnect, Inc.*,[132] the Federal Circuit affirmed the district court's dismissal of ChargePoint's complaint because the claims were ineligible for patenting under § 101.[133] The claimed technology generally related to charging stations for electronic vehicles, and ChargePoint's patents were specifically

124. Hooke's law is a natural law that "describes the relationship between an object's mass, its stiffness, and the frequency at which the object vibrates." *Id.* at 1360.

125. Friction damping occurs due to "the resistive friction and interaction of two surfaces that press against each other as a source of energy dissipation." It is a well-known phenomenon in the art. *Id.*

126. *Id.* at 1361–67.

127. *Id.* at 1366–67.

128. *Id.* at 1368 (Moore, J., dissenting).

129. *Id.* at 1370–74.

130. *Id.* at 1374.

131. *Id.* at 1375.

132. 920 F.3d 759 (Fed. Cir. 2019).

133. *Id.* at 763.

directed to connecting those charging stations to a "networked" infrastructure.[134] According to ChargePoint, this "network connectivity allows the stations to be managed from a central location, allows drivers to locate charging stations in advance, and allows all users to interact intelligently with the electricity grid."[135]

Applying the first step of the *Alice/Mayo* framework, the Federal Circuit held the claims, irrespective of whether they were apparatus or method claims, were directed to the abstract idea of "communication over a network for interacting with a device, [just] applied to the context of electric vehicle charging stations."[136] It explained the specification could generally aid this analysis, either to the extent claim construction might be needed or to analyze what the patent describes as the invention.[137] Here, the court reasoned that the specification served to confirm that the claims covered no more than the abstract idea of "communication over a network for device interaction."[138]

At step two of the *Alice/Mayo* inquiry, the court determined that the claims did not recite an inventive concept to transform the abstract idea into eligible subject matter.[139] The court noted ChargePoint's argument that it had solved known problems in an unconventional way through its ability to turn on electric supply based on communications from a remote server; "network-controlled" charging system; and charger station receiving communications from a remote server.[140] But, in the court's view, ChargePoint's "alleged 'inventive concept' . . . is [simply] that the charging stations are network-controlled," and such network control "is the abstract idea itself."[141] It could not supply an inventive concept sufficient to save the claims. As a result, the court concluded the claims recited an abstract-idea-based solution

134. *Id.* at 763–64.
135. *Id.* at 763.
136. *Id.* at 768; *see also id.* at 766–73 ("[W]hile the eight claims on appeal vary in some respects, they are all directed to the abstract idea of communication over a network for device interaction. Communication over a network for that purpose has been and continues to be a 'building block of the modern economy.'" (citation omitted)).
137. *Id.* at 767.
138. *Id.* at 769. The court also expressed concern with the sheer breadth of the claims and their potential to preempt the use of any networked charging station. *See, e.g.*, *id.* at 768–69.
139. *Id.* at 775.
140. *Id.* at 774.
141. *Id.*

implemented with generic technical components in a conventional way and were, thus, patent ineligible.[142]

B. Anticipation

Several of the court's cases involved an anticipation analysis. In *ATEN International Co. v. Uniclass Technology Co.*,[143] the Federal Circuit reversed the district court's denial of judgment as a matter of law on anticipation.[144] In the court's view, substantial evidence did not support the jury verdict finding anticipation, and the district court erred in sustaining that verdict.[145]

At trial, the defendant presented two different theories of anticipation relying on (1) an earlier patentee product and/or its user manual and (2) a Great Britain patent.[146] The jury returned a verdict finding the claims anticipated, but it did not specify which prior art it relied upon.[147] The district court declined to overturn the verdict, and the Federal Circuit reversed.[148]

With regard to the earlier patentee product and/or user manual, the court held that the defendant failed to prove by clear and convincing evidence that this prior art predated the patent.[149] The undisputed critical date for the patent was July 24, 2006.[150] Thus, the defendant had to prove the earlier patentee product and/or user manual was available prior to July 24, 2006. The court noted, however, that the only evidence submitted by the defendant was expert testimony showing that the product and/or user manual were available generally in 2006, without specifying the date or month.[151] According to the court, this general proclamation of 2006, without more, was not substantial evidence sufficient to support the jury's verdict of anticipation, to the extent it relied upon this prior art theory.[152]

With regard to the Great Britain patent, the court held that the defendant's expert failed to opine on whether the reference disclosed

142. *Id.* at 774–75.
143. 932 F.3d 1364 (Fed. Cir. 2019).
144. *Id.* at 1364.
145. *Id.* at 1368.
146. *Id.* at 1367.
147. *Id.*
148. *Id.* at 1366.
149. *Id.* at 1368–69.
150. *Id.* at 1368.
151. *Id.*
152. *Id.*

one element in each of the asserted claims.[153] And, as it could not identify any place in the three pages of the Great Britain patent provided in the joint appendix that met this element, the court held no record evidence established that the reference disclosed each and every limitation.[154] Substantial evidence accordingly failed to support the jury's verdict of anticipation, to the extent it relied upon this alternative prior art theory.[155]

In *SRI International, Inc. v. Cisco Systems, Inc.*,[156] SRI International, Inc. ("SRI") sued Cisco Systems, Inc. ("Cisco") alleging infringement of two of its network surveillance patents.[157] Cisco moved for summary judgment on several issues, including that the claims were anticipated by the EMERALD 1997 reference.[158] The district court denied Cisco's motion for summary judgment of anticipation, and it sua sponte granted summary judgment of no anticipation.[159] Cisco appealed from the district court's decisions at summary judgment, presenting the question whether the district court erred in concluding on summary judgment that the EMERALD 1997 reference did not disclose detection of any of the network traffic data categories recited in the claims.[160] The Federal Circuit affirmed.[161] The court found persuasive that the USPTO considered the EMERALD 1997 during prosecution and several reexamination proceedings, repeatedly rejecting it as an anticipating reference.[162] And the court found persuasive that Cisco's expert provided inconsistent testimony regarding the purported disclosure and was "based on [] multiple layers of supposition."[163] The court held in view of this record that there was no genuine issue of material fact, and summary judgment of no anticipation was proper.[164]

In *Chamberlain Group, Inc. v. Techtronic Industries Co.*, the jury found that the asserted claims were not anticipated.[165] Techtronic Industries

153. *Id.* at 1368–69.
154. *Id.* at 1369.
155. *Id.*
156. 930 F.3d 1295 (Fed. Cir. 2019).
157. *Id.* at 1301.
158. *Id.*
159. *Id.* at 1302.
160. *Id.*
161. *Id.* at 1300.
162. *Id.* at 1301–02 n.2.
163. *Id.* at 1307 (alteration in original).
164. *Id.* at 1312.
165. 935 F.3d 1341, 1348–49 (Fed. Cir. 2019).

Co. ("TTI") moved for judgment as a matter of law that the Weik reference anticipates.[166] The district court denied TTI's motion, concluding substantial evidence supported the jury's no-anticipation verdict.[167] The district court stated TTI's anticipation theory required a combination of different embodiments in the same reference, and that such a theory was improper as a matter of law.[168] TTI appealed from the decision, and the Federal Circuit affirmed.[169] According to the court, although the district court erred in suggesting a blanket rule that two embodiments in a reference can never be considered in combination to find anticipation, the error was harmless under the circumstances because TTI (1) did not allege that the jury ever received such a recitation of the law and (2) did not appeal from the jury instructions.[170] It then concluded, "[b]ecause Weik's disclosure as to the possible combinability of the embodiments in the way TTI urges is less than clear," TTI failed to meet its burden of showing that the jury's no-anticipation verdict was not supported by substantial evidence.[171]

In *Guangdong Alison Hi-Tech Co. v. International Trade Commission*,[172] the Federal Circuit affirmed an International Trade Commission (ITC) decision finding the asserted claims were not anticipated.[173] Aspen Aerogels, Inc. filed a complaint with the Commission alleging that Guangdong Alison Hi-Tech Co. ("Alison") violated section 337 of the Tariff Act by importing allegedly infringing aerogel insulation materials.[174] Before the ITC, Alison argued that the claims were anticipated.[175] The Commission rejected Alison's challenge, finding

166. *Id.* at 1345.
167. *Id.* at 1344–45.
168. *Id.* at 1350.
169. *Id.*
170. *Id.* As the Court stated,

> a reference can anticipate a claim even if it do[es] not expressly spell out all the limitations arranged or combined as in the claim, if a person of skill in the art, reading the reference, would at once envisage the claimed arrangement or combination. Thus, even when a reference discloses elements in different locations in the disclosure, the relevant question is whether the reference is sufficiently clear in disclosing the combinability of those elements such that a skilled artisan would at once envisage the claimed combination.

Id. (internal quotations omitted).
171. *Id.*
172. 936 F.3d 1353 (Fed. Cir. 2019).
173. *Id.* at 1365.
174. *Id.* at 1356.
175. *Id.*

persuasive record evidence showing that the asserted reference was (1) identified and distinguished in the patent specification, (2) considered and distinguished by the examiner during prosecution because it lacked a "lofty . . . batting," and (iii) rejected in an *inter partes* review for also failing to disclose "lofty . . . batting."[176]

On appeal, the Federal Circuit affirmed.[177] Alison argued that the reference inherently disclosed the "lofty . . . batting" claim element with its disclosure of "glass wool" because the glass wool demonstrated both the "bulk and resilience" properties and "low density and thermal characteristics" disclosed in the asserted patent's specification.[178] The court rejected this argument.[179] It noted substantial evidence showed "glass wool" is not inherently lofty; these "bulk and resilience" properties were with respect to a composite, not any individual fibers, and expert testimony explained that "one cannot necessarily attribute the bulk and resilience of the composite to the fibers contained therein"; and both parties' experts agreed low density alone does not inherently create "lofty" batting.[180] The court further emphasized that the asserted patent not only identified, but clearly distinguished the reference, and the examiner and Patent Trial and Appeal Board both found this reference insufficient to disclose the "lofty . . . batting" element.[181]

C. Obviousness

Not surprisingly, many of the Federal Circuit's cases involved an obviousness analysis. While it is not possible to summarize every § 103 decision, the following is a sample of the more interesting cases.

In *Forest Laboratories, LLC v. Sigmapharm Laboratories, LLC*, several defendants filed Abbreviated New Drug Applications (ANDAs) seeking to market generic versions of Saphris, a drug product sold by Forest.[182] Forest sued for patent infringement.[183] Following a bench trial, the district court concluded the asserted claims were not obvious.[184] While it was undisputed that oral formulations of asenapine and sublingual

176. *Id.* at 1357–58.
177. *Id.* at 1365.
178. *Id.* at 1364.
179. *Id.*
180. *Id.*
181. *Id.* at 1365 ("Arguments and references already considered by the Patent Office may carry less weight with the fact finder." (citation omitted)).
182. 918 F.3d 928, 932 (Fed. Cir. 2019).
183. *Id.*
184. *Id.*

formulations of other drugs were known in the art, the district court found that there was not a motivation to develop a sublingual or a buccal formulation of asenapine.[185] The district court also found the resolution of cardiotoxic effects by sublingual administration was an unexpected result, and sublingual administration met the long-felt need for a safe, effective, and tolerable atypical antipsychotic to treat schizophrenia and mania.[186] In the district court's opinion, these indicia weighed in favor of concluding the claims were nonobvious.[187]

On appeal, the Federal Circuit vacated and remanded.[188] The court generally agreed with the district court's consideration, and dismissal, of several theories that defendants-appellants proposed for a motivation to combine, including dismissal of the notion that a desire to have multiple treatment options generally available would provide motivation to pursue a specific combination of the prior art elements.[189] And, it found no error in the district court reasoning that the inventors had discovered an unknown problem in the art, suggesting their solution to that problem might not have been obvious "because ordinary artisans would not have thought to try at all because they would not have recognized the problem."[190] The court nevertheless remanded because the district court failed to make any express finding whether a compliance concern for patients with trouble swallowing would provide sufficient motivation to combine the prior art elements.[191]

In *Nalpropion Pharmaceuticals, Inc. v. Actavis Laboratories FL, Inc.*,[192] the Federal Circuit affirmed the district court's decision that the sole claim asserted in one patent did not lack written description support and

185. *Id.* at 933–34.
186. *Id.* at 934.
187. *Id.* at 933–34.
188. *Id.* at 938.
189. *Id.* at 935.
190. *Id.* (citation and internal quotation marks omitted).
191. *Id.* at 936. The Court also held the district did not clearly err in finding the evidence of long-felt need weighed in favor of nonobviousness but held the district court did err in its analysis of unexpected results. *Id.* at 937 ("[A] person of ordinary skill could not have been surprised that the sublingual route of administration did not result in cardiotoxic effects because the person of ordinary skill would not have been aware that other routes of administration do result in cardiotoxic effects.").
192. 934 F.3d 1344 (Fed. Cir. 2019).

reversed the decision that the asserted claims of the other two patents would not have been obvious.[193]

Nalpropion Pharmaceuticals, Inc. ("Nalpropion") markets Contrave®, a drug used for weight management in overweight or obese adults.[194] Nalpropion listed three patents in the Orange Book covering Contrave®, and it asserted those three patents against Actavis Laboratories FL, Inc. ("Actavis") after Actavis filed an ANDA seeking to enter the market with a generic version.[195] Actavis contended that the claims of two of the three patents would have been obvious.[196] It argued that it would have been obvious for the skilled artisan to combine bupropion and naltrexone for treating overweight obesity because both drugs were known to cause weight loss.[197] The district court disagreed, and found Actavis's argument to simply be "a classic case of hindsight bias."[198]

On appeal, the Federal Circuit reversed on the issue of obviousness.[199] It held that the asserted prior art taught bupropion causes weight loss.[200] For example, one reference taught that a "sustained release bupropion was 'an effective adjunct to diet for weight loss in both non-depressed and depressed patients.'"[201] And, it held that the record also shows that naltrexone can cause weight loss.[202] For example, it found that one reference taught "naltrexone or similar drugs may have a role in the clinical treatment of obesity."[203] Given that both drugs had shown known weight loss effect, the court reasoned that a skilled artisan would have been motivated to combine them.[204]

Nalpropion argued the skilled artisan would nevertheless be dissuaded from combining these drugs because (1) bupropion had a largely insignificant effect on weight loss and thus failed to obtain FDA approval as a weight loss drug, (2) bupropion carried a seizure risk, and (3) bupropion's mechanism of action was unknown.[205] The court

193. *Id.* at 1356.
194. *Id.* at 1346.
195. *Id.* at 1346, 1348.
196. *Id.* at 1348.
197. *Id.*
198. *Id.*
199. *Id.* at 1351–56.
200. *Id.* at 1353.
201. *Id.*
202. *Id.*
203. *Id.* (internal quotation marks omitted).
204. *Id.* at 1354–55.
205. *Id.* at 1354.

rejected these contentions.[206] It reiterated that motivation to combine can come from a variety of places, and "[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."[207] It then stated that the "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," and that was enough for the court to find a motivation to combine.[208] After noting a motivation to combine the art, the court held that the prior art sufficiently disclosed the claim limitations, and that Nalpropion failed to submit persuasive secondary indicia.[209] The challenged claims were accordingly held invalid as obvious.[210]

In another ANDA case,[211] the asserted patent licensed by Endo Pharmaceuticals Inc. ("Endo") covered a process for producing morphinan alkaloid compounds, like oxymorphone, which are beneficial for pain relief.[212] The patent discussed processes for preparing pure morphinan-6-one products having a low concentration of impurities—known as α,β-unsaturated ketone intermediate compounds ("ABUKs")—by treating a mixture including morphinan-6-one and an ABUK with a sulfur containing compound.[213] The FDA mandated opioid manufacturers reduce ABUK impurities in oxycodone and oxymorphone to below 0.001%.[214] The asserted patent disclosed this solution and claimed "a hydrochloride salt of oxymorphone comprising less than 0.001% of 14-hydroxymorphinone."[215]

The district court held that the asserted claims would not have been obvious in view of a combination of three references.[216] On appeal, the Federal Circuit affirmed, reasoning that a skilled artisan would not have a reasonable expectation of success in combining the prior art because each had its own respective failures.[217] First, the court noted

206. *Id.*
207. *Id.* at 1354 (quoting Allergan, Inc. v. Sandoz Inc., 726 F.3d 1286, 1292 (Fed. Cir. 2013)).
208. *Id.* at 1354–55.
209. *Id.* at 1355–56.
210. *Id.* at 1356.
211. Endo Pharm. Inc. v. Actavis LLC, 922 F.3d 1365 (Fed. Cir. 2019).
212. *Id.* at 1367.
213. *Id.* at 1368.
214. *Id.* at 1373 n.9.
215. *Id.* at 1368.
216. *Id.* at 1369.
217. *Id.* at 1372–78.

that the skilled artisan would not reasonably expect to successfully employ one reference's "catalytic hydrogenation process for oxymorphone" with another's "process to remove diol during hydrogenation," as the reference did not provide key reaction conditions and its process produced an undesirable product that would "frustrate purification."[218] Second, the court noted that another reference disclosed a process that likewise produced a product that would "hinder purification," which is a necessary feature of the claimed invention.[219] And third, the court noted that the last of the three references failed to disclose a purifying process that led to the purity levels recited in the claims.[220] In the court's view, these references failed to equip the skilled artisan with the reasonable expectation that it could successfully combine their disclosures to achieve the claimed invention.[221] The court last considered the FDA's mandate, which identified market incentives for achieving the claimed purity level but concluded it could not provide a skilled artisan with a reasonable expectation of success to overcome the three references because it simply "recite[d] a goal without teaching how the goal is attained."[222]

In *Novartis Pharmaceuticals Corp. v. West-Ward Pharmaceuticals International Ltd.*,[223] the Federal Circuit affirmed the district court's determination that the challenged claims were nonobvious.[224] The challenged patent claims using "everolimus" to treat advanced renal cell carcinoma ("RCC") by inhibiting the growth of any RCC tumors.[225] Everolimus is the active ingredient in Novartis Pharmaceuticals Corp.'s ("Novartis") Affinitor product.[226] West-Ward Pharmaceuticals

218. *Id.* at 1374.
219. *Id.* at 1375.
220. *Id.* at 1376.
221. *Id.* at 1374–76.
222. *Id.* at 1376; *e.g.*, *id.* at 1376–78. In Judge Stoll's dissenting opinion, the FDA mandate disclosed the limitations of claim 1 and was the only reference to disclose the limitation prior to the invention at issue. *Id.* at 1378 (Stoll, J., dissenting). Judge Stoll accordingly believed the district court and panel majority erred in finding it lacked "anything substantive relevant to obviousness." *Id.* at 1378–79. Judge Stoll also opined that the district court committed legal error by "elevating the reasonable expectation of success standard to require that prior art provide a definitive solution to the problem and proof of actual success," and by "conflating the requirements of reasonable expectation of success and motivation to combine." *Id.* at 1379–80.
223. 923 F.3d 1051 (Fed. Cir. 2019).
224. *Id.* at 1053.
225. *Id.* at 1053–54.
226. *Id.* at 1053.

International Ltd. ("West-Ward") filed an ANDA seeking to make a generic version of Affinitor.[227]

Before the district court, West-Ward argued the asserted claims were obvious because the ordinary artisan would have been motivated based on a combination of prior art references to use everolimus to treat advanced RCC.[228] In particular, it relied on references that showed that (1) compounds called mTOR inhibitor produced effects, such as inhibition of hypoxia-inducible factor 1, that were hypothesized to inhibit tumor growth; (2) everolimus was a type of mTOR inhibitor; and (3) temsirolimus, another mTOR inhibitor, had shown responses in RCC patients in Phase I clinical trials.[229] West-Ward then argued that, based on the Phase I clinical trials and the knowledge of the skilled artisan about the molecular biology of advance RCC, antitumor activity of mTOR inhibitor, and safe dosing ranges for everolimus, that skilled artisan would have had a reasonable expectation of success in doing so.[230] The district court rejected these contentions and found West-Ward failed to prove by clear and convincing evidence a skilled artisan would have been motivated to combine references and select everolimus for treatment with a reasonable expectation of success.[231]

On appeal, the Federal Circuit noted the district court erred in its analysis of a motivation to combine but nevertheless affirmed because it agreed West-Ward failed to meet its burden to establish a reasonable expectation of success.[232]

With regard to the motivation to combine, the court faulted the district court for applying too high of a standard—instead of requiring West-Ward to prove that a skilled artisan would have been motivated to select everolimus, it was enough to show the prior art teachings led a skilled artisan to pursue everolimus as one of several methods to treat solid tumors, including advanced RCC.[233] With regard to expectation

227. *Id.*
228. *Id.* at 1057.
229. *Id.* at 1053–54.
230. *Id.* at 1057.
231. *Id.* at 1057–58.
232. *Id.* at 1059.
233. *Id.* at 1059–60 ("The proper inquiry is whether a person of ordinary skill would have been motivated to modify the prior art disclosing use of temsirolimus to treat advanced RCC with the prior art disclosing everolimus. This question was answered affirmatively when the district court found that a person of ordinary skill 'would have been motivated to pursue everolimus as one of several potential treatment options for

of success, the Federal Circuit agreed with the district court's factual findings.[234] It noted that West-Ward's reliance on the success of Phase I clinical results for temsirolimus was misplaced because those trial results came from studies designed to test safety, not efficacy, and Phase II clinical trials have a high rate of failure for anti-cancer drugs generally.[235] It also noted that evidence showed that the molecular biology of advanced RCC was not fully understood at the time, and that pharmacological differences in mTOR inhibitors (including everolimus and temsirolimus) would not have led the skilled artisan to reasonably expect they would have similar antitumor efficacy.[236]

Finally, in *Grunenthal GmbH v. Alkem Laboratories Ltd.*,[237] the Federal Circuit affirmed the district court's determination the asserted claims were nonobvious.[238] Grunenthal GmbH ("Grunenthal") was the assignee of two patents listed in the Orange Book with Grunenthal's NUCYNTA® ER tablet.[239] The first patent was related to the Form A polymorph, and its claims recited X-ray powder diffraction patterns.[240] The second was for a method of using tapentadol and tapentadol hydrochloride for the treatment of polyneuropathic pain.[241] Grunenthal sued several defendants seeking to market a generic version of its tapentadol product.[242] Before the district court, these defendants asserted, among other things, the patents were invalid as obvious.[243] The district court disagreed and confirmed the validity of the patents.[244]

On appeal, the Federal Circuit affirmed, holding that defendants failed to prove by clear and convincing evidence that the skilled artisan would have had a reasonable expectation of success producing the claimed Form A polymorph from an existing Form B, using methods described in the prior art.[245] The court noted the polymorphism of

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advanced solid tumors, including advanced RCC.'" (quoting Novartis Pharm. Corp. v. West-Ward Pharm. Int'l Ltd., 287 F. Supp. 3d 505, 516 (D. Del. 2017)).

234. *Id.* at 1060–62.
235. *Id.* at 1061.
236. *Id.* at 1061–62.
237. 919 F.3d 1333 (Fed. Cir. 2019).
238. *Id.* at 1336.
239. *Id.*
240. *Id.*
241. *Id.*
242. *Id.* at 1337–38.
243. *Id.* at 1338.
244. *Id.*
245. *Id.* at 1341–45.

tapentadol chloride was unknown, and that polymorphism does not occur in all compounds.[246] The court indicated the prior art relied upon at best presented a flow chart with a number of variables that could be adjusted to assess if polymorphism would occur, but failed to indicate when any solvents or mixtures should be used, and failed to provide guidelines regarding which variables (such as temperature, pH, agitation) would be more likely to result in a polymorph for a particular compound.[247] In the court's view, this prior art reference suggested the skilled artisan could manipulate a number of variables and ultimately fail to find a polymorph; it did not offer a reasonable expectation of successfully generating a Form A polymorph.[248] The court noted that defendants also argued the district court applied the wrong standard, requiring "absolute predictability" rather than a reasonable expectation of success.[249] The court rejected this and explained that, in this case, a skilled artisan would have had no reason to know that Form B is a polymorph, nor would the skilled artisan have known how the multiple variables at play would impact the analysis—the evidence of record precluded even a reasonable expectation of success.[250]

Last, defendants argued it would have been obvious to try as the prior art discloses but a finite number of solvents to use.[251] The court rejected this argument as well.[252] It reiterated for obvious to try, a defendant must establish (1) a design or market need to solve a problem and (2) that there are a finite number of identified, predictable solutions.[253] And, based on its review of the art, it concluded the prior art disclosed "a huge number of possible choices," not a finite number.[254] According to the court, it would not have been obvious to try to produce Form A based on the prior art.[255]

246. *Id.* at 1341.
247. *Id.* at 1342–43.
248. *Id.* at 1341–43.
249. *Id.* at 1343.
250. *Id.* at 1343–45.
251. *Id.* at 1345.
252. *Id.*
253. *Id.*
254. *Id.*
255. *Id.*

D. Indefiniteness

In *Guangdong Alison Hi-Tech Co. v. International Trade Commission*,[256] the Federal Circuit affirmed an ITC decision finding that asserted claims were not invalid as indefinite because, although the claims included a term of degree, namely, "lofty . . . batting," the specification adequately explained the objective boundaries of the term's scope with reasonable certainty.[257]

Aspen Aerogels, Inc. had filed a complaint with the Commission alleging that Guangdong Alison Hi-Tech Co. ("Alison") violated section 337 of the Tariff Act of 1930[258] by importing alleging infringing aerogel insulation materials.[259] Before the ITC, Alison argued that the claims were invalid for indefiniteness.[260] The Commission rejected this argument and adopted the express definition in the specification that "lofty . . . batting" was "[a] fibrous material that shows the properties of bulk and some resilience (with or without full recovery)."[261] The Commission emphasized the "bulk" and "resilience" components of the definition are set forth in detail in the specification and provide sufficient metes and bounds for the claim phrase.[262]

On appeal, the Federal Circuit affirmed.[263] In the court's view, Alison sought "a level of 'mathematical precision' beyond what the law requires."[264] It noted the specification provided express definitions for the term "lofty . . . batting" and its components.[265] In particular, it explained that "*lofty* batting" was defined as "[a] fibrous material that shows the properties of *bulk* and *some resilience* (with or without full recovery)," and the specification further provided "bulk" refers to "air or openness created by the web of fibers in a lofty batting" and "sufficiently resilient" indicated it "can be compressed to remove the air (bulk) yet spring back to substantially its original size and shape."[266]

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256. 936 F.3d 1353 (Fed. Cir. 2019).
257. *Id.* at 1356, 1360.
258. 19 U.S.C. § 1337 (2012).
259. *Guangdong Alison Hi-Tech Co.*, 936 F.3d at 1356.
260. *Id.* at 1357.
261. *Id.*
262. *Id.* ("In particular, the ALJ pointed to the specification's disclosure that bulk is 'air' and that a lofty batting is 'sufficiently resilient' if 'after compression for a few seconds it will return to at least 70% of its original thickness.'" (citations omitted)).
263. *Id.* at 1359.
264. *Id.* at 1360 (quoting Sonix Tech. Co. v. Publ'ns Int'l, Ltd., 844 F.3d 1370, 1377 (Fed. Cir. 2017)).
265. *Id.*
266. *Id.*

The court also noted that the patent specification detailed "functional characteristics" of a "lofty . . . batting" and had numerous "examples and metrics that further inform the meaning."[267] According to the court, this was sufficient support to conclude the term of degree was not indefinite.[268] It nevertheless noted that its understanding was further supported by the prosecution history, where the examiner "emphasized" the specification defined "lofty . . . batting," and the term offered a means for distinguishing the claims over the prior art.[269]

In *HZPN Medicines LLC v. Actavis Laboratories UT, Inc.*,[270] HZNP Medicines LLC ("Horizon") was the assignee of several patents relating to methods and compositions for treating osteoarthritis.[271] The patents were listed in the Orange Book for Horizon's PENNSAID®2% product for the treatment of osteoarthritis in the knee.[272] Actavis Laboratories UT, Inc. ("Actavis") sought to market a generic version and filed an ANDA.[273] Horizon sued Actavis for patent infringement.[274]

Before the district court, Actavis challenged the patents, alleging among other things, the claims were indefinite.[275] The district court agreed and found several terms indefinite, including (1) "the topical formulation produces less than 0.1% impurity A after 6 months at 25°C and 60% humidity" because "impurity A" is not knowable, (2) "the formulation degrades by less than 1% over 6 months" as neither the specification nor claims offered a means to evaluate the degradation, and (3) "consisting essentially of."[276] As to the latter, the district court reasoned that because the parties disputed the basic and novel properties that could not be affected by unlisted claim elements, any lack of informative disclosure as to the scope of those properties rendered the claims indefinite.[277] For example, because "better drying

267. *Id.* at 1361.
268. *Id.* at 1362.
269. *Id.* at 1361.
270. 940 F.3d 680 (Fed. Cir. 2019).
271. *Id.* at 683.
272. *Id.*
273. *Id.* at 684.
274. *Id.*
275. *Id.*
276. *Id.*
277. *Id.* at 684–85 ("The district court therefore concluded that '[b]ecause the basic and novel properties of an invention are part of the construction of a claim containing the phrase "consisting essentially of," the *Nautilus* standard applies to the assessment of an invention's basic and novel properties.'" (citation omitted)).

time" was one basic and novel property, the district court reasoned that the identification of inconsistent methods in the specification for evaluating "better drying time" rendered these claims indefinite.[278]

On appeal, the Federal Circuit affirmed.[279] First, the court addressed whether "impurity A" was indefinite and concluded it was.[280] The court noted "impurity A" only appeared in the claim and in one example in the specification.[281] In the court's view, the claim did not indicate the identity of "impurity A," as it recited the entire topical formulation having a number of excipients and it was unclear if "impurity A" would be a specific impurity.[282] In turning to the specification, the court noted it did not "expressly" identify what "impurity A" was.[283] And, last, in the court's view, the extrinsic evidence failed to establish that a skilled artisan would know what "impurity A" was based on limited testing parameters recited in the specification.[284]

Second, the court addressed whether "degrades" was indefinite and held that it was.[285] The court noted the proposed construction for "degrades" was "[l]ess than 1% of Impurity A" and thus relied on an understanding of "impurity A."[286] It accordingly reasoned, "[s]ince 'impurity A,' is indefinite, it logically follows that another term, such as the 'degrades' term, which [in turn] relies on 'impurity A' for its construction, must also be indefinite."[287]

Last, the court addressed whether "consisting essentially of" in this context is indefinite and concluded it was.[288] The court noted the known principle invoked by using "consisting essentially of" in a claim, namely, that the phrase permits inclusion of components not listed in the claim, provided they do not "materially affect the basic and novel properties of the invention."[289] It then remarked:

278. *Id.* at 685.
279. *Id.* at 688.
280. *Id.* at 688–89.
281. *Id.* at 688.
282. *Id.* at 690.
283. *Id.* at 690–91.
284. *Id.*
285. *Id.* at 691–92.
286. *Id.* at 692.
287. *Id.*
288. *Id.* at 692–99.
289. *Id.* at 693.

> By using the phrase 'consisting essentially of' in the claims, the inventor in this case incorporated into the scope of the claims an evaluation of the basic and novel properties. The use of 'consisting essentially of' implicates not only the items [expressly] listed after the phrase, but also those steps (in a process claim) or [the] ingredients (in a composition claim) that do not materially affect the basic and novel properties of the invention.[290]

Thus, in the court's view, assessing these properties and their associated disclosure was proper.[291]

Turning to the specification, the Federal Circuit held that the district court correctly identified basic and novel properties, including a "better drying time," and did not err in finding the specification failed to inform the skilled artisan as to the scope of a "better drying time."[292] In particular, the court agreed with the district court that the specification disclosed two different inconsistent ways for determining "better drying time": an in vitro method and an in vivo method.[293] Accordingly, the court held that the "consisting essentially of" limitation was invalid for indefiniteness.[294]

E. Written Description and Enablement

There were several cases dealing with § 112 issues.[295] In *CenTrak, Inc. v. Sonitor Technologies, Inc.*,[296] the dispute was over infringement of a patent for a real-time location system allowing users to identify portable devices in a facility. The Federal Circuit held that the district court erred in granting summary judgment that the claims were invalid for a lack of written description support.[297] According to the court, genuine issues of material fact that precluded summary judgment remained.[298]

The asserted claims recited, among other things, (1) ultrasonic base stations, (2) portable devices, (3) a server, (4) radio frequency base

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290. *Id.* at 693–94.
291. *Id.* at 696.
292. *Id.* at 693, 696–99.
293. *Id.* at 696–99.
294. *Id. But see id.* at 704, 706 (Newman, J., concurring in part and dissenting in part) ("It is hard to imagine a clearer statement than a list of the ingredients that the claimed formulation 'consists essentially of.'").
295. *See generally* 35 U.S.C. § 112 (2012) (codifying specification requirements for patent applications).
296. 915 F.3d 1360 (Fed. Cir. 2019).
297. *Id.* at 1362.
298. *Id.*

stations, and (5) a backbone that connects the server with the RF base stations.[299] Although all of the claims recited ultrasonic components, the court explained that a "vast majority of the specification focuses on infrared (IR) or RF components."[300] Before the district court, the defendant argued the only two sentences in the specification noting ultrasound failed to show the inventors had possession of an ultrasound-based system.[301] The district court agreed and granted summary judgment that the claims did not satisfy the written description requirement.[302] It reasoned that, although the specification "contemplated" ultrasound, that was not sufficient.[303] It explained "electromagnetic radiation and sound waves are not simply two species of the same genus"; they are "different types of phenomena" and one could not drop the ultrasonic transmitter into an IR system disclosed in the specification.[304]

On appeal, the Federal Circuit reversed.[305] It explained that just because the specification might focus on one embodiment, here an IR system, that does not mean another embodiment is not contemplated or sufficiently disclosed.[306] Quantity is not an exclusive metric.[307] As the court noted, the specification, albeit brief, disclosed an ultrasonic embodiment.[308] Whether it was sufficient for written description purposes depended on "the nature and scope of the claims and on the complexity and predictability of the relevant technology."[309] As the district court failed to consider factual questions regarding the complexity and predictability of ultrasonic systems, including testimony suggesting the differences between IR and ultrasound were incidental to carrying out the claimed invention, the Federal Circuit reversed the district court's award of summary judgment.[310]

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299. *Id.*
300. *Id.* at 1363.
301. *Id.* at 1364.
302. *Id.*
303. *Id.*
304. *Id.* at 1365 (quoting CenTrak, Inc. v. Sonitor Techs., Inc., No. CV 14-183-RGA, 2017 WL 3730617, at *8 (D. Del. Aug. 30, 2017)).
305. *Id.* at 1373–74.
306. *Id.* at 1366.
307. *See, e.g.*, *id.* ("[T]he fact that the bulk of the specification discusses a system with infrared components does not necessarily mean that the inventors did not also constructively reduce to practice a system with ultrasonic components.").
308. *Id.* at 1367.
309. *Id.* (quoting Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010)).
310. *Id.* at 1367–68.

In *In re Global IP Holdings LLC*,[311] the Federal Circuit vacated and remanded the case because the PTAB applied the wrong written description standard.[312] Global IP Holdings LLC ("Global") filed a reissue application to broaden its claims that were directed to carpeted automotive vehicle load floors.[313] That reissue application replaced the term "thermoplastic" with "plastic" in several independent claims, and the inventor filed a declaration explaining, among other things, that he was aware of using plastics other than thermoplastics.[314] The examiner rejected the proposed reissue claims for failing to comply with the written description requirement.[315] In particular, he reasoned that the specification only described components formed from thermoplastic materials, not generally from plastic materials.[316] Global appealed to the PTAB, and the PTAB affirmed.[317] The PTAB explained "*regardless of the predictability* of results of substituting alternatives, *or the actual criticality of thermoplastics* in the overall invention, [Global's] Specification, as a whole, indicates to one skilled in the art that the inventors had possession only of the skins and core comprising specifically thermoplastic."[318]

On appeal, the Federal Circuit vacated and remanded.[319] The court held the PTAB erred in its written description analysis.[320] It explained that the Board's statement of "regardless of the predictability of results of substituting alternatives" conflicted with precedent.[321] A written description inquiry will vary depending on the nature and scope of the claims, as well as "on the complexity and *predictability* of the relevant technology."[322] The predictability of substituting generic plastics for thermoplastics was the very question the PTAB was asked to resolve.[323] Similarly, the court noted that "criticality or importance of an unclaimed

311. 927 F.3d 1373 (Fed. Cir. 2019).
312. *Id.* at 1374.
313. *Id.* at 1375.
314. *Id.*
315. *Id.* at 1376.
316. *Id.*
317. *Id.*
318. *Id.* (emphases added) (quoting *Ex Parte* Preisler, No. 2018-000871, 2017 WL 6882664, at *3 (P.T.A.B. Dec. 29, 2017)).
319. *Id.* at 1374.
320. *Id.* at 1377.
321. *Id.*
322. *Id.*
323. *See id.*

limitation to the invention" is relevant to the written description inquiry and that the PTAB erred by failing to consider it.[324]

In *Enzo Life Sciences, Inc. v. Roche Molecular Systems, Inc.*,[325] the Federal Circuit affirmed the district court's determination that challenged claims from two patents were invalid for lack of enablement.[326] The claims from one asserted patent were directed to nonradioactive labeling of polynucleotides, where the label was attached at the phosphate position of a nucleotide.[327] They did not cover *specific* polynucleotides, "nor [did] they focus on the chemistry or linker used to attach a label, the number of labels to attach to a polynucleotide, or where within the polynucleotide to attach those labels."[328] According to the court, the "scope of the claims is quite broad."[329] The claims from the other asserted patent related to either *in situ* hybridization or liquid phase hybridization and were similarly broad.[330] The two patents shared a common specification.[331]

On appeal, the Federal Circuit concluded that the claims were not enabled.[332] According to the court, even if it were to assume the specification taught a skilled artisan how to make the *broad* range of labeled polynucleotides contemplated by the claims, it still *failed to teach* a skilled artisan "which combinations will produce a polynucleotide that is [both] hybridizable and detectable upon hybridization."[333] The court indicated that "[g]iven the unpredictability of the art at the time . . . , merely stating that a labeled polynucleotide will work as a probe is not sufficient to enable [a skilled artisan] to know that it would

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324. *Id.*
325. 928 F.3d 1340 (Fed. Cir. 2019).
326. *Id.* at 1342.
327. *Id.* at 1343.
328. *Id.* at 1343, 1346–47 (explaining "[c]laim 1 of the '180 patent encompasses all phosphate-labeled polynucleotides that are hybridizable and detectable. The claim places almost no limitations on the structure of the claimed polynucleotide, other than the fact that the label is attached to the phosphate portion of the nucleotide. It does not restrict the chemistry used to attach the label, the chemical linker used, the number of labels within a probe, or the location of the labels on the probe (i.e., whether they are terminal or internal). As to the type of non-radioactive label used, the claim provides broad categories . . . .").
329. *Id.* at 1346.
330. *Id.* at 1344; *see also id.* at 1349 ("Those claims are broader than the asserted claims of the '180 patent; rather than covering only phosphate-labeled polynucleotides, they also cover labeling at other locations on a nucleotide.").
331. *Id.* at 1343.
332. *Id.* at 1349.
333. *Id.* at 1346.

indeed function as a probe—i.e., be hybridizable and detectable upon hybridization."[334] In the court's view, it would have required undue experimentation to determine if the embodiments of the broad claims would exhibit this required functionality.[335]

In *Quake v. Lo*,[336] the Federal Circuit affirmed the PTAB's determination that the involved claims were unpatentable for lack of written description.[337] The claims generally covered a method of determining the presence of a chromosomal abnormality in fetuses using massively parallel sequencing (MPS) technology to sequence DNA fragments from a sample of the mother's blood that contains both maternal and fetal DNA.[338] The claims specifically recited *random MPS methods*, but the specification recited detection of *target sequences*.[339]

The PTAB determined the specification failed to provide support for the claimed random MPS method, and the Federal Circuit agreed.[340] The court reasoned that the MPS method was not "expressly described" in the specification, noting that (1) the specification does not recite "random MPS," (2) the process of amplifying DNA in any sample before sequencing is not described, as would be needed if a random MPS method was contemplated, and (3) even the patentee admitted no embodiment describes the statistical analysis needed to determine data generated from a random MPS method.[341] The court then noted, although the MPS method may be implicitly contemplated in two isolated locations, the "repeated discussion of targeted sequencing," when contrasted with the bare invocation of the MPS method, was insufficient for written description purposes.[342] As the court highlighted, "in the context of this patent," the two isolated statements were "a highly elliptical cryptic way to communicate possession of a second method," i.e., the MPS method.[343]

In *Nalpropion Pharmaceuticals, Inc. v. Actavis Laboratories FL, Inc.*, the Federal Circuit affirmed the district court's decision that the sole claim asserted in one patent did not lack written description support and

334. *Id.* at 1347.
335. *Id.* at 1349.
336. 928 F.3d 1365 (Fed. Cir. 2019).
337. *Id.* at 1367.
338. *Id.*
339. *Id.*
340. *Id.*
341. *Id.* at 1374.
342. *Id.* at 1376.
343. *Id.*

reversed the decision that the claims of the other patent would not have been obvious.[344]

Nalpropion Pharmaceuticals, Inc. ("Nalpropion") markets Contrave®, a drug used for weight management in overweight or obese adults.[345] Nalpropion listed three patents in the Orange Book covering Contrave®, and it asserted those three patents against Actavis Laboratories FL, Inc. ("Actavis") after Actavis filed an ANDA seeking to enter the market with a generic version.[346] Actavis asserted the claim in one patent was invalid for lack of written description.[347] It argued that the claimed dissolution profile was achieved using the "USP Apparatus 2 Paddle Method," but the specification disclosed data obtained using the "USP Apparatus 1 Basket Method."[348] The district court was not persuaded that use of a different method from what is in the claim presented a written description problem, stating "whether the dissolution data reported in the specification was obtained using the basket method or the paddle method is not relevant to whether the inventors had possession of the invention."[349] The district court credited Nalpropion's expert, who opined a skilled artisan would have recognized the inventors possessed the invention, irrespective whether the paddle method or a "'substantially equivalent method' was used."[350]

On appeal, the Federal Circuit affirmed.[351] The court reiterated the test for sufficiency of a written description is "whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession *of the claimed subject matter*," and "[i]t is not necessary that the exact terms of a claim be used *in haec verba* in the specification, and equivalent language may be sufficient."[352] In the court's view, the district court "performed precisely its fact-finding function" and made credibility determinations on each expert's opinions regarding the "substantial equivalence" of

344. 934 F.3d 1344, 1346 (Fed. Cir. 2019).
345. *Id.*
346. *Id.* at 1346, 1348.
347. *Id.* at 1348.
348. *Id.*
349. *Id.* (quoting Orexigen Therapeutics, Inc. v. Actavis Labs. FL, Inc., 282 F. Supp. 3d 793, 802 (D. Del. 2017)).
350. *Id.* (quoting *Orexigen Therapeutics, Inc.*, 282 F. Supp. 3d at 801).
351. *Id.* at 1351.
352. *Id.* at 1350 (quoting Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc)).

the paddle and the basket methods.[353] Declining to disturb that finding on appeal, the court agreed with the district court's finding that the two tables and data in the specification adequately showed the inventors possessed their invention.[354] It then concluded:

> While as a general matter written description may not be satisfied by so-called equivalent disclosure, in this case, buttressed by the district court's fact-finding, and where the so-called equivalence relates only to resultant dissolution parameters rather than operative claim steps, we affirm the district court's conclusion. Rigidity should yield to flexible, sensible interpretation.[355]

In *Nuvo Pharmaceuticals (Ireland) Designated Activity Co. v. Dr. Reddy's Laboratories, Inc.*,[356] an ANDA case, the generic drug manufacturer defendants appealed from the district court's decision confirming claims as adequately described under § 112.[357] The claims related to a pain medication that included a nonsteroidal anti-inflammatory drug and an acid inhibitor, such as a proton pump inhibitor ("PPI").[358] Notably, the claims recited an uncoated PPI that was effective to raise gastric pH levels.[359]

Before the district court, the generic drug manufacturer defendants argued that if they lost on the obviousness theory that a skilled artisan would have known and/or expected uncoated PPI to be effective to raise gastric pH levels, then the asserted claims necessarily lacked written description support because the specification failed to include experimental data or analytical reasoning to show actual possession of the claimed invention.[360] The district court disagreed, finding the claims adequately described.[361] On appeal, the Federal Circuit reversed.[362]

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353. *Id.*

354. *Id.* at 1351.

355. *Id.* Dissenting in part from the panel decision on written description, Chief Judge Prost maintained that the panel majority had introduced a new rule, whereby "substantially equivalent" disclosure may satisfy the written description requirement, in direct contravention of the Court's precedent. *Id.* at 1356 (Prost, C.J., dissenting in part). But even assuming that were the standard, she also found that the district court clearly erred in finding the patent specification includes some "substantially equivalent" disclosure to the claimed paddle method. *See id.* at 1356, 1358–59.

356. 923 F.3d 1368 (Fed. Cir. 2019).

357. *Id.* at 1371.

358. *Id.* at 1372.

359. *Id.* at 1377.

360. *Id.* at 1375.

361. *Id.*

362. *Id.* at 1384.

While the patents claimed uncoated PPI effective to raise gastric pH levels to at least 3.5, the court found persuasive the fact that the prior art *taught away* from such effectiveness.[363] In such a circumstance, the court reasoned that it was fatal for the specification to lack "experimental data, or some reason, theory, or alternative explanation" showing the inventor possessed the patented treatment.[364]

In *Idenix Pharmaceuticals LLC v. Gilead Sciences Inc.*,[365] Idenix Pharmaceuticals appealed the District of Delaware's judgment as a matter of law finding that Idenix's patent was invalid for lack of enablement, and Gilead Sciences further argued that the patent was invalid for lack of written description.[366] The court affirmed the district court's decision on enablement and further sided with Gilead on the written description issue.[367] Idenix's patent was directed to a method of treatment for hepatitis C virus by administering nucleoside compounds having a specific chemical and stereochemical structure: (1) a sugar ring with five carbon atoms to which different atoms or groups of atoms can be attached in either up or down positions and (2) various possible 2'-methyl-up nucleosides (methyl substitutions at the second carbon on the ring).[368] Gilead argued this was overly broad because there were billions of potential structures that could result.[369] The patent itself also disclosed "enormous quantities" of the 2'-methyl-up nucleosides that could be effective against HCV.[370] The Federal Circuit agreed and held that a person of ordinary skill in the art would not know, without undue experimentation, which 2'-methyl-up nucleosides would be effective to treat HCV.[371] Because the

363. *Id.* at 1376, 1378, 1380 ("[T]he record evidence demonstrates that a person of ordinary skill in the art would not have known or understood that uncoated PPI is effective.").

364. *Id.* at 1376, 1380–81 ("[O]ur case law does not require experimental data demonstrating effectiveness . . . . In light of the fact that the specification provides nothing more than the mere claim that uncoated PPI might work, even though persons of ordinary skill in the art would not have thought it would work, the specification is fatally flawed. It does not demonstrate that the inventor possessed more than a mere wish or hope that uncoated PPI would work, and thus it does not demonstrate that he actually invented what he claimed: an amount of *uncoated* PPI that is *effective* to raise the gastric pH to at least 3.5." (internal citation omitted)).

365. 941 F.3d 1149 (Fed. Cir. 2019).

366. *Id.* at 1153.

367. *Id.*

368. *Id.* at 1154–55.

369. *Id.* at 1155.

370. *Id.* at 1157.

371. *Id.* at 1156.

pharmaceutical had to be effective in treating hepatitis C, the claims had both a structural requirement (molecular structure) and a functional requirement (effective treatment).[372] Idenix did not provide enough support for either. As for written description, the patent "fail[ed] to provide sufficient blaze marks to direct a POSA to the specific subset of 2'-methyl-up nucleosides that are effective in treating HCV" or show that the inventor possessed them.[373]

Judge Newman dissented, opining that though there were a large number of unclaimed variants, the claims of the patent itself were very narrow, and a reasonable jury would have understood them to be directed to the nucleosides specifically described and shown to have antiviral activity.[374] She concluded that "[t]he majority's holding that validity under [§] 112 is determined based on whether unclaimed subject matter is described and enabled, provides a new path of uncertainty and unreliability of the patent grant."[375]

F. Statutory Bars

There was only one case involving statutory bars. In *Barry v. Medtronic, Inc.*,[376] Dr. Mark Barry brought an action in patent infringement against Medtronic, Inc. ("Medtronic"), alleging Medtronic induced surgeons to infringe two patents directed to a method and system for correcting spinal column anomalies.[377] Among other things, Medtronic argued the patents were invalid under the public-use and on-sale bars.[378] In post-trial rulings on jury issues, the district court rejected these challenges and confirmed the jury's verdict finding the asserted patents valid.[379] Medtronic appealed, and the Federal Circuit affirmed.[380]

1. Ready for patenting

As set forth by the Supreme Court and Federal Circuit, the public use and on-sale bars of Section 102(b) apply where the invention or

372. *Id.*
373. *Id.* at 1164.
374. *Id.* at 1165–66 (Newman, J., dissenting).
375. *Id.* at 1166.
376. 914 F.3d 1310 (Fed. Cir. 2019).
377. *Id.* at 1316–17.
378. *Id.* at 1316.
379. *Id.* at 1320.
380. *Id.* at 1316.

method is "ready for patenting."[381] This requires a finding that the invention was reduced to practice, which means the method was performed and "shown or known to work for its intended purpose."[382]

Medtronic alleged that Dr. Barry performed surgeries using his claimed invention in both August and October 2003, and thus, his invention was reduced to practice as of those times.[383] The court disagreed and held that the evidence instead allowed for the reasonable finding that Dr. Barry *did not know* his invention would work for its intended purpose until January 2004, when he completed follow-ups on those surgeries.[384] According to the court, Dr. Barry established that the final follow-up appointments were "reasonably needed for the determination that the invention worked for its intended purpose."[385]

The court also rejected Medtronic's argument that only a single surgery was needed to determine if the invention worked for its intended purpose.[386] The court explained that an "'intended purpose' need not be stated in claim limitations that define the claim scope," but can come from the specification as well.[387] In this case, Dr. Barry was addressing three types of scoliosis, and the record reflected that three separate surgeries were required to ensure the invention worked for the intended purpose of resolving *each type*.[388] The court concluded that substantial evidence supported the jury's finding that the claimed invention was not "ready for patenting."[389]

2. Public use

The court also held the invention was not "in public use."[390] Contrasting the case with the famous Supreme Court corset case, *Egbert v. Lippmann*,[391] the court pointed to evidence showing that very few people in the operating room had a clear view of the surgical field where Dr. Barry was using his invention, and those in the operating

381. *Id.* at 1320, 1322 (quoting Polara Eng'g Inc. v. Campbell Co., 894 F.3d 1339, 1348 (Fed. Cir. 2018)).
382. *Id.* at 1321–22 (quoting *Polara Eng'g Inc.*, 894 F.3d at 1348).
383. *Id.* at 1323.
384. *Id.*
385. *Id.* at 1322–23.
386. *Id.* at 1324.
387. *Id.* at 1325.
388. *Id.* at 1328.
389. *Id.* at 1326.
390. *Id.* at 1321.
391. 104 U.S. 333, 335 (1881).

room were under an implied duty of confidentiality covering at least the tools and the techniques used.[392] The court accordingly noted in dictum that, even if the claimed invention was ready for patenting, it was "not exposed or accessible to the public" more than one year before the relevant priority date.[393]

3. Experimental use

Moreover, even if the claimed invention was ready for patenting, and had been available to the public, the court noted in dictum that the experimental use exception would apply and save the challenged claims.[394] When discussing experimental use, the court considered (1) whether Dr. Barry lacked confidence the device would work with different types of scoliosis; (2) whether the claimed technique is why he attracted patients; (3) whether he was the only one to perform the claimed method using his device; and (4) whether he surrendered control of the invention before the critical date.[395] After considering these factors, the court held that substantial evidence showed Dr. Barry's surgeries were experimental, and further that he did not surrender control of the invention when he performed his surgeries.[396]

4. On-sale bar

With respect to the on-sale bar, Medtronic challenged a jury instruction that stated that "there is a difference between 'experimental use' in the context of patent law and the way that the word 'experiment' is used in the context of medicine."[397] The court rejected this contention, holding the jury's instruction was appropriate given the context of the case.[398]

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392. *Barry*, 914 F.3d at 1327.

393. *Id.*

394. *Id.* at 1328 ("An inventor's use, while public in one sense, will not be considered a statutory public use if the use was experimental.").

395. *Id.* at 1328–29 (citing Allen Eng'g Corp. v. Bartell Indus. Inc., 299 F.3d 1336, 1353 (Fed. Cir. 2002)).

396. *Id.* at 1330–31 (quoting Lough v. Brunswick Corp., 86 F.3d 1113, 1120 (Fed. Cir. 1996)) (emphasizing that objective evidence of experimentation and control of the invention are "critically important" for a finding of experimentation).

397. *Id.* at 1331–32.

398. *Id.* (finding that "[i]n light of Medtronic's suggestions regarding the impropriety of medical experimentation without informed consent, it was reasonable for the court to address potential confusion").

G. Utility

Again, only one case involved utility last year. In *Grunenthal GmbH v. Alkem Laboratories, Ltd.*, the Federal Circuit addressed the doctrine of patent utility.[399] The court explained that the "bar for utility is not high."[400] A patent must have (1) specific utility—that is, a "well-defined and particular benefit to the public"—and it must have (2) substantial (or practical) utility—that is, a "significant and presently available benefit to the public."[401] For pharmaceutical patents, the court explained practical utility may be shown by evidence of "any pharmacological activity."[402]

On appeal, defendants argued the patents lacked a specific utility because the specification only vaguely states "Crystalline Form A . . . has the same pharmacological activity as Form B but is more stable under ambient conditions" and "can be advantageously used as [an] active ingredient in pharmaceutical compositions."[403] The court rejected this argument, explaining that the specification taught the crystalline Form A "is used for the treatment of pain or the treatment of urinary incontinence," and that was sufficient to disclose a practical benefit to the public.[404] The defendants also argued that the patents lacked a substantial utility because they fail to prove Form A's "superior stability over Form B" by test data.[405] The court rejected this argument as well, explaining that requiring test data for utility is too high a bar—"[a]ll that is necessary is evidence that a POSA would accept the claimed utility as correct," and the involved specifications satisfied that standard.[406]

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399. 919 F.3d 1333 (Fed. Cir. 2019).

400. *Id.* at 1345.

401. *Id.* (citing *In re* Fisher, 421 F.3d 1365, 1371 (Fed. Cir. 2005)).

402. *Id.* (citing Fujikawa v. Wattanasin, 93 F.3d 1559, 1564 (Fed. Cir. 1996)).

403. *Id.* at 1345–46 (alteration in original).

404. *Id.* at 1346 ("The prior art confirms that tapentadol hydrochloride was known as an analgesic at the time of filing . . . . Therefore, the [patent] concretely discloses the practical benefit of Form A.").

405. *Id.*

406. *Id.* ("While test results often support claims of utility in patents concerning pharmacological arts, such testing is not always required." (citing Rasmusson v. SmithKline Beecham Corp., 413 F.3d 1318, 1323 (Fed. Cir. 2005)).

III. INFRINGEMENT

A. Doctrine of Equivalents

In *Duncan Parking Technologies, Inc. v. IPS Group, Inc.*,[407] the court also addressed appeals from two related district court decisions granting summary judgment of noninfringement of U.S. Patent No. 7,854,310 ("the '310 patent") and U.S. Patent No. 8,595,054 ("the '054 patent").[408] The court affirmed the district court's summary judgment of noninfringement of the '310 patent, holding that the district court correctly applied the term "cover panel" and found the accused device not literally infringing because its keypad is an extension of the device through an opening in the housing, not a part of the device itself as IPS contended.[409] The court also rejected IPS's argument under the doctrine of equivalents, holding that it would vitiate claim limitations requiring keypad buttons to be located on the cover panel included in the housing, which the patent repeatedly distinguished from the device itself.[410]

The court, however, vacated and remanded the district court's judgment of noninfringement of the '054 patent, holding it erred in construing the term "receivable within" to require the device to fit "entirely" within the claimed housing and incorrectly excluded the preferred embodiment.[411] The court held that, consistent with the plain meaning of the term and the intrinsic record, "receivable within" should be construed as "capable of being contained substantially inside" the housing base, and remanded for further proceedings on the issue of infringement under the proper construction.[412]

In *UCB, Inc. v. Watson Laboratories Inc.*,[413] UCB asserted infringement by Watson of the patents in suit—U.S. Patent Nos. 6,884,434 ("the '434 patent") and 8,232,414 ("the '414 patent")—covering UCB's branded drug Neupro, which is a rotigotine transdermal patch without using

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407. 914 F.3d 1347 (Fed. Cir. 2019).

408. *Id.* at 1351.

409. *Id.* at 1360–61.

410. *Id.* at 1361–62 ("Allowing IPS to greatly expand the scope of the '310 patent claims, to cover a parking meter with buttons located nearly anywhere on the outside of the meter, would disserve members of the public who seek to avoid infringing those claims.").

411. *Id.* at 1363–65 ("[A] departure from th[e] general rule [that a patentee is normally entitled to the full scope of its claim language] may be warranted only where the patentee either clearly sets forth a different definition of a claim term in the specification or disavows the full scope of the claim term during prosecution.").

412. *Id.* at 1365.

413. 927 F.3d 1272 (Fed. Cir. 2019).

water.[414] The Federal Circuit affirmed the district court's judgment that (1) Watson's proposed generic product infringed the '434 patent under the doctrine of equivalents;[415] (2) the '434 patent claims were not invalid as anticipated or obvious;[416] and (3) the '414 patent claims were invalid as anticipated because they were "known or used by others" in the United States before the date of invention.[417]

Application of the doctrine of equivalents in *UCB* involved whether a polyisobutylene adhesive used in Watson's proposed product is interchangeable with the claimed acrylate-based or silicone-based polymer adhesives.[418] Watson made several arguments relying on (1) prosecution history estoppel, (2) narrow claiming, (3) vitiation, and (4) ensnarement, to limit the application of the doctrine.[419] The court rejected each, reasoning that (1) UCB's election "with traverse" to prosecute claims to an silicone- or acrylate-based polymer adhesive system in response to the restriction requirement did not surrender polyisobutylene as an equivalent;[420] (2) there was insufficient indication from the specification or claims, or the inventor's knowledge, to conclude that UCB surrendered polyisobutylene as an equivalent;[421] (3) finding polyisobutylene to be an equivalent does not vitiate the silicone-based or acrylate-based limitation;[422] and (4) Watson failed to prove UCB's equivalence theory ensnares the prior art.[423]

The court also agreed with the district court's substantive application of the doctrine of equivalents finding polyisobutylene was interchangeable with silicone in the claimed polymer adhesive system.[424] In so doing, the court rejected the argument that the district

414. *Id.* at 1275.
415. *Id.* at 1286.
416. *Id.* at 1286–89.
417. *Id.* at 1289, 1291.
418. *Id.* at 1278.
419. *See id.* at 1278–84.
420. *Id.* at 1278–80.
421. *Id.* at 1280–82 (contrasting the facts with an earlier case where the court held that infringement was not supported under the doctrine of equivalents).
422. *Id.* at 1283 ("As explained below, the district court here conducted a specific analysis as to whether polyisobutylene would be covered, and it had adequate reasons for why a skilled would understand that [it] would work just as well as acrylate or silicone for the claimed transdermal patch.").
423. *Id.*
424. *Id.* at 1284–85.

court had clearly erred by relying on evidence comparing UCB's branded product with the accused generic product.[425]

Amgen Inc. v. Coherus BioSciences Inc.[426] involved the issue of prosecution history estoppel in the doctrine of equivalents analysis.[427] Amgen sued Coherus alleging infringement of U.S. Patent No. 8,273,707 ("the '707 patent") under the doctrine of equivalents based on Coherus's filing of an abbreviated Biologic License Application (aBLA) seeking FDA approval for a biosimilar version of Amgen's biologic drug product Neulasta.[428] The district court granted Coherus's motion to dismiss, holding that prosecution history estoppel barred Amgen from asserting the doctrine of equivalents.[429] The Federal Circuit affirmed.[430]

The Federal Circuit first explained that prosecution history estoppel may come up "either (1) by making a narrowing amendment to the claim ('amendment-based estoppel') or (2) by surrendering claim scope through argument to the patent examiner ('argument-based estoppel')."[431] The court agreed with the district court that argument-based estoppel applied because Amgen distinguished a prior art reference by arguing that it did not teach or suggest the "particular combinations of salts" that Amgen claimed.[432] The court held that Amgen "clearly and unmistakably surrendered unclaimed salt combinations during prosecution" and were thus estopped from arguing that Coherus's aBLA, which does not use the claimed combinations of salts, infringed the '707 patent under the doctrine of equivalents.[433]

Amgen argued that estoppel does not apply because it distinguished the prior art reference for other reasons.[434] The court disagreed, holding Amgen asserted multiple reasons and "estoppel can attach to

425. *Id.* at 1285–86.
426. 931 F.3d 1154 (Fed. Cir. 2019).
427. *Id.* at 1156.
428. *Id.* at 1156, 1158.
429. *Id.* at 1158.
430. *Id.* at 1156.
431. *Id.* at 1159 (quoting Conoco, Inc. v. Energy & Envtl. Int'l, L.C., 460 F.3d 1349, 1363 (Fed. Cir. 2006)).
432. *Id.* at 1160.
433. *Id.*
434. *Id.* ("Amgen asserted three bases for distinguishing [the patent]: (1) '[n]o combinations of salts [are] taught nor suggested in the . . . patent'; (2) 'nor [are] the *particular* combinations of salts recited in the pending claims taught nor suggested in [the patent]'; and (3) '[t]here is no description or suggestion in [the patent] for the use of any combination of salts to increase the dynamic capacity of a HIC.'").

each argument."[435] Amgen also argued that its final submission before allowance, which did not include the argument that the reference failed to disclose the claimed salt combinations, "must be the focus" of the analysis.[436] The court held this argument not supported by case law and disagreed that Amgen could "erase[]" its prior statements by not including them in a later submission.[437]

In an appeal from the ITC, the Federal Circuit in *Ajinomoto Co. v. International Trade Commission*[438] affirmed the Commission, including its determination of infringement by certain products of CJ CheilJedang Corp. ("CJ")[439] under the doctrine of equivalents. Ajinomoto owned a patent claiming *E. coli* bacteria genetically modified with the ability to produce increased volumes of aromatic L-amino acids such as L-tryptophan.[440] Ajinomoto sued CJ alleging that it imported products using infringing strains of *E. coli* bacteria.[441]

The Federal Circuit held that the Commission properly rejected CJ's prosecution history estoppel argument based on a claim amendment made during prosecution because the "tangential relation" exception applied.[442] The court agreed with the Commission that the reason for the narrowing amendment was "peripheral, or not directly relevant" to the equivalent in question.[443] The court further rejected CJ's substantive challenge to the Commission's application of the "function-way-result" test, concluding the Commission's finding of equivalence for each prong of the test was supported by substantial evidence.[444]

In *Amgen Inc. v. Sandoz Inc.*,[445] Amgen sued Sandoz for infringement under the Biologics Price Competition and Innovation Act[446] and appealed the district court's claim construction and summary judgment of noninfringement.[447] The Federal Circuit affirmed the claim construction that Amgen's method claims reciting the "washing"

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435. *Id.*
436. *Id.* at 1161.
437. *Id.*
438. 932 F.3d 1342 (Fed. Cir. 2019).
439. *Id.* at 1345–46.
440. *Id.*
441. *Id.* at 1347.
442. *Id.* at 1353–56.
443. *Id.* at 1354.
444. *Id.* at 1356.
445. 923 F.3d 1023 (Fed. Cir. 2019).
446. 42 U.S.C. § 262 (2012).
447. *Amgen Inc.*, 923 F.3d at 1025.

and "eluting" steps required the two steps as a separate process performed by adding discrete solutions in sequence.[448] Since Sandoz's biosimilar products involved a one-step process—applying a solution with no separate washing or eluting steps—and thus did not meet this limitation, the court affirmed that Sandoz did not literally infringe.[449] Amgen also asserted infringement by equivalents; however, the court concluded that the district court correctly held Sandoz's one-step, one-solution process did not function in substantially the same way as the claimed three-step, three-solution process.[450] The court explained that extending claim scope to cover the Sandoz process as Amgen urged was not warranted because the doctrine of equivalents is not "regularly available to extend protection beyond the scope of the claims."[451]

B. Literal Infringement

In *CenTrak, Inc. v. Sonitor Technologies, Inc.*, CenTrak asserted that Sonitor infringed as a "final assembler" of the accused system, and appealed the district court's summary judgment of noninfringement.[452] The Federal Circuit first clarified that "a final assembler can be liable for making an infringing combination—assuming the evidence supports such a finding—even if it does not make each individual component element."[453] Finding a triable issue of fact based on CenTrak's cited evidence that Sonitor oversaw the "installation" of the accused system and performed the "configuration" and "data entry" for the system to work, the court reversed and remanded for further proceedings.[454]

In *Eli Lilly & Co. v. Hospira, Inc.*,[455] the Federal Circuit addressed both literal infringement and infringement by equivalents.[456] The court reversed the district court's finding of literal infringement, reasoning that it erred in holding the claimed step of "administration of pemetrexed disodium" was

448. *Id.* at 1028–29.
449. *Id.* at 1029.
450. *Id.*
451. *Id.* (quoting London v. Carson Pirie Scott & Co., 946 F.2d 1534, 1538 (Fed. Cir. 1991)).
452. 915 F.3d 1360, 1364, 1373 (Fed. Cir. 2019) ("A reasonable jury could find that before an accused Sonitor system goes online, Sonitor personnel complete at least a portion of the final system configuration . . . in other words, that Sonitor makes a combination of hardware and software that is 'configured' to infringe.").
453. *Id.* at 1372.
454. *Id.* at 1372–74.
455. 933 F.3d 1320 (Fed. Cir. 2019).
456. *Id.* at 1327.

met because the accused pemetrexed ditromethamine product was dissolved before administration and contained pemetrexed and chloride anions and sodium and tromethamine cations.[457] To literally infringe, the court concluded, the pemetrexed disodium itself must be administered.[458] The court held the accused product was not literally infringing because it did not administer the pemetrexed disodium salt.[459]

The Federal Circuit, however, affirmed the district court's finding of infringement under the doctrine of equivalents.[460] The defendants argued that Lilly's claim was precluded by prosecution history estoppel, and the disclosure-dedication rule, under which what is disclosed but not claimed is "considered dedicated to the public."[461] With respect to prosecution history estoppel, the court agreed with Lilly that the "tangential" exception applied and held that the claim amendment made during prosecution was "merely tangential" to the equivalent in question, pemetrexed ditromethamine, holding the prosecution history to support the reason for the amendment was not to surrender other functionally identical pemetrexed salts.[462] The court also agreed with Lilly that the disclosure-dedication rule was inapplicable because the asserted patent did not "disclose" methods of treatment using pemetrexed ditromethamine.[463] The court further rejected the defendants' substantive challenge to the district court's application of the doctrine of equivalents and agreed with Lilly that the chemical differences between sodium and tromethamine were not clinically relevant because the two chemicals did not possess therapeutic activity.[464]

C. Indirect Infringement

In *Grunenthal GmbH v. Alkem Laboratories Ltd.*, the Federal Circuit affirmed the lower court's decision that the defendants did not induce infringement of or contributorily infringe claims of the asserted patent

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457. *Id.* at 1328–29.

458. *Id.* at 1329.

459. *Id.* ("There is no dispute that Hospira has only sought approval to market pemetrexed ditromethamine and that neither its proposed product nor methods of administering it will constitute administering the pemetrexed disodium salt." (citation omitted)).

460. *Id.* at 1336.

461. *Id.* at 1331, 1334.

462. *Id.* at 1331 ("As a general matter, we find Appellants' view of prosecution history estoppel, and the tangential exception in particular, too rigid.").

463. *Id.* at 1334.

464. *Id.* at 1335 ("As the district court found, [the defendant's] product will accomplish an identical aim, furnishing the same amount of pemetrexed to active sites in the body; in exactly the same way.").

covering treatment of polyneuropathic pain.[465] The defendants sought FDA approval to market a generic version of Nucynta® ER containing tapentadol hydrochloride and filed "Section viii" statements under 21 U.S.C. § 355(j)(2)(A)(viii) to carve out polyneuropathic pain and identify in the proposed labels only severe chronic pain that is not covered by the patent.[466] With respect to induced infringement, the court held the proposed labels did not sufficiently support the specific intent of the defendants to encourage users to treat polyneuropathic pain with the proposed generic product, noting that even if, as the plaintiffs contended, severe chronic pain could be polyneuropathic pain, it also included non-polyneuropathic pains.[467] The issue in the contributory infringement case was whether there were "substantial," or "not unusual," noninfringing uses indicated for the proposed generic product to defeat contributory infringement.[468] The court agreed with the district court's conclusion based on credibility determinations of experts on both sides that treating non-polyneuropathic pains with tapentadol hydrochloride would be not unusual.[469]

IV. EQUITABLE DEFENSES

A. Licensing

In *Fraunhofer-Gesellschaft Zur Förderung Der Angewandten Forschung E.V. v. Sirius XM Radio Inc.*,[470] the Federal Circuit vacated the district court's granting of Sirius XM's motion to dismiss based on a patent license defense.[471] Here, Fraunhofer entered into an exclusive license agreement with WorldSpace International Network, Inc. ("WorldSpace") related to its multicarrier modulation technology.[472] "Multicarrier modulation is a method for transmitting a main data stream over multiple carrier data streams."[473] WorldSpace entered into a sublicense agreement with Sirius XM, which was allowed under the license agreement with

465. 919 F.3d 1333, 1338 (Fed. Cir. 2019).
466. *Id.* at 1339–40.
467. *Id.* (noting that the appellants failed to establish that the proposed labels "implicitly or explicitly encourage or instruct users to take action that would inevitably lead to use of tapentadol hydrochloride for treatment of polyneuropathic pain").
468. *Id.* at 1340.
469. *Id.* at 1340–41.
470. 940 F.3d 1372 (Fed. Cir. 2019).
471. *Id.* at 1374.
472. *Id.* at 1375.
473. *Id.*

Fraunhofer; WorldSpace, however, filed for bankruptcy ten years later and rejected the license agreement with Fraunhofer.[474] While rejecting a licensing agreement during bankruptcy was deemed to be a breach of contract under the holding in *Mission Product Holdings, Inc. v. Tempnology, LLC*,[475] Fraunhofer never terminated the agreement.[476]

Fraunhofer—years later—sued Sirius XM for patent infringement.[477] Sirius XM countered by indicating it possessed a license to use Fraunhofer's technology.[478] The issues here were (1) whether Fraunhofer terminated the agreement with WorldSpace and (2) whether the sublicense could survive even if the agreement with WorldSpace was terminated.[479] The Federal Circuit held that the district court failed to consider whether Fraunhofer successfully terminated the agreement with WorldSpace.[480] The Federal Circuit instructed the district court to consider on remand whether Fraunhofer gave notice of termination "within a reasonable time."[481] Further, assuming the agreement was terminated, the court held the agreement lacked a provision indicating whether sublicenses' rights survived termination of the agreement.[482] As such, the court remanded this issue for the district court to consider extrinsic evidence to determine whether the parties intended for sublicensee's rights to survive termination.[483]

V. PATENT OFFICE APPEALS

A. PTAB Procedures

A massive part of the Federal Circuit's jurisprudence this year was addressing procedures at the PTAB. Certainly, no case was bigger than *Arthrex, Inc. v. Smith & Nephew, Inc.* ("*Arthrex II*").[484] In *Arthrex II*, Arthrex argued that the inter partes review (IPR) that invalidated its patent was unconstitutional because the appointment of the PTAB's administrative patent judges (APJs) violated the Appointments Clause of the

474. *Id.* at 1375–76.
475. 139 S. Ct. 1652, 1666 (2019).
476. *Fraunhofer-Gesellschaft*, 940 F.3d at 1376.
477. *Id.*
478. *Id.* at 1377.
479. *Id.* at 1378, 1380.
480. *Id.* at 1380.
481. *See id.* at 1379.
482. *Id.* at 1381.
483. *Id.* at 1382.
484. 941 F.3d 1320 (Fed. Cir. 2019).

Constitution.[485] The Appointments Clause provides that "[The President] . . . shall nominate, and by and with the Advice and Consent of the Senate, shall appoint . . . Judges of the supreme Court, and all other Officers of the United States."[486] Arthrex claimed that APJs were such officers.[487]

The Federal Circuit agreed. According to the Supreme Court's decision in *Buckley v. Valeo*,[488] an Officer of the United States is one "who 'exercise[es] significant authority pursuant to the laws of the United States.'"[489] As neither party nor the government contested that APJs were at least Officers of the United States by this definition, the court turned to determining whether APJs were inferior or principal officers.[490] This analysis considered three factors: "(1) whether an appointed official has the power to review and reverse the officers' decision; (2) the level of supervision and oversight an appointed official has over the officers; and (3) the appointed official's power to remove the officers."[491] The Federal Circuit determined that all these factors favored considering APJs to be principal officers and thus subject to the Appointments Clause of the Constitution.[492]

Having decided that the entirety of the IPR system was unconstitutional, the Federal Circuit sought the narrowest remedy possible to bring the system back into favorable light with the Constitution.[493] This remedy, it decided, was to sever the restriction of removal by the Director of the USPTO of APJs.[494] By statute, APJs could only be removed by the Director "only for such cause as will promote the efficiency of the service."[495] Making APJs removable without cause, the court concluded, rendered APJs as inferior officers that are not subject to the Appointments Clause.[496]

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485. *Id.* at 1327.
486. U.S. CONST. art. II, § 2, cl. 2.
487. *Arthrex II*, 941 F.3d at 1327.
488. 424 U.S. 1 (1976) (per curiam).
489. *Arthrex II*, 941 F.3d at 1327–28 (alteration in original) (quoting *Buckley*, 424 U.S. at 125–26).
490. *Id.* at 1328.
491. *Id.* at 1329 (citing Edmond v. United States, 520 U.S. 651, 664–65 (1997)).
492. *Id.* at 1329, 1331–32, 1334–35.
493. *Id.* at 1335, 1338.
494. *Id.* at 1338.
495. *Id.* at 1333 (quoting 5 U.S.C. § 7513(a)(2012)); *see also id.* at 1338 ("Title 35 U.S.C. § 3(c) declares the applicability of Title 5 rights to 'Officers and employees of the Office.'").
496. *Id.* at 1336.

In *AC Technologies S.A. v. Amazon.com, Inc.*,[497] the court affirmed a decision of the PTAB ruling the claims of the challenged patent unpatentable.[498] The PTAB initially instituted review on the first two grounds of the three presented in the petition.[499] After a final written decision finding some but not all claims to be unpatentable, Amazon moved for reconsideration on the third ground, which the PTAB granted.[500] Following additional briefing and submission of evidence, the PTAB found that Amazon showed the remaining claims to be unpatentable.[501] On appeal, AC argued that the Board exceeded its statutory authority and violated due process when it invalidated the claims based on a noninstituted ground in the original institution decision.[502] The court held AC's argument foreclosed by the Supreme Court's decision in *SAS Institute Inc. v. Iancu*,[503] which held the PTAB must institute on all claims and grounds presented in the petition or not at all.[504] The court also held no due process violation occurred because AC had notice and an opportunity to be heard and never requested a hearing on the third ground.[505]

In *SIPCO, LLC v. Emerson Electric Co.*,[506] the Federal Circuit analyzed whether a patent was directed to a "technological invention" and therefore barred from covered business method (CBM) review under the America Invents Act.[507] The claims at issue required a "low-power transceiver" connected to the internet and wirelessly connected to a remote device.[508]

The court first turned to 37 C.F.R. § 42.301(b), promulgated by the USPTO, which defined the statutory phrase "technological invention" as requiring the claimed subject matter as a whole (1) to recite a "novel and unobvious" technological feature and (2) to "solve[] a technical problem using a technical solution."[509] After reviewing both the claims and the specification, the court concluded that the claimed invention satisfied part two, holding that it "implements a communication system that connects an

497. 912 F.3d 1358 (Fed. Cir. 2019).
498. *Id.* at 1360.
499. *Id.* at 1363.
500. *Id.* at 1364.
501. *Id.*
502. *Id.*
503. 138 S. Ct. 1348 (2018).
504. *Id.* at 1354–55.
505. *AC Techs. S.A.*, 912 F.3d at 1365.
506. 939 F.3d 1301 (Fed. Cir. 2019).
507. *Id.* at 1303.
508. *Id.* at 1304.
509. *Id.* at 1311.

unconnected, remote device with a central station" and that the patent identified certain problems and offers the solution of creating a communication system "through a low-power, i.e., limited transmission range, transceiver."[510] But because the Board did not examine part one of § 42.301(b), the court remanded the issue to the Board.[511]

The Federal Circuit's disposition of the technological invention exception was predicated upon its disagreement with the Board's construction of "low-power transceiver."[512] The court held the term "low-power" to mean that a transceiver operates at a power level corresponding to "limited transmission range," reversing the Board's construction that a transceiver consumes less power.[513] The court held the specification consistently tied the low-power transceiver to a limited transmission distance and rejected the Board's finding that "low-power" was not necessarily coextensive with a limited transmission range.[514]

In *General Electric Co. v. United Technologies Corp.*,[515] the Federal Circuit dismissed General Electric's (GE) appeal from the PTAB for lack of Article III standing.[516] The PTAB found that GE did not show the challenged patent claims to be unpatentable for obviousness.[517] On appeal, the Federal Circuit held that GE failed to show a sufficient injury-in-fact to confer Article III standing to appeal.[518] The court rejected GE's theories of alleged competitive harms and economic injuries, finding them too speculative to support constitutional standing and untethered to the asserted patent.[519] The court also upheld that estoppel under 35 U.S.C. § 315(e)—which prohibits an IPR petitioner from later asserting in a court action any invalidity ground that it "raised or reasonably could have raised" during the IPR—alone does not create injury-in-fact.[520]

In *Papst Licensing GMBH & Co. KG v. Samsung Electronics America, Inc.*,[521] the Federal Circuit affirmed the Board's decision finding certain claims of

510. *Id.* at 1312.
511. *Id.* at 1313–14.
512. *Id.* at 1308–09.
513. *Id.* at 1309.
514. *Id.*
515. 928 F.3d 1349 (Fed. Cir. 2019).
516. *Id.* at 1351.
517. *Id.* at 1352.
518. *Id.* at 1353.
519. *Id.* at 1353–54.
520. *Id.* at 1355; *id.* at 1359 (Hughes, J., concurring).
521. 924 F.3d 1243 (Fed. Cir. 2019).

U.S. Patent No. 9,189,437 unpatentable for obviousness.[522] Not only rejecting the appeal on the merits, the court also held issue preclusion provides an alternative ground to affirm.[523] Weeks before the Board decision, the Board rendered final written decisions in two other proceedings involving patents that shared a specification with the '437 patent and contained related claim terms.[524] The Board found the claims of those patents unpatentable, relying on the same prior art references cited against the '437 patent claims.[525] Papst voluntarily dismissed appeals of the two decisions shortly before the scheduled oral argument.[526] Relying on *B&B Hardware, Inc. v. Hargis Industries, Inc.*,[527] the Federal Circuit held that issue preclusion applied to the '437 patent appeal because the decision from the related proceeding became "final" based on voluntary dismissal of the appeal and the issues resolved against Papst in that proceeding were "essential" to the Board's decision against the '437 patent claims.[528] The court concluded that Papst's course of action did not support an exception to issue preclusion because, after all, Papst litigated all the way through to final written decisions and up to the eve of appellate oral argument.[529]

In *Regents of University of Minnesota v. LSI Corp.*,[530] the Federal Circuit held that state sovereign immunity does not apply to IPR proceedings.[531] University of Minnesota (UMN) appealed the USPTO's decisions declining to dismiss petitions for IPR brought against UMN's patents on state sovereign immunity grounds.[532] Citing *Saint Regis Mohawk Tribe v. Mylan Pharmaceuticals Inc.*[533] as controlling authority, the Federal Circuit rejected UMN's argument that state sovereign immunity applies to IPR proceedings where the state is the patent owner.[534] The court relied on the same rationale articulated in *Saint Regis* to deny trial sovereign immunity and concluded that the same factors are "equally applicable to state sovereign immunity," i.e., (1) "the Director, . . . not the private

522. *Id.* at 1246.
523. *Id.*
524. *Id.* at 1249.
525. *Id.*
526. *Id.*
527. 575 U.S. 138 (2015).
528. *Papst Licensing GMBH & Co. KG*, 924 F.3d at 1250–52.
529. *Id.* at 1252.
530. 926 F.3d 1327 (Fed. Cir. 2019).
531. *Id.* at 1342.
532. *Id.* at 1330.
533. 896 F.3d 1322 (Fed. Cir. 2018).
534. *Regents of Univ. of Minn.*, 926 F.3d at 1338.

party, [is] who ultimately decides whether to proceed against the sovereign;" (2) even if the parties elect not to partake in the proceeding, the Board can continue to a final written decision; and (3) IPR is procedurally distinct from civil litigation.[535] The court also concluded that the differences between tribal and state sovereign immunity did not support a departure from the reasoning in *Saint Regis* that IPR is an agency's reconsideration of a patent grant that is "aided by information supplied by a third party."[536]

In *TQ Delta, LLC v. Dish Network LLC*,[537] the Federal Circuit addressed Patent Owner's procedural rights under the Administrative Procedure Act (APA) in an IPR proceeding.[538] While also affirming the PTAB's claim construction and obviousness finding, the court held the PTAB did not violate Patent Owner's APA rights by interpreting a claim term in its final written decision.[539] Patent Owner argued that it was denied notice and an opportunity to be heard under the APA because the PTAB sua sponte construed the term that neither party requested.[540] The court rejected Patent Owner's APA argument, holding that the PTAB never construed the term in its institution decision and therefore did not "change course" midstream by construing the term in the final written decision.[541] The court also held that Patent Owner was on adequate notice of the claim construction issue and was given the opportunity to respond during and after the oral hearing.[542]

In *Mayne Pharma International Pty. Ltd. v. Merck Sharp & Dohme Corp.*,[543] the Federal Circuit affirmed the PTAB's decision finding certain claims of the challenged patent as unpatentable for anticipation and obviousness.[544] The main issue on appeal was whether Merck Sharp & Dohme's (MSD) petition was time-barred under 35 U.S.C. § 315(b) because it did not list MSD's parent company—Merck & Co., Inc. (MCI)—as a real-party-in-interest until more than a year after the service of Mayne Pharma's complaint naming both MSD and

535. *Id.* at 1339.
536. *Id.* at 1341.
537. 929 F.3d 1350 (Fed. Cir. 2019).
538. *Id.* at 1354–55.
539. *Id.* at 1356–57.
540. *Id.* at 1354–55.
541. *Id.* at 1355.
542. *Id.* at 1355–56.
543. 927 F.3d 1232 (Fed. Cir. 2019).
544. *Id.* at 1234.

MCI.[545] The Board allowed MSD to amend its mandatory notice to name MCI without altering the petition's filing date.[546] Mayne Pharma argued that the Board should have reset the filing date to the date of the amendment.[547] MSD countered that the Board decision was not appealable and, if it was, should be affirmed because the Board did not err in permitting the amendment.[548]

The Federal Circuit sided with MSD, concluding that, whether or not it was appealable, the Board did not err in permitting the amendment to MSD's real-party-in-interest disclosure without altering the petition's filing date.[549] Citing the Board's finding of "no indication of intentional concealment, no bad faith on MSD's part, no attempt to circumvent the estoppel rules, or any other material benefit to it in its delay in naming MCI as real party in interest," the court held the Board did not err in finding that MSD's amendment would serve the "interest of justice" under 37 C.F.R. § 42.5(c)(3).[550] The court rejected that 37 C.F.R. § 42.104(c), which provides for the correction of a mistake in a petition, was the sole avenue for amending a petition without changing its filing date, citing Board practice and cases to the contrary.[551]

In *BioDelivery Sciences International, Inc. v. Aquestive Therapeutics, Inc.*,[552] the Federal Circuit, in a motions panel order, dismissed appeals from the PTAB's decisions to not institute IPR under 35 U.S.C. § 314(d).[553] BioDelivery filed three petitions for IPR containing a combined total of seventeen grounds.[554] The Board instituted review on one ground from each petition and found all claims subject to the instituted grounds not unpatentable in the final written decisions, which BioDelivery appealed.[555] After oral argument, the Supreme Court decided *SAS Institute, Inc. v. Iancu*, requiring institution to be on all or no claims and grounds.[556] BioDelivery then moved to remand

545. *Id.* at 1237.
546. *Id.* at 1235.
547. *Id.* at 1237.
548. *Id.* at 1237–38.
549. *Id.* at 1238–39.
550. *Id.* at 1239.
551. *Id.* at 1240.
552. 935 F.3d 1362 (Fed. Cir. 2019).
553. *Id.* at 1363.
554. *Id.*
555. *Id.* at 1363–64.
556. *See id.* at 1364 (citing 138 S. Ct. 1348 (2018)).

based on *SAS*, which the Federal Circuit granted.[557] The Board on remand decided not to institute on any of the grounds, relying on its discretion under § 314(a), and BioDelivery, again, appealed.[558]

The motions panel of the Federal Circuit dismissed the appeals, stating that § 314(d) "plainly states that the Patent Office's decision whether to institute IPR is not appealable."[559] The panel reasoned that "[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.'"[560] The panel additionally noted that, even when a petitioner shows a reasonable likelihood of success with respect to at least one claim challenged, the Board has discretion to not institute.[561] Judge Newman dissented, arguing that the Board failed to comply with the remand order by not addressing all the claims and grounds raised by the petition, consistent with *SAS*.[562]

In *VirnetX Inc. v. Apple Inc.*,[563] the Federal Circuit addressed estoppel under 35 U.S.C. § 317(b) (pre-AIA), which estopped parties that had failed to prove invalidity of a patent in district court from requesting inter partes reexamination at the USPTO.[564] VirnetX sued Apple in district court, asserting infringement of four patents, and Apple filed requests for inter partes reexamination of the two patents asserted in the district court.[565] VirnetX prevailed in the district court, which found all asserted claims infringed and not invalid.[566] The Federal Circuit affirmed the finding of no invalidity but vacated and remanded the infringement and damages issues related to the two patents in reexamination, and Apple did not further appeal to the Supreme Court.[567] Meanwhile, in the reexamination proceedings, the PTO examiner found all claims of the two patents unpatentable.[568] VirnetX appealed the decision to the Board and also petitioned the PTO to

557. *Id.*
558. *Id.* at 1364–65.
559. *Id.* at 1366–67.
560. *Id.* at 1366 (quoting Medtronic, Inc. v. Barry, 839 F.3d 1368, 1383 (Fed. Cir. 2018)).
561. *Id.*
562. *Id.* at 1369–70 (Newman, J., dissenting). *See generally* 138 S. Ct. 1348 (2018).
563. 931 F.3d 1363 (Fed. Cir. 2019).
564. *Id.*
565. *Id.* at 1367–68.
566. *Id.* at 1368.
567. *Id.*
568. *Id.*

terminate the reexaminations based on the estoppel provision of § 317(b).[569] The PTO denied the petition, and the Board subsequently affirmed the examiner's decision of unpatentability.[570] VirnetX's appeal to the Federal Circuit followed.[571]

The Federal Circuit agreed with VirnetX that Apple's reexaminations were barred by § 317(b), which provides that a "final decision" in a civil action triggers estoppel in reexamination proceedings.[572] Because the issue of invalidity was decided against Apple in the district court and affirmed on appeal, the court held the validity decision was "final," triggering estoppel in Apple's reexamination proceedings.[573] The court rejected Apple's arguments—that the validity decision was not final because the infringement and damages issues were remanded and because it may file a petition for certiorari on those issues—as contrary to the established case law and the statutory text and purpose of § 317(b).[574] Consequently, the court vacated and remanded the case to the Board with instructions to terminate the reexaminations.[575] Judge Reyna dissented in part, arguing that the estoppel provision of § 317(b) should not be triggered because Apple may still appeal the issues of infringement and invalidity together to the Supreme Court.[576]

In *Celgene Corp. v. Peter*,[577] the Federal Circuit addressed whether "the retroactive application of IPR proceedings to pre-AIA patents is . . . an unconstitutional taking under the Fifth Amendment."[578] In addition to affirming the PTAB's decisions of unpatentability for obviousness, the Federal Circuit exercised its discretion to hear Celgene's constitutional argument despite it not having been raised before the Board.[579] The court recognized the importance of this issue and decided to hear the constitutional challenge, pointing that the Supreme Court's holding

569. *Id.*
570. *Id.*
571. *Id.* at 1369.
572. *Id.* (quoting 35 U.S.C. § 317(b) (2006)).
573. *Id.* at 1370–72.
574. *Id.* at 1370–75, 1378.
575. *Id.* at 1378.
576. *Id.* at 1382–83 (Reyna, J., dissenting).
577. 931 F.3d 1342 (Fed. Cir. 2019).
578. *Id.* at 1346.
579. *Id.* at 1355–57.

in *Oil States Energy Services, LLC v. Greene's Energy Group, LLC*[580] did not directly resolve the issue.[581]

The Federal Circuit held that the retroactive application of IPR proceedings to pre-AIA patents is not an unconstitutional taking, reasoning that there was not a significant difference between IPRs and district court and pre-AIA reexamination proceedings.[582] While acknowledging that IPR proceedings differ from these existing proceedings, the Federal Circuit held that the similarities between IPR and pre-AIA reexamination proceedings were "far more significant."[583] In both proceedings, "patents are reviewed on the same substantive grounds," applying the same preponderance of the evidence standard of proof and the same broadest reasonable interpretation standard for claim construction.[584] Additionally, the Federal Circuit highlighted that both proceedings sought to serve the same purpose: reviewing an earlier agency decision to grant a patent.[585] Consequently, the Federal Circuit held that the differences between IPRs and the district court and pre-AIA reexamination proceedings do not create a constitutional issue when IPR is applied to pre-AIA patents.[586]

In *Arthrex, Inc. v. Smith & Nephew, Inc.* (*Arthrex I*),[587] the Federal Circuit addressed a patent owner's procedural rights and opportunity to be heard under the Administrative Procedure Act (APA).[588] The issue on appeal stemmed from the Board's characterization in the final written decision of a particular process as "preferred," rather than "well-known," "accepted," or "simple" as it was described in the petition.[589] Arthrex argued that the Board violated its APA rights by relying on a new theory of motivation to combine that was not raised in the petition without giving adequate notice of the change.[590] The Federal Circuit held that in finding motivation to combine, the Board relied on the same disclosure of a reference, the same combination of the asserted references, and the same theory of obviousness presented

580. 138 S. Ct. 1365 (2018).
581. *Celgene Corp.*, 931 F.3d at 1356.
582. *Id.* at 1358.
583. *Id.* at 1360.
584. *Id.*
585. *Id.* (quoting Cuozzo Speed Techs., LLC v. Lee, 136 S. Ct. 2131, 2144 (2016)).
586. *Id.* at 1362.
587. 935 F.3d 1319 (Fed. Cir. 2019).
588. *Id.* at 1322.
589. *Id.* at 1326–27.
590. *Id.* at 1326.

by the petition and disputed by the parties.[591] Under the circumstances, the court held that the Board had not violated the APA because the Board's "minor variation" in wording did not deprive Arthrex of an opportunity to be heard.[592] Ultimately, the Federal Circuit affirmed the Board's decision finding the challenged patent claims unpatentable for obviousness.[593]

In *Trading Technologies International, Inc. v. IBG LLC* (*Trading Technologies I*),[594] the Federal Circuit affirmed the PTAB's decisions holding that the patents were eligible for Covered Business Method (CBM) review and the claims were patent ineligible under 35 U.S.C. § 101.[595] The patents at issue in *Trading Technologies I* disclosed a graphical user interface ("GUI") for electronic trading.[596] The court agreed with the PTAB that these patents were eligible for CBM review because their claims were directed to a financial trading method used by a computer and not for a "technological invention" defined in 37 C.F.R. § 42.301(b).[597] The court stated that the claimed inventions were focused on improving the trader, not the computer, and therefore did not provide a "technical solution to a technical problem."[598] The court also held the claims patent ineligible under § 101, holding that the claims were directed to a patent ineligible concept and the claim elements did not transform the nature of the claims into a patent-eligible application.[599]

In *Trading Technologies International, Inc. v. IBG LLC* (*Trading Technologies II*),[600] the Federal Circuit addressed a patent directed to displaying financial market information on a screen.[601] The court agreed with the PTAB that the challenged patent in *Trading Technologies II*, like the patents in *Trading Technologies I*, was eligible for

591. *Id.* at 1327–28.
592. *Id.* at 1322.
593. *Id.* at 1329.
594. 921 F.3d 1084 (Fed. Cir. 2019).
595. *Id.* at 1087 (defining a CBM patent as a "patent that claims a method or corresponding apparatus for performing data processing or other operations used in the practice, administration, or management of a financial product or service" but does not include patents for technological inventions).
596. *Id.*
597. *Id.* at 1089–91.
598. *Id.* at 1090.
599. *Id.* at 1092–94.
600. 921 F.3d 1378 (Fed. Cir. 2019).
601. *Id.* at 1381.

CBM review because it sought to solve the problem that traders needed additional information on a trading screen to effectively analyze the market and therefore was not for a "technological invention."[602] The court also held the claims patent ineligible under § 101 for similar reasons as *Trading Technologies I*: the purported advance over the prior art was an abstract idea of "providing a trader with additional financial information to facilitate market trades," and the claim elements, either individually or as an ordered combination, did not transform the claims into a patent-eligible application.[603]

In *AVX Corp. v. Presidio Components, Inc.*,[604] AVX appealed a decision from the PTAB upholding the patentability of certain claims of the challenged patent.[605] The Federal Circuit, however, dismissed the appeal without reaching its merits because AVX did not have Article III standing to appeal.[606] Although AVX had a statutory right to petition for an IPR at the PTAB because Article III requirements do not apply to administrative agencies, it would lack Article III standing to appeal without showing an injury-in-fact, either through the existing record or through supplementing the record on appeal with affidavits or other evidence.[607] The court rejected AVX's arguments in support of its standing to appeal.

First, AVX argued that it was injured by the Board's decision because the statutory estoppel provision of 35 U.S.C. § 315(e) would prevent it from asserting the same challenges against the upheld claims if Presidio were to assert those claims against AVX in the future.[608] The court rejected this argument for two reasons: (1) the court in previous cases already rejected invocation of the estoppel provision as a sufficient basis for injury in fact,[609] and (2) the court had not yet decided whether estoppel under § 315(e) would be triggered even when the petitioner lacked Article III standing to appeal.[610] The court declined to decide the preclusive effect of § 315(e) because the parties did not brief the issue.[611]

602. *Id.* at 1382–83.
603. *Id.* at 1383–85.
604. 923 F.3d 1357 (Fed. Cir. 2019).
605. *Id.* at 1359.
606. *Id.*
607. *Id.* at 1361–62.
608. *Id.* at 1362.
609. *Id.* at 1362–63.
610. *Id.* at 1363.
611. *Id.* at 1363.

Second, AVX asserted that the PTAB's decision reduced AVX's ability to compete with Patent Owner Presidio Components.[612] The court rejected this argument relying on "competitor standing," which often arises in cases involving government or regulatory actions that impact a business's ability to compete through, for example, lowering prices or limiting sales.[613] The court recounted several such cases where "the challenged government action nonspeculatively threatened economic injury to the challenger by the ordinary operation of economic forces."[614] The court held that the only government action here was upholding certain patent claims, which could have been harmful if AVX was "currently using the claimed features or nonspeculatively planning to do so in competition";[615] however, AVX failed to show that it was engaging, or "nonspeculatively" planning to engage in, conduct arguably covered by the upheld patent claims.[616]

In *Neptune Generics, LLC v. Eli Lilly & Co.*,[617] several IPR petitioners appealed a PTAB decision upholding the patentability of the claims of the challenged patent directed to a method of treatment involving administration of folic acid and a methylmalonic acid lowering agent (e.g., vitamin B12) before administering a particular chemotherapy agent.[618] On appeal, the petitioners argued that the claims were not directed to patentable subject matter, an issue arising under 35 U.S.C. § 101.[619] The Federal Circuit declined to reach this issue because "Congress expressly limited the scope of inter partes review to a subset of grounds that can be raised under 35 U.S.C. §§ 102 and 103"; therefore, § 101 issues cannot be addressed on appeal of an IPR.[620]

In *Power Integrations, Inc. v. Semiconductor Components Industries, LLC*,[621] the Federal Circuit vacated the Board's decision in an IPR finding the challenged patent claims unpatentable and held the IPR time-barred under 35 U.S.C. § 315(b).[622] Prior to the IPR, Patent Owner sued Fairchild for infringement of several patents, including the

612. *Id.*
613. *Id.* at 1363–64.
614. *Id.*
615. *Id.* at 1365.
616. *Id.*
617. 921 F.3d 1372 (Fed. Cir. 2019).
618. *Id.* at 1374.
619. *Id.* at 1378.
620. *Id.*
621. 926 F.3d 1306 (Fed. Cir. 2019).
622. *Id.* at 1308, 1319.

challenged patent in the IPR.[623] Petitioner entered into a merger agreement with Fairchild and, while the merger was pending, filed this IPR more than one year after Fairchild was served with the complaint alleging infringement of the challenged patent.[624] The issue on appeal was "whether privity and RPI [real-party-in-interest] relationships arising after filing but before institution should be considered for purposes of the § 315(b) time-bar."[625] The Federal Circuit held the IPR time-barred "because Fairchild was an RPI at the time the IPR was instituted, even though it was not an RPI at the time the petition was filed."[626] Accordingly, the court remanded for the Board to dismiss the IPR.[627]

In *In re IPR Licensing, Inc.*,[628] the Federal Circuit reversed an IPR decision because the Board erred by relying on a prior art reference that was not cited by the petitioner to support its invalidity argument.[629] The petition asserted three grounds of invalidity, but the Board had only instituted one and the reference at issue was cited only in support of a noninstituted ground.[630] The court explained that the Board's decision could not "rely on evidence relating solely to grounds on which it never instituted," which "a patent owner has no ability to rebut or anticipate."[631] By withdrawing from the appeal, the petitioner had waived its right to request institution of the noninstituted grounds under *SAS*.[632]

In *Amerigen Pharmaceuticals Ltd. v. UCB Pharma GMBH*,[633] the Federal Circuit affirmed the Board's holding in an IPR that the challenged patent's claims were not unpatentable as obvious.[634] The claims related to chemical compounds used to formulate an antimuscarinic drug used to treat urinary incontinence.[635] The court held that Amerigen had appellate standing because the asserted patent blocked Amerigen's launch of its tentatively approved abbreviated new drug

623. *Id.* at 1309.
624. *Id.*
625. *Id.* at 1313.
626. *Id.* at 1318.
627. *Id.* at 1319.
628. 942 F.3d 1363 (Fed. Cir. 2019).
629. *Id.* at 1365.
630. *Id.* at 1368–69.
631. *Id.* at 1369 (citing *In re* Magnum Oil Tools Int'l, Ltd., 829 F.3d 1364, 1381 (Fed. Cir. 2016)).
632. *Id.* at 1372.
633. 913 F.3d 1076 (Fed. Cir. 2019).
634. *Id.* at 1078.
635. *Id.*

application, and invalidation of the patent would advance the drug's launch, which constituted a "concrete, economic interest."[636]

In *Mylan Pharmaceuticals Inc. v. Research Corp. Technologies*,[637] Research Corporation Technologies ("RCT") sued Mylan, Breckenridge, and Alembic (collectively, "Appellants") for patent infringement in 2013.[638] In 2015, another entity, Argentum, petitioned for IPR of RCT's patent, and the Board instituted Argentum's petition on two grounds.[639] Three days after institution, Appellants each filed their own petitions for IPR with concurrent motions for joinder.[640] The Board instituted Appellants' petitions and joined each proceeding with the Argentum proceeding, relying upon the provision of § 315(c), which states that the one-year time bar for IPRs does not apply to requests for joinder.[641] The Board then concluded that none of the challenged claims had been shown to be unpatentable.[642] Appellants appealed, but Argentum did not.[643]

On appeal to the Federal Circuit, RCT did not challenge the Board's joinder decision, but did challenge whether Appellants had standing to appeal.[644] The Federal Circuit looked to the plain text of 35 USC § 315(c), which provides that the Board may join as a party any person who properly files a petition.[645] Next, the court looked to 35 U.S.C. § 319, which provides that "[a]ny party to the inter partes review shall have the right to be a party to the appeal."[646] The court held that once the Board joined Appellants as parties, they had a statutory right to appeal under § 319.[647]

B. Anticipation

As expected, many of the cases appealed to the Federal Circuit from the PTAB centered on anticipation and obviousness issues. Indeed, the court in *Artic Cat Inc. v. GEP Power Products, Inc.*[648] held that the Board

636. *Id.* at 1083–85.
637. 914 F.3d 1366 (Fed. Cir. 2019).
638. *Id.* at 1371.
639. *Id.* at 1370–71.
640. *Id.* at 1371.
641. *See id.* at 1371–72.
642. *Id.*
643. *Id.* at 1372.
644. *Id.*
645. *Id.* at 1373.
646. *Id.*
647. *Id.*
648. 919 F.3d 1320 (Fed. Cir. 2019).

erred by applying "too rigid a standard" in a diligence analysis.[649] Here, even though a prior art patent was filed seven months before the priority date of the patent at issue, the inventor conceived of the invention and diligently reduced it to practice prior to the filing date of the prior art patent.[650] The court explained that "diligence need not be perfectly continuous—only *reasonably* continuous."[651] The court noted that most of the "identified gaps in [the inventor's] personal activity" could be attributed to third-party testing of the invention and further held third-party testing "does not give rise to an inference of unreasonable delay or abandonment."[652] As a result, the earlier filed patent was not prior art.[653] Therefore, with respect to one of the patents in issue, the court reversed in part, vacated in part, and remanded for further proceedings consistent with its opinion.[654]

Similarly, the Federal Circuit in *Samsung Electronics Co. v. Infobridge PTE, Ltd.*[655] vacated and remanded the Board's decision for incorrectly dating a prior art reference. Here, the Board determined, "Samsung failed to show that a certain prior art reference was publicly accessible before the . . . critical date [of the patent at issue] and thus could not be considered prior art."[656] Judge O'Malley first discussed Samsung's standing to appeal the Board's decision.[657] Samsung argued that it was being deprived of royalties which could be traced to the validity of Infobridge's patent, and the court agreed, stating "[w]hile other licensing and royalty structures might compel a different result where other standard-essential patents are involved, the unique pool license here satisfies us that Samsung has standing in this appeal."[658]

Second, the court held the Board erred in evaluating whether a prior art reference, named Working Draft 4 ("WD4 reference"), had been publicly accessible.[659] The WD4 reference was discussed at meetings, available on websites, and distributed through listservs to a group of

649. *Id.* at 1331.
650. *Id.* at 1325, 1331–32.
651. *Id.* at 1331.
652. *Id.* at 1332 (citing Perfect Surgical Techniques, Inc. v. Olympus Am., Inc., 841 F.3d 1004, 1009 (Fed. Cir. 2016)).
653. *Id.* at 1332.
654. *Id.* at 1333.
655. 929 F.3d 1363 (Fed. Cir. 2019).
656. *Id.* at 1365.
657. *Id.* at 1367.
658. *Id.* at 1368.
659. *Id.* at 1365, 1375.

about 250 participants of a July 2011 meeting in Torino, Italy.[660] However, in analyzing whether the WD4 reference was publicly available, given the factual circumstances surrounding the distribution of reference, "the Board should have considered whether Samsung's evidence established that an ordinarily skilled artisan could have accessed the WD4 reference, after exercising reasonable diligence, based on the listserv email."[661] The court further concluded that the Board had inappropriately focused on whether persons of ordinary skill actually received the listserv email.[662]

And, in *ATI Technologies ULC v. Iancu*,[663] the Federal Circuit reversed the Board's decision that patents directed to computer 3D-imaging software were unpatentable over prior art for the applicant's failure to show diligent reduction to practice.[664] The court held that the Board erred by requiring a showing of "continuous reasonable diligence" instead of the correct "reasonably continuous diligence" standard.[665] ATI had presented almost 1300 pages of documentary evidence of activity on "every business day" before ATI's effective filing date, including document logs and folder histories showing the work done, when and by whom it was done, and the stages of the product over time.[666] The Board had reasoned that the evidence was "not self-explanatory and [did] not explain meaningfully as to which tasks [were] reasonably necessary" for reduction to practice of claimed elements and optional features, and that ATI failed to identify unexplained lapses.[667] The Federal Circuit criticized this overly strict standard and explained that ATI had more than met its burden with its evidence, and the Board had no basis for finding ATI's technology had not been diligently pursued.[668]

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660. *Id.* at 1366.
661. *Id.* at 1374–75.
662. *Id.*
663. 920 F.3d 1362 (Fed. Cir. 2019).
664. *Id.* at 1364–65. Under 37 CFR § 1.131, prior art references may be "sw[orn] behind" if the applicant shows either prior reduction to practice or prior conception coupled with due diligence. *See id.* at 1369 (citing MANUAL OF PATENT EXAMINING PROCEDURE (MPEP) § 715 (9th ed. 2018)). This case concerns the latter. Proving conception and due diligence requires documentary support in the form of affidavits or declarations supported by original exhibits of drawings or records. *Id.*; *see also* 37 C.F.R. § 1.131(b).
665. *ATI Techs. ULC*, 920 F.3d at 1370.
666. *Id.*
667. *Id.* at 1372.
668. *Id.* at 1373.

In *Telefonaktiebolaget LM Ericsson v. TCL Corp.*,[669] the Federal Circuit addressed whether a foreign publication was available as a prior art reference against the patent at issue.[670] The patent involved an "improvement over conventional modes of receiving and processing wireless signals from communication systems that operate at differing frequencies."[671]

At the PTAB, petitioner, TCL, attempted to rely on an article published in the May/June 1996 edition of a German journal.[672] Patent owner, Ericsson, argued that the publication was not publicly available more than one year before the filing date of July 1, 1997.[673] TCL attempted to establish public availability by submitting the statement of a German librarian stating that the reference was available before the critical date, but it was excluded as hearsay when the librarian refused to give a sworn statement or testify.[674]

TCL then submitted the sworn statement of a second German librarian, and Ericsson objected, stating that the submission was inadmissible because it was untimely, and thus not in compliance with the Board's rules.[675] The Board ultimately held that the declaration met regulatory standards, accepted the submission of the statement, and found the claims to be unpatentable.[676]

On appeal, the Federal Circuit first held that the Board did not abuse its discretion by allowing the second librarians sworn statement in as evidence because the evidence was "reasonably viewed as material, and the opponent [had an] adequate opportunity to respond."[677] The court then went on to hold that the reference at issue was publicly available prior to the critical date of the patent and that there was substantial evidence supporting the Board's decision.[678] The Federal Circuit also affirmed the Board's decision that the patent claims were obvious.[679]

In *Honeywell International Inc. v. Arkema Inc.*,[680] the Federal Circuit concluded that the PTAB abused its discretion when it rejected

669. 941 F.3d 1341 (Fed. Cir. 2019).
670. *Id.* at 1342.
671. *Id.* at 1342–43.
672. *Id.* at 1344.
673. *Id.*
674. *Id.* at 1344–45.
675. *Id.* at 1345.
676. *Id.* at 1342, 1345.
677. *Id.* at 1345.
678. *Id.* at 1347.
679. *Id.* at 1351.
680. 939 F.3d 1345 (Fed. Cir. 2019).

Honeywell's request to file a motion for leave to seek a certificate of correction from the PTO Director.[681] Honeywell's patent, issued in 2015, recited a chain of priority applications dating back to 2002; however, when Honeywell canceled all twenty claims and added new matter to its application, it failed to make those amendments in the priority applications.[682] As a result, the patent's priority date was challenged during post-grant review due to a lack of written description in the priority applications.[683] Because the PTAB has exclusive jurisdiction over post-issuance review proceedings, Honeywell requested permission for a motion to leave in order to then request a certificate of correction from the PTO Director to amend the priority chain.[684] Under 35 U.S.C. § 255, the Director alone has the discretion to determine when a certificate of correction is appropriate.[685] The Board cannot review the merits of the patentee's position on whether a mistake is correctable but must only determine whether there is a sufficient basis to support that position.[686] The Board decided that Honeywell had failed to show that the requirements of § 255 were met. By deciding Honeywell's petition on the merits, the Board incorrectly assumed the authority delegated to the Director by § 255.[687]

C. Obviousness

Many of the court's obviousness opinions were for appeals originating in the PTAB. One such case was *Realtime Data, LLC v. Iancu*.[688] In this appeal from an *IPR*, the Federal Circuit affirmed the PTAB's final written decision finding all challenged claims unpatentable as obvious over the asserted prior art.[689] On appeal, Realtime Data, LLC ("Realtime") challenged whether the PTAB erred in its determination that an ordinary artisan would have been

681. *Id.* at 1346.
682. *Id.*
683. *Id.*
684. *Id.* at 1347–48 (citing 37 C.F.R. § 1.323 (2019)).
685. A certificate of correction is appropriate when there is a "mistake of a clerical or typographical nature, or of minor character, which was not the fault of the Patent and Trademark Office." 35 U.S.C. § 255 (2012); *see also Honeywell*, 939 F.3d at 1348 (holding the PTAB abused its discretion by assuming the power held by the Director to issue certificates of correction under 35 U.S.C. § 255).
686. *Honeywell*, 939 F.3d at 1349.
687. *Id.* at 1347, 1350.
688. 912 F.3d 1368 (Fed. Cir. 2019).
689. *Id.* at 1369–70.

motivated to combine teachings from two prior art references.[690] The court rejected Realtime's contention, holding that the specific obviousness ground raised by the petitioner did not require the PTAB to make any findings as to the motivation to combine.[691] In particular, although the ground identified two references, it in actuality was a single reference obviousness challenge that merely cited a second reference to inform how an ordinary artisan would understand the first—not for any element or teaching it might include.[692]

In *Personal Web Technologies, LLC v. Apple, Inc.*,[693] Apple Inc. petitioned for IPR of a patent owned by Personal Web Technologies, LLC ("Personal Web"), alleging its claims would have been obvious in view of two prior art references.[694] The claims covered a method and an apparatus for avoiding problems that arise during traditional naming of protocols in a conventional data processing system, such as duplication of a data item.[695] The PTAB determined the claims would have been obvious in part by finding that one of the prior art references inherently taught a claim limitation.[696]

The Federal Circuit reversed, holding this inherency finding lacked substantial evidentiary support.[697] The court explained that, although it was possible that the prior art used the claim limitation, the patentee identified an equally plausible, "if not more plausible," understanding of the prior art that *would not use* the claim element.[698] Because inherency cannot be shown by probabilities or possibilities but must necessarily exist, the court held that the patentee's equally-plausible alternative precluded a holding that the prior art reference inherently disclosed the claim element.[699] The PTAB's reliance on inherency to establish obviousness was, therefore, deemed improper.[700]

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690. *Id.* at 1372.

691. *Id.* at 1373. The Court noted that the petitioner raised its ground in the alternative, either (1) as a single reference obviousness ground that relied on a second reference to explain how a skilled artisan would understand the first, or (2) as a two-reference obviousness ground. *Id.* at 1372–73. The PTAB adopted the former theory in its final written decision. *Id.* at 1372.

692. *Id.* at 1373.

693. 917 F.3d 1376 (Fed. Cir. 2019).

694. *Id.* at 1377.

695. *Id.* at 1377–78.

696. *Id.* at 1378, 1381.

697. *Id.* at 1377.

698. *Id.* at 1382.

699. *Id.*

700. *Id.* at 1382–83.

In *Game & Technology Co. v. Activision Blizzard Inc.*,[701] the Federal Circuit affirmed a PTAB final written decision determining that challenged claims would have been obvious.[702] The patent disclosed a method and system for providing game items to Internet game characters and generating a type of avatar, which the patent referred to as a "gamvatar," that is equipped with particular game items.[703] The PTAB determined the claims would have been obvious in view of a manual alone, or in view of the manual and a published U.S. patent application.[704] On appeal, the patentee challenged the PTAB's conclusion that the manual disclosed or rendered obvious the claimed "gamvatar."[705] In particular, it argued that the manual did not describe using a "gamvatar" in a location distinct from a specific game or using one that had layers for performing certain game item functions.[706] It also argued one reference could not provide the basis for an obviousness challenge.[707] The Federal Circuit rejected these contentions, stating that substantial evidence supported the PTAB's finding regarding the manual's teachings and that a single reference may provide the basis for an obviousness challenge.[708]

In *Kolcraft Enterprises, Inc. v. Graco Children's Products, Inc.*,[709] the Federal Circuit affirmed the PTAB's determination that the patentee failed to antedate the prior art and thereby affirmed the PTAB's decision holding the claims unpatentable.[710] Graco Children's Products, Inc. ("Graco") filed two petitions for IPR that challenged two design patents owned by Kolcraft Enterprises, Inc. ("Kolcraft").[711] Kolcraft did not submit a patent owner preliminary response, but after the PTAB instituted both petitions, Kolcraft submitted a brief patent owner response that included an inventor declaration, with exhibits purporting to show conception and reduction to practice before the prior art.[712] The exhibits appended to the declaration did not, on their

701. 926 F.3d 1370 (Fed. Cir. 2019).
702. *Id.* at 1373.
703. *Id.*
704. *Id.* at 1380.
705. *Id.*
706. *Id.*
707. *Id.* at 1381.
708. *Id.* at 1380–81.
709. 927 F.3d 1320 (Fed. Cir. 2019).
710. *Id.* at 1321.
711. *Id.* at 1322.
712. *Id.* at 1322–23.

face, identify a specific conception date or author, and the declaration redacted relevant date information "using blank spaces where relevant dates would have been."[713] During deposition, the inventors explained that relevant date information was in the metadata of computer files containing the exhibits.[714] Before the hearing, Kolcraft filed an unredacted version of the declaration.[715] Kolcraft never submitted the computer files with the metadata.[716]

The PTAB declined to review the unredacted declaration, considering it waived because it was raised for the first time at the oral hearing.[717] In view of the other remaining evidence of record, the PTAB concluded Kolcraft failed to show conception and reduction to practice before the prior art.[718] In particular, it reasoned the inventors' testimony was not sufficiently corroborated by noninventor testimony, documents, or other evidence.[719] Kolcraft failed to antedate the prior art and the PTAB held the challenged claims were unpatentable.[720]

On appeal, Kolcraft only challenged the PTAB's decision on conception and reduction to practice.[721] The Federal Circuit affirmed the PTAB's decision, holding that it was supported by record evidence.[722] The court held Kolcraft failed to corroborate its inventors' testimony because it did not submit testimony, documents, or evidence that did not derive from the inventors.[723] It noted that although the court was "capable of comparing the photos and sketches," the exhibits were undated and lacked a showing of authorship; thus, they could not offer corroboration.[724] Likewise, the metadata could not corroborate the exhibits as it was not entered into the record.[725] As Kolcraft did not antedate the prior art reference, the PTAB's conclusion of obviousness was proper.[726]

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713. *Id.* at 1323.
714. *Id.*
715. *Id.*
716. *Id.*
717. *Id.*
718. *Id.*
719. *Id.*
720. *Id.* at 1321.
721. *Id.* at 1323–24.
722. *Id.* at 1326.
723. *Id.* at 1323–24.
724. *Id.* at 1325.
725. *Id.*
726. *Id.* at 1325–26.

In *Cisco Systems, Inc. v. TQ Delta, LLC*,[727] the Federal Circuit vacated and remanded the PTAB's decision confirming the patentability of certain claims, holding that the PTAB relied on an incorrect construction of the term "synchronization signal."[728] According to the court, the PTAB improperly imported limitations from the specification and limited the term to "the 'advantageous' clock-based preferred embodiment."[729] In the court's view, the specification broadly prescribed a number of "[o]ther forms of timing signals."[730] It therefore reasoned that the broadest reasonable interpretation of the term is "not limited to describing what the signal must synchronize or to a particular type of synchronization."[731] In light of this understanding, the court construed "synchronization signal" to mean "'used to establish or maintain a timing relationship between transceivers between the transmitter of the signal and the receiver of the signal,' meaning synchronization signal includes frame synchronization."[732] It then remanded the case for the PTAB to assess the asserted ground of unpatentability in view of the new construction in the first instance.[733]

In *Sony Corp. v. Iancu*,[734] the Federal Circuit vacated the PTAB's claim construction and remanded for the PTAB to consider patentability in view of a new claim construction.[735] The relevant term to be construed was "reproducing means," and there was no dispute this term was a means-plus-function limitation.[736] The parties agreed the relevant function was "reproducing the audio data of the channel designated by the default value stored in the storing means."[737] The parties disputed, however, what structure corresponded to that function.[738] Sony argued that the corresponding structure was a computer and the

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727. 928 F.3d 1359 (Fed. Cir. 2019).
728. *Id.* at 1361–63.
729. *Id.* at 1363 (citing Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 913 (Fed. Cir. 2004)).
730. *Id.*
731. *Id.*
732. *Id.* at 1364.
733. *Id.*
734. 924 F.3d 1235 (Fed. Cir. 2019).
735. *Id.* at 1237.
736. *Id.* at 1239.
737. *Id.*
738. *See id.* (stating that Sony agreed with the Director as to the function performed by the reproducing means but argued that the PTAB misconstrued the reproducing means limitation).

associated algorithm needed to carry out the claimed function.[739] The PTAB disagreed and concluded that the limitation was instead implemented in hardware, a controller and a synthesizer, or equivalent, and therefore did not require any algorithm.[740]

The court agreed with Sony.[741] According to the court, the patent related to a computer-implementation of the reproducing means and was therefore limited to the algorithm provided in the specification.[742] If the reproducing means were implemented in hardware, as the PTAB determined, the court stated it would expect the specification to describe the circuitry in the controller required to perform the claimed function—such an indication was absent.[743] As the PTAB had not assessed whether the asserted prior art disclosed the claimed algorithm, the court remanded for the PTAB to make that assessment in the first instance.[744]

In *Samsung Electronics Co. v. Elm 3DS Innovations, LLC*,[745] the Federal Circuit affirmed the PTAB's final written decisions confirming the patentability of the challenged claims.[746] At issue were thirteen IPR proceedings challenging 105 claims across eleven patents related to semiconductor fabrication.[747] Each ground of unpatentability relied upon the combination of a primary reference, Bertin or Yu, with Leedy.[748] Each of these references described different dielectric materials and fabrication techniques, and Leedy was relied upon for its disclosure of "flexible membranes formed of very thin low stress dielectric materials" deposited via plasma-enhanced chemical vapor deposition.[749] The PTAB found that a skilled artisan would not have had a reasonable expectation of success in combining the teachings.[750]

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739. *Id.* at 1240.
740. *Id.*
741. *Id.*
742. *Id.*
743. *Id.*
744. *Id.* at 1241. However, in Judge Newman's view, the Court lacked jurisdiction to hear Sony's appeal because the patent-in-suit "expired in August 2017; the IPR petitioner, ARRIS, decline[d] to defend its PTAB victory; and the parties have settled the infringement suit in district court"—there was not a live case or controversy to satisfy the requirements of Article III. *Id.* at 1241 (Newman, J., dissenting).
745. 925 F.3d 1373 (Fed. Cir. 2019).
746. *Id.* at 1375.
747. *Id.*
748. *Id.* at 1380.
749. *Id.*
750. *Id.* at 1380–81.

Crediting the patentee's expert testimony explaining the complexity and nuances involved in fabricating integrated circuits, the PTAB found petitioners' contentions that Leedy suggested a benefit for using its material and technique, and that the references were in the same field, insufficient to satisfy their burden.[751]

The Federal Circuit affirmed, holding substantial evidence supported the PTAB's finding of no reasonable expectation of success.[752] It found persuasive, in view of the "complexity of semiconductor fabrication," that a skilled artisan would not reasonably expect to successfully change the primary reference's fabrication to use Leedy's dielectric material and fabrication technique.[753] It noted eighteen factors are considered when selecting a dielectric and method of formation and "most of these factors are unknown here with respect to Leedy's dielectric" and formation.[754] It also noted the fabrication technique in Leedy was "quite different" than those disclosed in the primary references and would introduce impurities incompatible with the designs in the primary references.[755] The court agreed with the PTAB that this would all in turn prevent a skilled artisan from "conclud[ing] that it would have been obvious to make the proposed substitution."[756]

In *Celgene Corp. v. Peter*, the Federal Circuit affirmed the Board's obviousness determination for patent claims directed to methods for delivering a drug such that adverse effects were prevented.[757] The Federal Circuit affirmed that the Board's finding of no long-felt need was not irreconcilable with finding a motivation to combine the prior art references to reach the claims at issue.[758] The Federal Circuit agreed that, especially when safety is involved, there is "no conflict between finding a motivation to improve the safety of existing systems even though the existing systems were mostly successful."[759]

Neptune Generics, LLC and Mylan Laboratories Ltd. appealed a series of IPR decisions concerning Eli Lilly's patents directed to a

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751. *Id.* at 1381.
752. *Id.* at 1383.
753. *Id.* at 1381–82.
754. *Id.* at 1381.
755. *Id.* at 1382.
756. *Id.* at 1381–82.
757. 931 F.3d 1342, 1464 (Fed. Cir. 2019).
758. *Id.* at 1352–53.
759. *Id.* at 1353.

method of treatment involving administration of folic acid and vitamin B12 with a particular chemotherapy agent in *Neptune Generics, LLC v. Eli Lilly & Co.*[760] The Federal Circuit affirmed the Board's decision that the patents were not obvious, and held that substantial evidence supported the Board's conclusions.[761] In particular, the FDA did not support Eli Lilly's addition of folic acid and vitamin B12 to the treatment during clinical trials but allowed the trials to continue regardless of its concerns.[762] The Board and Federal Circuit determined that agency concern or lack of support did constitute actual skepticism, as skepticism need not only be premised on whether claimed subject matter is "technically infeasible," "unworkable," or "impossible" and would work for its intended purpose.[763] The Federal Circuit explained that precedent "recognizes a range of third-party opinion that can constitute skepticism," including sentiments of worry or surprise.[764] The court also noted that while evidence that third parties found the invention impossible might be due *more* weight, the Board did not err in giving weight to the skepticism evidence here.[765]

In *Henny Penny Corp. v. Frymaster LLC*,[766] the Federal Circuit affirmed an IPR decision holding the challenged claims not unpatentable as obvious.[767] As an initial matter, the Federal Circuit held that the Board did not abuse its discretion in disregarding an argument for obviousness that was first raised in the petitioner's reply.[768]

As for the Board's obviousness decision, Henny Penny argued that the Board, in analyzing the motivation to combine references, placed too much weight on the disadvantages of combining references.[769] The Federal Circuit rejected the argument, concluding that the Board's factual analysis was "consistent with the longstanding principle that the prior art must be considered for all its teachings, not selectively" and moreover was supported by substantial evidence.[770] The court also

760. 921 F.3d 1372, 1374 (Fed. Cir. 2019).
761. *Id.* at 1374–75.
762. *Id.* at 1377–78.
763. *Id.* at 1378.
764. *Id.* (citing Circuit Check Inc. v. QXQ Inc., 795 F.3d 1331, 1337 (Fed. Cir. 2015)).
765. *Id.*
766. 938 F.3d 1324 (Fed. Cir. 2019).
767. *Id.* at 1326.
768. *Id.* at 1330–31.
769. *Id.* at 1331.
770. *Id.* at 1332.

affirmed the Board's decision regarding industry praise.[771] The Board held that the claim was "commensurate in scope" and that "the evidence of praise was generally directed to the claimed invention as a whole."[772] The Federal Circuit affirmed the Board, noting that "industry praise is probative of nonobviousness even if it was not precisely limited to the point of novelty of the claimed combination."[773]

The Federal Circuit addressed the "analogous art" doctrine in *Airbus S.A.S. v. Firepass Corp.*[774] This case started as an inter partes reexamination where the patent owner appealed an examiner's rejection based on obviousness.[775] In an appeal to the Board, the patent owner, Firepass, argued that the references used against it were not analogous art.[776] The Board agreed with Firepass and reversed the examiner's rejection, and Airbus appealed.[777]

As an initial matter, the Federal Circuit explained the standard of analogous art, stating,

> [t]wo separate tests define the scope of analogous prior art: "(1) whether the art is from the same field of endeavor, regardless of the problem addressed and, (2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved."[778]

The Federal Circuit agreed with the Board's finding under the first prong of the test, but it disagreed with the analysis under the second, reasonably pertinent, prong.[779] The court held that when making a determination of whether a prior art reference is reasonably pertinent, making it analogous art, "a reasonable factfinder should consider record evidence cited by the parties to demonstrate the knowledge and perspective of a person of ordinary skill in the art at the time of the invention."[780]

By not considering Airbus's cited references, the Federal Circuit held that the Board essentially refused to consider record evidence offered by the patent challenger.[781] The court also held that this refusal

771. *Id.* at 1333–34.
772. *Id.* at 1333.
773. *Id.* at 1334.
774. 941 F.3d 1374, 1375 (Fed. Cir. 2019).
775. *Id.* at 1377.
776. *Id.* at 1379.
777. *Id.*
778. *Id.* (quoting *In re* Bigio, 381 F.3d 1320, 1325 (Fed. Cir. 2004)).
779. *Id.* at 1380–84.
780. *Id.* at 1383.
781. *Id.*

was erroneous, and thus, it vacated the Board's decisions and remanded the case.[782]

In *OSI Pharmaceuticals, LLC v. Apotex Inc.*,[783] the Federal Circuit reversed the PTAB's finding that claims forty-four through forty-six and fifty-three of OSI's cancer treatment patents were unpatentable as obvious. OSI's patent covered a method of using erlotinib to treat non-small cell lung cancer (NSCLC).[784] Prior art broadly disclosed several compounds with anti-cancer activity and the use of erlotinib as an epidermal growth factor receptor inhibitor to potentially treat some cancers, not including NSCLC.[785] The Board found that a person of ordinary skill in the art would have been motivated to combine these references with a reasonable expectation of success.[786] The court disagreed and held that the Board's decision that the references provide a reasonable expectation of success was not supported by substantial evidence.[787] The prior art did not disclose any preclinical or clinical data about erlotinib's efficacy in treating NSCLC.[788] Though efficacy data is not normally required to show a reasonable expectation of success, it was necessary here because NSCLC treatment was highly unpredictable at the time, with over 99.5% rate of failure for drugs entering Phase II clinical studies.[789]

In *Liqwd, Inc. v. L'Oreal USA, Inc.*,[790] the Federal Circuit vacated and remanded the PTAB's post-grant decision that Liqwd's claims directed to keratin treatment formulations and methods were obvious because the Board erred in its weighing of evidence.[791] During the PGR, the PTAB found that claims one through eight and ten were invalid as obvious over prior art references.[792] When considering arguments and evidence of objective indicia of nonobviousness such as copying and unfelt need, the Board found that L'Oreal would not have developed its products without having access to Liqwd's confidential

782. *Id.* at 1384.
783. 939 F.3d 1375 (Fed. Cir. 2019).
784. *Id.* at 1378–79.
785. *Id.* at 1384–85.
786. *Id.* at 1381.
787. *Id.* at 1383.
788. *Id.*
789. *Id.* at 1385.
790. 941 F.3d 1133 (Fed. Cir. 2019).
791. *Id.* at 1134–35.
792. *Id.* at 1135.

information.[793] But the Board disregarded this finding as legally irrelevant because Liqwd had not shown that L'Oreal copied a specific product.[794] Distinguishing its earlier case *Iron Grip Barbell Co. v. USA Sports, Inc.*,[795] where it stated that "copying requires the replication of a specific product," the court held that the Board erred.[796] Unlike cases where the only circumstantial evidence of copying is a competitor's product arguably falling within the scope of the patent, evidence of actual copying—a competitor having access to publications, patents, or other proprietary information and then using for their own product—is always relevant.[797] Liqwd provided evidence of L'Oreal's copying efforts which should have been considered in the Board's obviousness analysis.[798]

D. Inventorship

Interestingly, the court had an opportunity to issue a ruling regarding inventorship. In *Duncan Parking Technologies, Inc. v. IPS Group, Inc.*,[799] Duncan Parking Technologies, Inc. ("DPT") appealed an IPR decision that certain of IPS Group's ("IPS") patents were not shown to be unpatentable as anticipated under pre-AIA 35 U.S.C. § 102(e).[800]

The two patents at issue in the IPR were unrelated, but both directed to similar parking meter technology.[801] While U.S. Patent No. 8,595,054 ("the '054 patent") issued from an application filed more than one year prior to the filing of the application that issued as U.S. Patent No. 7,854,310 ("the '310 patent"), both patents named IPS's founder and CEO, Dave King, as an inventor.[802] The '054 patent additionally listed IPS's Chief Technical Officer Alexander Schwartz as an inventor, while the '310 patent listed several engineers from an outside design firm.[803] IPS did not dispute anticipation on the merits but instead argued that the anticipating portions of the '054 patent were solely the invention of King, and not that of "another" as required

793. *Id.* at 1136.
794. *Id.*
795. 392 F.3d 1317 (Fed. Cir. 2004).
796. *Id.* at 1325; *see Liqwd, Inc.*, 941 F.3d at 1137.
797. *Liqwd, Inc.*, 941 F.3d at 1137–38.
798. *Id.* at 1138–39.
799. 914 F.3d 1347 (Fed. Cir. 2019).
800. *Id.* at 1351.
801. *Id.* at 1352–54.
802. *Id.* at 1352–53.
803. *Id.*

by § 102(e).[804] DPT argued that Schwartz conceived at least a portion of the anticipating disclosure.[805] The Board had agreed with IPS, being "skeptical that the general recitation . . . of connections and operative associations of components constitutes more than what Mr. King broadly envisioned."[806] "The Board ultimately held that King was the sole inventor of the anticipating disclosure of the '054 patent" and thus several claims of the '310 patent "were held not unpatentable as anticipated by the '054 patent."[807]

The Federal Circuit reversed, holding that the Board had committed clear error in finding that Schwartz was not a joint inventor of the anticipating portions of the '054 patent, rendering it a disclosure "by another" for purposes of § 102(e).[808] The Federal Circuit articulated that whether a reference patent is "by another" for § 102(e) purposes required the Board to

> (1) determine what portions of the reference patent were relied on as prior art . . . , (2) evaluate the degree to which those portions were conceived "by another," and (3) decide whether that other person's contribution is significant enough, when measured against the full anticipating disclosure, to render him a joint inventor of the applied portions of the reference patent.[809]

Applying this standard, the court held that Schwartz was a joint inventor of the anticipating disclosure, having contributed significantly to conceiving details of the '054 device's electrical system, beyond King's broad initial idea.[810]

E. Patent Term Adjustment

The Federal Circuit issued three cases surrounding patent term adjustment ("PTA").

First, in *Supernus Pharmaceuticals, Inc. v. Iancu*,[811] the court determined that the USPTO exceeded its statutory authority when issuing a reduction in PTA for a drug patent based on unavoidable delay.[812] The question before the Federal Circuit was whether the

804. *Id.* at 1356.
805. *Id.*
806. *Id.*
807. *Id.*
808. *Id.* at 1357.
809. *Id.* at 1358.
810. *Id.* at 1359.
811. 913 F.3d 1351 (Fed. Cir. 2019).
812. *Id.* at 1352.

USPTO could reduce PTA by a period that exceeded the "time during which the applicant failed to engage in reasonable efforts to conclude prosecution."[813] Because there were no efforts that Supernus could have taken during most of the delay, the Federal Circuit held that the USPTO's assessment was contrary to the plain meaning of the statute.[814] The total reduction was not equal to the period during which Supernus failed to engage in reasonable efforts to conclude prosecution.[815] As such, the Federal Circuit reversed and remanded the district court's final judgment.[816]

Second, the court in *Mayo Foundation for Medical Education & Research v. Iancu*[817] evaluated whether PTA was available where there was continued examination after an interference proceeding had concluded.[818] Here, Mayo argued that declaration of an interference terminates an applicant's request for continued examination time for the purposes of calculating patent office delay such that it comprises an indication of allowability, much like notice of allowance.[819] As such, Mayo believed that PTA should include all of the time after the expiration of the interference, as any further evaluation of patentability would constitute delay attributable to the USPTO, not the applicant.[820] The USPTO, the district court, and ultimately the Federal Circuit disagreed.[821] Relying mostly on USPTO procedures and statutory interpretation, the Federal Circuit affirmed, stating that it upheld the USPTO's interpretation of "any time consumed by continued examination of the application requested by the applicant under [35 U.S.C. §] 132(b)."[822] The Federal Circuit explained that following the filing of a Request for Continued Examination ("RCE"), "the time between termination of an interference and the date of mailing of the Notice of Allowance is 'time consumed by continued examination of the application requested by the applicant.'"[823]

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813. *Id.* at 1357 (quoting 35 U.S.C. § 154(b)(2)(C)(i)(2012)).
814. *Id.* at 1360–61.
815. *Id.* at 1360.
816. *Id.* at 1361.
817. 938 F.3d 1343 (Fed. Cir. 2019).
818. *Id.* at 1345.
819. *Id.* at 1348.
820. *Id.*
821. *Id.* at 1348–51.
822. *Id.* at 1345 (quoting 35 U.S.C. § 154(b)(1)(B)(i) (2012)).
823. *Id.* at 1351 (quoting § 154(b)(1)(i)).

Finally, in *Intra-Cellular Therapies, Inc. v. Iancu*,[824] the Federal Circuit again addressed the issue of PTA.[825] This appeal came out of a district court's decision to uphold the determination of PTA by the USPTO.[826] The primary issue before the Federal Circuit was "whether an applicant submission, filed after a *final* Office action, that continues to argue the merits of the examiner's rejection, without good cause" may accumulate applicant delay for PTA.[827]

Ultimately, the Federal Circuit held that the USPTO properly constructed the PTA statute with respect to its interpretation of an after-final submission that failed to put the application in condition for allowance.[828] The court held that Intra-Cellular's response constituted a "fail[ure] to engage in reasonable efforts to conclude prosecution," and as such, the district court properly granted summary judgment in favor of the USPTO.[829]

F. Federal Circuit Procedures

The court had occasion to analyze Federal Circuit standing after an IPR. In *Momenta Pharmaceuticals, Inc. v. Bristol-Myers Squibb Co.*,[830] Momenta Pharmaceuticals, Inc. ("Momenta") petitioned for an IPR of a patent owned by Bristol-Myers Squibb Company ("BMS").[831] The patent covered a product that BMS marketed under the brand name Orencia®.[832] At the time Momenta petitioned for IPR, it was attempting to develop a biosimilar counterpart to the Orencia® product.[833] The Board sustained patentability of the claims and Momenta appealed to the Federal Circuit.[834]

On appeal, the Federal Circuit dismissed Momenta's appeal for lack of standing and mootness.[835] BMS argued that Momenta lacked standing because its proposed product had failed clinical trials and had

824. 938 F.3d 1371 (Fed. Cir. 2019).
825. *Id.* at 1373.
826. *Id.*
827. *Id.* at 1379.
828. *Id.* at 1381.
829. *Id.* at 1380–81, 1384 (alteration in original).
830. 915 F.3d 764 (Fed. Cir. 2019).
831. *Id.* at 765.
832. *Id.* at 765–66.
833. *Id.* at 766.
834. *Id.* at 765–66.
835. *Id.* at 770.

been withdrawn.[836] BMS supported this assertion with press releases and SEC filings from Momenta that revealed it had terminated its participation in the development program for the biosimilar.[837] The Federal Circuit held that because of this termination, Momenta had failed to show "an invasion of a legally protected interest" that was "actual or imminent, not conjectural or hypothetical."[838] Further, IPR estoppel did not create an injury-in-fact because Momenta was no longer engaged in any activity that would give rise to a possible infringement suit.[839] As a result, Momenta further lacked standing to appeal.[840] The Federal Circuit also determined that the appeal was moot because Momenta ceased the potential infringement and thus ended the potential for injury.[841]

VI. REMEDIES

A. Attorney Fees

Attorney fees were a hot topic in the Federal Circuit this year. In *Elbit Systems Land & C4I Ltd. v. Hughes Network Systems, LLC*,[842] following a finding that Hughes infringed Elbit's '073 patent, the jury at the district court awarded Elbit over $21 million in damages.[843] Notably, the district court also found this case was exceptional and awarded Elbit attorney fees.[844] At issue on appeal was infringement of claims two through four of the '073 patent and the exceptionality determination; as the district court did not quantify the award of attorney fees, the Federal Circuit only addressed the district court's exceptionality finding.[845]

The Federal Circuit, while affirming the jury's damages award, held it lacked jurisdiction to rule on whether this was an exceptional case and whether Elbit was entitled to attorney fees.[846] Relying on *Budinich v. Becton Dickinson & Co.*,[847] "the Supreme Court insisted on cleanly

836. *Id.* at 766.
837. *Id.* at 767.
838. *Id.* at 768 (quoting Lujan v. Defs. of Wildlife, 504 U.S. 555, 560 (1992)).
839. *Id.* at 768–69.
840. *Id.* at 770.
841. *Id.*
842. 927 F.3d 1292 (Fed. Cir. 2019).
843. *Id.* at 1295.
844. *Id.*
845. *Id.* at 1295–96.
846. *Id.* at 1303.
847. 486 U.S. 196 (1988).

separating, for finality purposes, the decision on the merits of a case from the decision on attorney's fees."[848] The court explained that an award of attorney fees is not a final decision entitled to appellate review until the award has been quantified.[849] Further, the court rejected Hughes' argument that 28 U.S.C. § 1292(c)(2) provided a basis "to review entitlement to fees before quantification."[850] While § 1292(c)(2) provides appellate review of fees that are otherwise reviewable except for "accounting" issues, the Federal Circuit explained that § 1292(c)(2) only dealt with issues involving merits of the case: "[a]s already explained, under *Budinich*, unquantified fees are not part of what is reviewable under § 1295 and so they are not part of what § 1292(c)(2) makes appealable."[851] The court also rejected Hughes' argument that the court should exercise pendent appellate jurisdiction and concluded it lacked jurisdiction in determining whether attorney fees were warranted.[852]

The Federal Circuit, in *Cellspin Soft, Inc. v. Fitbit, Inc.*,[853] vacated the district court's award of attorney fees.[854] Cellspin asserted a number of patents directed toward "connecting a data capture device, e.g., a digital camera, to a mobile device so that a user can automatically publish content from the data capture device to a website."[855] The district court granted Fitbit's motion to dismiss because it held Cellspin's claims were directed toward the abstract idea of "acquiring, transferring, and publishing data and multimedia content on one or more websites."[856] As such, the patents were unpatentable vis-à-vis 35 U.S.C. § 101.[857] The lower court also found this case to be exceptional, concluding Cellspin's "claims were 'exceptionally meritless'" because they were directed to an abstract idea.[858]

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848. *Elbit*, 927 F.3d at 1303 (citing *Budinich*, 486 U.S. at 196, 202–03).
849. *Id.* at 1303–04.
850. *Id.*
851. *Id.* at 1304–05 (stating Special Devices, Inc. v. OEA, Inc., 269 F.3d 1340, 1343 n.2 (Fed. Cir. 2001) indicates attorney fees are not an "accounting").
852. *Id.* at 1305–06.
853. 927 F.3d 1306 (Fed. Cir. 2019).
854. *Id.* at 1320.
855. *Id.* at 1309.
856. *Id.* at 1313 (quoting Cellspin Soft, Inc. v. Fitbit, Inc., 316 F. Supp. 3d 1138, 1150 (N.D. Cal. 2018)).
857. *Id.*
858. *Id.* at 1314.

The Federal Circuit held the district court erred in various aspects of its analysis.[859] Regarding attorney fees, the court rejected the district court's allegation that Cellspin should have "filed a 'test case' before asserting its patents" because there is a presumption of validity of patents and a presumption that "the Patent and Trademark Office has already examined whether the patent satisfies 'the prerequisites for issuance of a patent,' including § 101."[860] The Federal Circuit also held that the district court erred in "amending its complaint just a few days before the scheduled hearing" to align with the district court's scheduling order because "Cellspin's amendment was timely based on a scheduling order entered by the district court just three days before Cellspin's amendment."[861] "The district court's error in granting the motions to dismiss necessitate[d] vacatur of its attorney fees award."[862]

In *ATEN International Co. v. Uniclass Technology Co.*,[863] the Federal Circuit affirmed the district court's decision the case did not meet an "exceptional case" worthy of an award of attorney fees under 35 U.S.C. § 285.[864] On appeal, appellants argued that the cost of litigation was not proportional to the award sought.[865] Appellants attempted to argue that the cost of litigation, which included over $700,000 in expert witness fees alone, was not proportional to the maximum $678,337 in reasonable royalty damages that could be awarded.[866] The Federal Circuit rejected this argument and explained that "[t]here is no per se rule that a case is exceptional if litigation costs exceed the potential damages."[867] The Federal Circuit reasoned that parties bring suit for more reasons than monetary damages and identified that ATEN additionally sought injunctive relief.[868] According to the Federal Circuit, nothing in the record supported the argument that the district court abused its discretion in holding that this case was not exceptional under the totality of the circumstances, and thus, ATEN was not entitled to attorney fees.[869]

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859. *Id.* at 1320.
860. *Id.* at 1319 (quoting Microsoft Corp. v. i4i Ltd. P'ship, 564 U.S. 91, 95–96 (2011)).
861. *Id.* at 1319–20.
862. *Id.* at 1319.
863. 932 F.3d 1371 (Fed. Cir. 2019).
864. *Id.* at 1374; *see* 35 U.S.C. § 285 (2012) (providing that a court "in exceptional cases may award reasonable attorney fees to the prevailing party").
865. *ATEN Int'l Co.*, 932 F.3d at 1373.
866. *Id.*
867. *Id.*
868. *Id.*
869. *Id.* at 1373–74.

In *ThermoLife International LLC v. GNC Corp.*,[870] ThermoLife International LLC ("ThermoLife") appealed a district court decision awarding attorney fees under 35 U.S.C. § 285 as an exceptional case.[871] ThermoLife, the exclusive licensee of four patents from Stanford University, filed eighty-one infringement suits (including those against defendants Hi-Tech and Vital) alleging that defendants directly and indirectly infringed Stanford's patents directed to methods and compositions of the amino acids arginine and lysine to enhance vascular function and physical performance.[872] ThermoLife supported its allegations by pointing to the defendants' labels and advertisements.[873] The Federal Circuit agreed with the district court that ThermoLife was unjustified in alleging infringement because it failed to investigate with even simple tests of the accused products to determine their ingredients.[874] Furthermore, without an adequate pre-filing investigation, ThermoLife irresponsibly brought infringement suits against an excessive amount of defendants and exhibited a pattern of misconduct that suggested ThermoLife "brought suit against many defendants *without carefully reviewing their claims* as a calculated risk that might yield nuisance-value settlements."[875] The Federal Circuit found no abuse of discretion in the district court's decision to call this an exceptional case and award attorney fees.[876] Although infringement was not litigated and adjudicated, and thus the case history provided an "unusual basis" for fees, the plaintiffs were not denied any procedural rights.[877] The defendants' failure to give early notice of the defects in ThermoLife's infringement contentions was also not a basis for finding the fees award to be an abuse of discretion.[878]

The Federal Circuit addressed the issue of whether Facebook was a prevailing party warranting a costs award in *B.E. Technology, L.L.C. v.*

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870. 922 F.3d 1347 (Fed. Cir. 2019).
871. *Id.* at 1350.
872. *Id.* at 1350, 1352.
873. *Id.* at 1352.
874. *Id.* at 1355, 1358. The district court determined that one gram of L-arginine or its salt form was required to show infringement, *id.* at 1359, and plaintiffs did not deny that the products were publicly available, or that simple tests existed to determine the accused product's composition. *Id.* at 1354.
875. *Id.* at 1355 (quoting ThermoLife Int'l, LLC v. Myogenix Corp., No. 13cv651 JLS (MDD), 2017 WL 1235766, at *7 (S.D. Cal. Apr. 4, 2017)).
876. *Id.* at 1356.
877. *Id.* at 1357.
878. *Id.* at 1357–58.

Facebook, Inc.[879] In this case, B.E. Technology, L.L.C. ("B.E.") sued Facebook, Inc. ("Facebook") alleging patent infringement.[880] Ultimately, those patent claims were found to be unpatentable in IPR proceedings at the USPTO.[881] Facebook moved the district court for judgment on the pleadings to dismiss the case with prejudice and costs under Federal Rules of Civil Procedure 12(c) and 54(d).[882] The district court, agreeing with B.E., dismissed the case as moot, but it also found that Facebook was a "prevailing party" and awarded $4,424.20 in costs.[883]

On appeal, the Federal Circuit addressed its own and Supreme Court precedent on the question of what constituted a "prevailing party."[884] The Federal Circuit noted that "[a] decision [by the district court] with judicial *imprimatur* is required to give rise to prevailing party status."[885] "That the merits of the decision cancelling the claims occurred in the PTO rather than the district court does not change the fact that the district court dismissed the claims it had before it, albeit for mootness. It thereby placed a judicial *imprimatur* upon B.E.'s claim for patent infringement."[886]

B. Willful Infringement

The Federal Circuit had occasion to discuss willful infringement this year. In *SRI International, Inc. v. Cisco Systems, Inc.*, the jury had awarded treble damages after finding that Cisco had willfully infringed SRI's patent.[887] Cisco appealed, arguing that it was not aware of the patent until SRI sent Cisco a notice letter.[888] The Federal Circuit agreed. The court noted that without knowledge of the patent, there could be no willful infringement, and treble damages were inappropriate.[889]

879. 940 F.3d 675, 676 (Fed. Cir. 2019).
880. *Id.*
881. *Id.*
882. *Id.* at 676–77.
883. *Id.* at 677.
884. *Id.* at 677–78.
885. *Id.* at 678.
886. *Id.* at 679.
887. 930 F.3d 1295, 1302 (Fed. Cir. 2019).
888. *Id.* at 1308–09.
889. *Id.* at 1309–10.

VII. DISTRICT COURT

A. Procedural

The Federal Circuit's 2019 rulings on procedural issues touched on many important topics. In *Quest Integrity USA, LLC v. Cokebusters USA Inc.*,[890] the Federal Circuit reversed a district court's summary judgment decision on invalidity because it improperly disregarded expert declarations under the sham affidavit doctrine.[891] The district court held that five of Quest Integrity USA, LLC's ("Quest's") patented claims were invalid under 35 U.S.C. § 102(b), the on-sale bar.[892] The Federal Circuit affirmed the district court's summary judgment of invalidity as to three of the asserted claims but reversed the judgment as to the other two because the district court improperly dismissed two of Quest's declarations as sham affidavits.[893] These declarations were from two of Quest's experts and testified as to whether the invention met a disputed claim limitation.[894] The Federal Circuit ruled that the district court misapplied the sham affidavit doctrine as to the first affidavit because, though this affidavit did contradict earlier testimony of the other expert, it did not contradict the earlier testimony of this affidavit's author.[895] The other declaration, the Federal Circuit said, was not a sham affidavit because it did not simply contradict the earlier testimony but plausibly explained in great detail why the former testimony was incorrect.[896] The court noted that the testimony of this affidavit was corroborated by other evidence of record.[897]

In *Omega Patents, LLC v. CalAmp Corp.*,[898] the Federal Circuit denied CalAmp Corp.'s ("CalAmp's") appeal of the district court's ruling on

890. 924 F.3d 1220 (Fed. Cir. 2019).

891. *Id.* at 1222. A sham affidavit is a declaration by a witness that contradicts his or her earlier testimony, therefore calling that witness's credibility into question. *Id.* at 1232. Courts in the Third Circuit (where this case arose) are especially weary of sham affidavits during motions for summary judgment. *See id.*

892. *Id.* at 1222. Quest's activities met the on-sale bar because even though it did not sell its furnace inspection hardware or software, it used its method, computer-readable medium, and system commercially to perform services for a paying customer. *Id.* at 1227.

893. *Id.* at 1222.

894. *Id.* at 1226.

895. *Id.* at 1232–33.

896. *Id.* at 1233.

897. *Id.* at 1234.

898. 920 F.3d 1337 (Fed. Cir. 2019).

invalidity for failing to satisfy Federal Rule of Civil Procedure 46.[899] Although CalAmp properly preserved its issue for appeal under Federal Rule of Civil Procedure 51, it failed to specifically identify the grounds for the appeal under Rule 46,[900] which requires "'a party, at the time the ruling or order of the trial judge is . . . sought, make known to the court the action that he desires the court to take . . . and the grounds therefor,' otherwise a claim of error is typically forfeited."[901] At trial, the jury found the claims not invalid based on prior art presented at trial.[902] CalAmp asserted on appeal that had the district court adopted its proposed claim constructions, its validity defenses would have included additional prior art references that are now irrelevant.[903] But CalAmp failed to specifically identify during or after the *Markman* proceeding any prior art that would be impacted by the claim construction ruling.[904] CalAmp appealed the invalidity findings by referring to additional prior art, but the Federal Circuit declined CalAmp's "invitation to speculate as to how additional prior art may have been rendered irrelevant under the court's claim construction."[905]

Finally, in *TEK Global, S.R.L. v. Sealant Systems International, Inc.*,[906] the Federal Circuit reversed the district court's denial of Sealant Systems International, Inc.'s ("SSI") motion for a partial new trial on validity.[907] After a prior appeal in which the Federal Circuit instructed the district court to rule that TEK Global's ("TEK") patents were not invalid based on an obviousness theory combining the Bridgestone and Eriksen references, the district court barred SSI from presenting other obviousness theories based on those same references.[908] The Federal Circuit held that one foreclosed obviousness theory did not preclude SSI from presenting other obviousness theories based on new

899. *Id.* at 1341, 1343.
900. *Id.* at 1343.
901. *Id.* at 1342 (alternation in original) (quoting 9B CHARLES A. WRIGHT & ARTHUR R. MILLER, FEDERAL PRACTICE AND PROCEDURE § 2472 (3d ed. 2018)).
902. *Id.*
903. *Id.*
904. *Id.* at 1342–43.
905. *Id.* at 1343.
906. 920 F.3d 777 (Fed. Cir. 2019).
907. *Id.* at 780.
908. *Id.* at 784.

combinations of the Bridgestone and Eriksen references that were not previously before the court.[909]

However, the court also affirmed the district court's denial of SSI's motion for a new trial on infringement.[910] During its closing argument at trial, TEK indirectly compared the accused product to its commercial product. SSI objected on the ground that for an infringement analysis, the factfinder must only compare the accused product to the claims of the patent, not the plaintiff's patent.[911] The district court allowed TEK to make the product-to-product comparison because TEK's product was a commercial embodiment of the patent, and the comparison was merely in response to SSI's own comparisons of the products.[912] The Federal Circuit held that the district court did not abuse its discretion in allowing the comparison for this limited purpose and sufficiently mitigated any potential jury confusion or prejudice when it instructed the jury not to perform a product-to-product comparison to decide the infringement issue.[913]

B. Motion to Amend Complaint

In *Anza Technology, Inc. v. Mushkin, Inc.*,[914] the Federal Circuit reversed a district court decision that declined to apply the relation-back doctrine and barred the lawsuit.[915] The case started in March 2017 when Anza Technology, Inc. ("Anza") sued Mushkin, Inc. ("Mushkin") alleging patent infringement.[916] Anza filed a first amended complaint on September 6, 2017, joining Avant Technology, Inc. as a codefendant.[917] The district court then granted a motion severing the claims against Mushkin and transferred the case to the District of Colorado.[918] After the transfer, Anza conceded that the claims against

909. *Id.* The Federal Circuit of course warned the district court to exercise caution during retrial and to not allow the parties to present evidence of related noninstitution decisions by the PTO. *Id.* at 784 n.1.
910. *Id.* at 789.
911. *Id.* at 787–88 (citing Zenith Labs., Inc. v. Bristol-Myers Squibb Co., 19 F.3d 1418, 1423 (Fed. Cir. 1994)).
912. *Id.* at 788–89.
913. *Id.* at 789.
914. 934 F.3d 1359 (Fed. Cir. 2019).
915. *Id.* at 1362.
916. *Id.*
917. *Id.* at 1363.
918. *Id.*

Mushkin were not viable after engaging in mediation.[919] This led to Anza filing a second amended complaint, which Mushkin moved to dismiss.[920]

Anza's second amended complaint removed the original infringement allegations and added new allegations of infringement of two different patents.[921] Additionally, it involved two products that had not been involved in the original complaint.[922] Ultimately, the district court granted Mushkin's motion to dismiss because the amended complaint did not relate back to the original complaint, and the alleged infringing activity occurred more than six years before the date the second amended complaint was filed.[923]

The Federal Circuit reviewed this determination through a "'logical relationship' standard" by looking at five factors: "the overlap of parties, products or processes, time periods, licensing and technology agreements, and product or process development and manufacture."[924] The court held that the overlap of the parties and products was quite clear, but the focus of its analysis was on the underlying technology and the time periods.[925]

The court held that, regarding the technology, the products in the second amended complaint sought to solve the same problems using the same methods.[926] Additionally, the court held that, with respect to time periods, there would be "no lack of notice and no substantial prejudice to Mushkin from having to defend against independent claims over a *shorter* period than the period set forth in the original complaint."[927] In light of this analysis, the Federal Circuit reversed the dismissal of claims toward the overlapping products and vacated the dismissal and remanded to determine relation back with respect to the newly added product.[928]

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919. *Id.* at 1364.
920. *Id.* at 1364–65.
921. *Id.* at 1364.
922. *Id.*
923. *Id.* at 1365–66.
924. *Id.* at 1369 (citing Futurewei Techs., Inc. v. Acacia Research Corp., 677 F.3d 704, 710 (Fed. Cir. 2013); *In re* EMC Corp., 677 F.3d 1351, 1359–60 (Fed. Cir. 2012)).
925. *Id.* at 1370, 1372–73.
926. *Id.* at 1370.
927. *Id.* at 1372.
928. *Id.* at 1373.

C. Declaratory Judgment Jurisdiction

The Federal Circuit addressed jurisdiction in a declaratory judgment action in *Genetic Veterinary Sciences, Inc. v. LABOKLIN GmbH & Co. KG.*[929] LABOKLIN GmbH & Co. KG ("LABOKLIN"), a German company, licensed a patent owned by the University of Bern, an instrumentality of the Swiss Confederation.[930] LABOKLIN sent a cease and desist letter to Paw Prints Genetics ("PPG"), a U.S. company doing business as Genetic Veterinary Sciences, Inc., at its business in Spokane, Washington.[931] In response to the cease and desist letter, PPG sought a declaratory judgment that the patent being enforced was invalid under 35 U.S.C. § 101.[932]

The Federal Circuit agreed with the district court that it had jurisdiction over LABOKLIN and the University, citing Federal Rule of Civil Procedure 4(k)(2).[933] This rule instructs a court to look at a litigant's minimum contacts with the United States generally, rather than any specific state.[934] With respect to LABOKLIN, the Federal Circuit held the company had sufficient minimum contacts based on the fact that it sent a cease and desist letter into the United States, threatened a U.S. company's business, and additionally licensed the patent to two other U.S. companies.[935] The court held that it was "reasonable and fair" for it to have jurisdiction under the circumstances because LABOKLIN "availed itself of the benefits and protections of U.S. laws."[936]

The court analyzed jurisdiction over the University under the Foreign Sovereign Immunities Act (FSIA).[937] Under the FSIA, "a foreign state is presumptively immune from the jurisdiction of United States courts" unless an exception applies.[938] Immunity is detached if a foreign state "engages in 'commercial activity . . . in the United

929. 933 F.3d 1302, 1307 (Fed. Cir. 2019).
930. *Id.*
931. *Id.*
932. *Id.* at 1308.
933. *Id.* at 1308–09, 1312.
934. *Id.* at 1309 (citing Synthes (U.S.A.) v. G.M. Dos Reis Jr. Ind. Com de Equip. Medico, 536 F.3d 1285, 1291, 1295 (Fed. Cir. 2009)).
935. *Id.* at 1310–11.
936. *Id.* at 1311.
937. *Id.* at 1312; *see* 28 U.S.C. §§ 1330 *et. seq.*
938. *Genetic Veterinary Scis.*, 933 F.3d at 1312 (quoting Saudi Arabia v. Nelson, 507 U.S. 349, 355 (1993)).

States.'"[939] Federal Circuit precedent states that obtaining and subsequently licensing or enforcing a U.S. patent is sufficient commercial activity to overcome the FSIA's presumption.[940] Here, the University not only obtained the patent but also participated in the enforcement of it with LABOKLIN.[941] For these reasons, the Federal Circuit affirmed the district court's jurisdiction decision for each party.[942] The court subsequently held the patent to be ineligible under § 101 as claiming a natural phenomenon.[943]

D. Venue

Venue continued to be a hot topic at the Federal Circuit in the wake of *TC Heartland LLC v. Kraft Foods Group Brands LLC*.[944] In *In re Google LLC*,[945] the Federal Circuit elected not to decide en banc "whether servers . . . are a *regular and established place of business*, such that venue is proper under 35 U.S.C. § 1400(b)."[946]

SEVEN Networks alleged Google, LLC's ("Google") servers, stored in a third-party ISP's facility, where the allegedly infringing activities occurred, were a regular and established place of business, establishing proper venue under 35 U.S.C. § 1400(b).[947]

The district court denied Google's motion to dismiss for improper venue.[948] As a result, Google petitioned the Federal Circuit for a writ of mandamus directing the district court to dismiss or transfer the case for improper venue.[949] On appeal, the panel majority found mandamus relief inappropriate because "it is not known if the district court's ruling involves the kind of broad and fundamental legal questions relevant to § 1400(b)," and "it would be appropriate to allow the issue to percolate in the district courts so as to more clearly define

939. *Id.* (alteration in original) (quoting 28 U.S.C. § 1605(a)(2) (2012)).
940. *Id.* at 1312–13.
941. *Id.* at 1314.
942. *Id.*
943. *Id.* at 1318.
944. *See* 137 S. Ct. 1514, 1517 (2017) (holding that, for purposes of the patent venue statute, a domestic corporation only "resides" in its state of incorporation).
945. 914 F.3d 1377 (Fed. Cir. 2019) (en banc) (per curiam).
946. *Id.* at 1378 (Reyna, J., dissenting).
947. *Id.*
948. Seven Networks, LLC v. Google LLC, 315 F. Supp. 3d 933, 937 (E.D. Tex. 2018).
949. *In re* Google LLC, No. 2:17-cv-00442-JRG, 2018 WL 5536478, at *1 (Fed. Cir. Oct. 29, 2019) (per curiam).

the importance, scope, and nature of the issue for us to review."[950] Google petitioned for panel rehearing and for rehearing en banc.[951] The panel denied the petition for panel rehearing, and, after a poll of the full Federal Circuit was taken, the petition for rehearing en banc was also denied.[952]

Then, in *Westech Aerosol Corp. v. 3M Co.*,[953] Westech Aerosol Corp. ("Westech") appealed the District Court for the Western District of Washington's decision of granting 3M's motion to dismiss for improper venue.[954] The procedural history of *Westech* is complex: during pendency of the case, the Supreme Court issued its decision in *TC Heartland LLC* and the Federal Circuit released its opinions in *In re Cray Inc.*[955] and *In re ZTE (USA) Inc.*[956] The district court concluded that Westech failed to prove that 3M Co. ("3M") had a regular and established place of business in the Western District of Washington and granted 3M's motion.[957]

On appeal, the Federal Circuit affirmed the district court decisions, concluding that Westech had failed to demonstrate venue or that defendant had a "regular and established place of business physically located within the judicial district," as required by *ZTE* and *In re Cray*.[958] In fact, the court held Westech failed to plead "any facts" establishing 3M's regular and established place of business.[959] In discussing 3M's motion for sanctions, the court held that because *ZTE* was decided post-filing the appeal, Westech did not frivolously file the appeal; however, Westech's appeal was frivolous as argued because Westech was aware of the holding of *In re Cray* and *ZTE* and proceeded with the appeal.[960] The court ultimately held the district court properly granted 3M's motion to dismiss and denied 3M's motion for sanctions.[961]

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950. *Id.* at *2–3.
951. *In re Google*, 914 F.3d at 1377–78 (per curiam).
952. *Id.* at 1378.
953. 927 F.3d 1378 (Fed. Cir. 2019).
954. *Id.* at 1380.
955. 871 F.3d 1355, 1360 (Fed. Cir. 2017) (outlining the requirements for proper venue under 28 U.S.C. § 1400(b) including that the defendant has a physical place in the district that serves as a regular and established place of business).
956. 890 F.3d 1008, 1013 (Fed. Cir. 2018) (holding that the plaintiff has the burden of establishing proper venue under 28 U.S.C. § 1400(b)).
957. *Westech*, 927 F.3d at 1381.
958. *Id.* at 1382 (citing *In re Cray Inc.*, 871 F.3d at 1360, 1364–67).
959. *Id.*
960. *Id.* at 1383.
961. *Id.*

E. Subject Matter Jurisdiction

Interestingly, the court was asked to perform a federal question analysis. The dispute in *Inspired Development Group, LLC v. Inspired Products Group, LLC*[962] started as a business dispute around patent licensing.[963] Both parties to the case relied on diversity jurisdiction to bring the lawsuit and corresponding counterclaims in federal court.[964]

While on appeal, the U.S. Court of Appeals for the Eleventh Circuit spotted a "potentially fatal problem"; namely, there were doubts that diversity of citizenship existed.[965] Under Eleventh Circuit law, there must be diversity between all members of both limited liability corporations involved in the dispute, something that both parties agreed did not exist.[966] Then, for the first time, the appellee argued that the case involved a federal question because the case involved patent law.[967] The Eleventh Circuit then remanded the case to let the district court answer that question.[968] The district court ultimately found that there was a federal question, and thus, federal subject matter jurisdiction existed, so the case was transferred to the Federal Circuit.[969]

Once at the Federal Circuit, the discussion focused on whether the claims were deemed to arise under federal law based on the four part test highlighted in *Gunn v. Minton*.[970] The Federal Circuit quickly disposed of the first two factors of analysis, holding that resolving a question of infringement was not a "necessary element" of the case and that, while patent infringement was actually disputed, it was not a necessary element of any claim.[971] The court's focus was on the third factor, whether the federal issue was "substantial."[972] Relying on Eleventh Circuit precedent, the Federal Circuit stated that a substantial federal issue is "more likely to be present" when (1) "a pure issue of [federal] law is dispositive of the case"; (2) "the court's resolution of the issue will control numerous other cases"; and (3) [t]he Government . . . has a direct interest in the availability of the

962. 938 F.3d 1355 (Fed. Cir. 2019).
963. *Id.* at 1358.
964. *Id.* at 1359.
965. *Id.*
966. *Id.*
967. *Id.* at 1360.
968. *Id.*
969. *Id.*
970. 568 U.S. 251, 258 (2013).
971. *Inspired Dev.*, 938 F.3d at 1363.
972. *Id.*

federal forum to vindicate its own administrative action."[973] The court ultimately held that the third *Gunn* factor did not support a finding of federal subject matter jurisdiction because the patent infringement claim was not a substantial issue in the case.[974]

F. Personal Jurisdiction and Sovereign Immunity

Public universities in two patent cases challenged the courts' ability to hear infringement cases due to sovereign immunity. In *University of Florida Research Foundation, Inc. v. General Electric Co.*,[975] the Federal Circuit affirmed the district court's grant of General Electric's ("GE") motion to dismiss University of Florida Research Foundation's ("UFRF") allegations of infringement.[976] In 2017, UFRF sued GE alleging infringement of the '251 patent, which described "a method and system for 'integrat[ing] physiologic data from at least one bedside machine.'"[977] GE filed a motion to dismiss, arguing that the claims of the '251 patent were directed to ineligible subject matter under 35 U.S.C. § 101, which the district court granted.[978]

On appeal, UFRF argued that the district court did not have subject matter jurisdiction to hear GE's § 101 eligibility challenge because UFRF enjoyed sovereign immunity under the Eleventh Amendment.[979] The Federal Circuit held that UFRF consented to federal court jurisdiction, thus waiving its Eleventh Amendment immunity, when it brought the infringement claim against GE.[980] The Federal Circuit explained that the waiver of immunity extends not only to the cause of action but to any relevant defenses GE brought, including the § 101 challenge.[981] After confirming subject matter jurisdiction on the § 101 eligibility challenge, the Federal Circuit affirmed the district court's finding that UFRF's '251 patent was directed to an abstract idea.[982]

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973. *Id.* at 1364 (alterations in original) (quoting NeuroRepair, Inc. v. Nath Law Grp., 781 F.3d 1340, 1345 (Fed. Cir. 2015)).
974. *Id.* at 1368.
975. 916 F.3d 1363 (Fed. Cir. 2019).
976. *Id.* at 1364.
977. *Id.* at 1366 (alteration in original).
978. *Id.* at 1364.
979. *Id.*
980. *Id.* at 1365.
981. *Id.* at 1366.
982. *Id.* at 1368–69.

The court in *Board of Regents of the University of Texas System v. Boston Scientific Corp.*[983] addressed issues of venue and state sovereignty. Here, the Board of Regents for the University of Texas sued Boston Scientific in the Western District of Texas.[984] The Board of Regents acted as an arm of the state of Texas, and Boston Scientific was a Delaware corporation.[985]

Acknowledging that Boston Scientific had little to no ties in Texas, the Board of Regents argued that venue was proper because it had state sovereignty, the district court had personal jurisdiction over Boston Scientific and because it would "offend the dignity of the State to require it to pursue persons who have harmed the State outside that territory of Texas."[986] The Board of Regents further argued that the Eleventh Amendment protected it from being compelled to respond to counterclaims outside its territory.[987] The district court held that Boston Scientific did not have an established place of business in the Western District of Texas, rejected the state sovereignty argument, and ultimately transferred the case to the District of Delaware.[988]

On appeal, the court held that state sovereignty does not grant the right to bring suit in an otherwise improper venue.[989] First, the court explained, sovereign immunity does not apply when challenging a venue transfer where the State acts solely as a plaintiff.[990] The Board of Regents also argued that "the Original Jurisdiction Clause ensures a State cannot be forced to sue in a court located in another State."[991] The Federal Circuit disagreed, stating that the Original Jurisdiction Clause does not allow a State to bring suit in any forum that it would like, as long as there is personal jurisdiction.[992] The clause grants the ability of States "to sue in lower courts *in addition to* the Supreme Court"—not any forum regardless of venue rules.[993] Additionally, the Federal Circuit held that "[w]hen a state sues in federal court, it waives sovereign immunity with respect to its asserted claims, subjecting itself

983. 936 F.3d 1365 (Fed. Cir. 2019).
984. *Id.* at 1369.
985. *Id.*
986. *Id.*
987. *Id.*
988. *Id.* at 1370.
989. *Id.* at 1374.
990. *Id.* at 1377.
991. *Id.*
992. *Id.* at 1379.
993. *Id.* at 1378.

to the jurisdiction of the federal courts" and it must comply with federal rules and procedures, including venue rules.[994]

The Board of Regents's last argument, that it was not subject to the District of Delaware's jurisdiction because it did not waive its sovereignty in Delaware, was rejected, too.[995] The Federal Circuit again stated that sovereign immunity did not apply to a state acting solely as a plaintiff, and thus, the issues of waiver were irrelevant.[996]

G. Appellate Jurisdiction

In another interesting case, the Federal Circuit was asked to determine whether it had jurisdiction under 28 U.S.C. § 1295 to hear a patent licensing case. In *Princeton Digital Image Corp. v. Office Depot Inc.*,[997] Princeton Digital licensed the patent at issue to Adobe and promised not to sue Adobe or Adobe's customers for claims arising "in whole or part owing to an Adobe Licensed Product."[998] When Princeton Digital brought lawsuits against Adobe's customers, Adobe intervened and asserted a claim against Princeton Digital for breach of contract and sought damages.[999] On summary judgment, the district court held that Adobe could only recover fees associated with defending its customers, as opposed to the affirmative claim for breach of contract.[1000] But the district court substantially limited Adobe's request for damages prior to trial, rendering further litigation possibly financially unreasonable.[1001] To accelerate the district court's damage-limiting decision toward appeal, Adobe then asked the court to enter judgment for Princeton Digital, on the grounds that it did not have evidence of damages to present at trial, which it contended was an element of its claim.[1002] The district court granted Adobe's request, but specifically stated that there were defensive damages that could be proven on the existing record.[1003]

The Federal Circuit reversed, holding that the "final judgment" entered in the district court lacked the finality required by the Federal

994. *Id.* at 1380.
995. *Id.* at 1381–82.
996. *Id.* at 1382.
997. 913 F.3d 1342 (Fed. Cir. 2019).
998. *Id.* at 1344.
999. *Id.*
1000. *Id.* at 1345.
1001. *Id.*
1002. *Id.*
1003. *Id.*

Rules to warrant appellate jurisdiction.[1004] The court held that because Adobe could have proceeded to trial on one of its claims, there was no final decision on the merits, even though Adobe "persuade[d] [the] district court to issue an order purporting to end the litigation."[1005]

H. Standing

The court issued two opinions on party standing. In *Lone Star Silicon Innovations LLC v. Nanya Technology Corp.*,[1006] Lone Star was a licensee of Advanced Micro Devices's ("AMD") patents.[1007] The lower court applied the "all substantial rights" test in determining whether Lone Star could bring suit.[1008] While the agreement indicated "'all right[s], title, and interest' in the asserted patents [belonged] to Lone Star," Judge O'Malley indicated the court must "examine the 'totality' of the agreement to determine whether a party other than the original patentee has established that it obtained all substantial rights in the patent."[1009] The court, focusing on enforcement and alienation amongst other patent rights, concluded that because AMD did not transfer these rights to Lone Star, "Lone Star is therefore not the relevant patentee and cannot assert . . . patents in its own name under § 281."[1010] The court also held that the district court erred in dismissing the case.[1011] The court concluded that the district court inaccurately interchanged standing requirements with patent rights: "whether a party possesses all substantial rights in a patent does not implicate standing or subject-matter jurisdiction."[1012] As such, and in accordance with Federal Rule of Civil Procedure 19, the Federal Circuit remanded to the district court to determine whether AMD's joinder was required.[1013]

Also, in *Sanofi-Aventis U.S., LLC v. Dr. Reddy's Laboratories, Inc.*,[1014] Sanofi sued multiple defendants for infringement of two of its patents.[1015] While the district court case was pending, the USPTO

1004. *Id.* at 1349–50.
1005. *Id.* at 1350 (alterations in original).
1006. 925 F.3d 1225 (Fed. Cir. 2019).
1007. *Id.* at 1228.
1008. *Id.* at 1229.
1009. *Id.* at 1228–29.
1010. *Id.* at 1231.
1011. *Id.* at 1237–39.
1012. *Id.* at 1235–36.
1013. *Id.* at 1239.
1014. 933 F.3d 1367 (Fed. Cir. 2019).
1015. *Id.* at 1371.

instituted IPR of one of the patents.[1016] The Board held claims one through five and seven through thirty unpatentable as obvious and would not allow Sanofi to amend the claims subsequently.[1017] Sanofi did not appeal the decision with respect to claims seven, eleven, fourteen through sixteen, and twenty-six, but it did, however, file a statutory disclaimer as to those claims.[1018] Despite having notice of the statutory disclaimer, the district court concluded that a case or controversy still existed, and it invalidated the claims as obvious.[1019]

On appeal, the Federal Circuit stated that an actual case or controversy must exist at all stages of the case.[1020] The court concluded that when Sanofi filed the disclaimer "it 'effectively eliminated those claims from the . . . patent.'"[1021] Thus, any case or controversy that existed was moot.[1022] The Federal Circuit noted that in some cases, a case or controversy may exist even when there is no risk of infringement, but the defendants have not demonstrated that in this case.[1023] Because of these reasons, the Federal Circuit vacated the district court's decision.[1024]

I. Ethical Representation

In a rare case, the Federal circuit decided motions to disqualify counsel. In *Dr. Falk Pharma GmbH v. Generico, LLC*,[1025] two attorneys representing Mylan Pharmaceuticals, Inc. changed firms and continued to represent Mylan in the related actions.[1026] The attorneys' new firm was engaged in a concurrent trademark representation for a corporate affiliate of two parties adverse to Mylan in the appeal.[1027] The court held there was no applicable framework in the precedent of the relevant regional circuits, so the court applied a two-factor test from

1016. *Id.*
1017. *Id.*
1018. *Id.*
1019. *Id.* at 1372.
1020. *Id.* at 1373.
1021. *Id.* (alteration in original) (quoting Vectra Fitness, Inc. v. TNWK Corp., 162 F.3d 1379, 1383 (Fed. Cir. 1998)).
1022. *Id.*
1023. *Id.* at 1374.
1024. *Id.*
1025. 916 F.3d 975 (Fed. Cir. 2019).
1026. *Id.* at 978.
1027. *Id.* at 979.

the Second Circuit.[1028] The test required examining the degree of operational commonality between the affiliated entities and the extent to which they were financially interdependent.[1029] Ultimately, the court held that the two adverse entities were sufficiently interrelated with the firm's client to give rise to an affiliate conflict.[1030]

J. Inventorship

Coda filed a complaint against Goodyear in *Coda Development S.R.O. v. Goodyear Tire & Rubber Co.*,[1031] seeking correction of inventorship on several Goodyear patents and alleged misappropriation of Coda's trade secrets.[1032] Coda alleged that Goodyear's patents were the result of misappropriated Coda trade secrets, and, as a result, the Coda engineer that invented the technology should be listed as an inventor on the patents.[1033] The district court dismissed the complaint for failure to state a claim upon which relief could be granted, and denied Coda leave to amend their complaint.[1034]

The Federal Circuit reversed, holding that the facts in the complaint, including those identified above, lead to reasonable inferences that Coda was entitled to a correction of inventorship.[1035] The Federal Circuit also held that the district court erred when it denied leave to file an amended complaint, given the policy of liberally allowing such leave and a preference for deciding cases on the merits.[1036]

VIII. DESIGN PATENTS

As design patent litigation becomes more prevalent, Federal Circuit appeals of design patent litigation have become more common. This year, there were two precedential design patent appeals. First, in *Curver Luxembourg, SARL v. Home Expressions Inc.*,[1037] the Federal Circuit addressed the rare issue of design patent claim construction, ultimately abrogating a sixty-year-old precedent.[1038] This case involved a design

1028. *Id.* at 984.
1029. *Id.*
1030. *Id.* at 985.
1031. 916 F.3d 1350 (Fed. Cir. 2019).
1032. *Id.* at 1355.
1033. *Id.*
1034. *Id.* at 1357.
1035. *Id.* at 1359.
1036. *Id.* at 1362.
1037. 938 F.3d 1334 (Fed. Cir. 2019).
1038. *Id.* at 1336.

patent titled "Pattern for a Chair" and claiming an "ornamental design for a pattern for a chair."[1039] During prosecution, the patent owner amended the patent to include such language as to designate a "particular article" for the design to overcome the examiner's objection.[1040] The defendant made baskets with a similar pattern to the plaintiff's chairs.[1041] The district court construed the claim such that it was limited to chairs and reached a finding of noninfringement.[1042]

On appeal, the plaintiff, Curver, argued that the lower court erred in limiting the claim to only include chairs.[1043] Specifically, Curver pointed out that none of the figures showed a chair.[1044] The Federal Circuit rejected this argument and held that

> design patents are granted only for a design applied to an article of manufacture, and not a design *per se*, we hold that claim language can limit the scope of a design patent where the claim language supplies the only instance of an article of manufacture that appears nowhere in the figures.[1045]

Curver also argued that *In re Glavas*,[1046] a long-standing precedent in design patent cases, supported its infringement argument.[1047] Curver used the reasoning in Glavas to argue that when a design is patentable, the use of the article of the design is immaterial if the design itself has a substantially similar appearance to that of the applicant's design.[1048] Further, "so far as anticipation by a single prior art disclosure is concerned, there can be no question as to non-analogous art in design cases."[1049] The Federal Circuit rejected this argument, stating that the standard for design patent infringement changed with the opinion in *Egyptian Goddess, Inc. v. Swisa, Inc.*[1050] Consequently, the statement in *Glavas* relating to anticipation was no longer good law, and Curver's reliance on it "lack[ed] merit."[1051]

1039. *Id.*
1040. *Id.* at 1337.
1041. *Id.*
1042. *Id.* at 1338.
1043. *Id.* at 1339.
1044. *Id.*
1045. *Id.* at 1340.
1046. 230 F.2d 447 (CCPA 1956).
1047. *Curver*, 938 F.3d at 1342.
1048. *Id.*
1049. *Id.*
1050. *Id.* at 1342 (citing Egyptian Goddess, Inc. v. Swisa, Inc., 543 F.3d 665, 683 (Fed. Cir. 2008) (en banc)).
1051. *Id.* at 1343.

Then, in *Campbell Soup Co. v. Gamon Plus, Inc.*,[1052] the PTAB found that two proposed references were not proper primary references because each failed the "basically the same" test.[1053] The PTAB found that the first reference required substantial modifications, like adding a cylindrical object, to appear visually similar to the challenged design.[1054] The second reference failed because making that design "basically the same" as the challenged design would require changing its dimensions and removing parts.[1055]

The Federal Circuit agreed with the PTAB that the second reference required modifications such that it could not be a proper primary reference, but the Federal Circuit disagreed regarding the first reference.[1056] The court vacated the PTAB's findings and partially remanded the claims because "the ever-so-slight differences in [the] design [of one of the patents], in light of the overall similarities," created "'basically the same' visual impression as the claimed designs" and thus allowed that reference to qualify as a primary reference for a design patent obviousness analysis.[1057]

IX. REISSUE PATENTS

The Federal Circuit also reviewed the validity of a reissue patent in *Forum US, Inc. v. Flow Valve, LLC*.[1058] There, Flow Valve added seven claims to its reissue patent but made no changes to the written description or drawings of the original patent.[1059] The district court granted summary judgment in favor of Forum "on the basis that the written description and drawings of the Reissue patent do not 'explicitly and unequivocally' indicate the invention claimed the reissue claims."[1060] The Federal Circuit affirmed this decision, indicating the new claims of the Reissue patent did not comply with the original patent requirement of 35 U.S.C. § 251: "the specification of the original patent must do more than merely suggest or indicate the invention recited in reissue claims; . . . the original patent 'must clearly and unequivocally disclose the newly claimed invention as a separate invention.'"[1061]

1052. 939 F.3d 1335 (Fed. Cir. 2019).
1053. *Id.* at 1041.
1054. *Id.* at 1340.
1055. *Id.* at 1341–42.
1056. *Id.*
1057. *Id.* at 1341–42.
1058. 926 F.3d 1346, 1348 (Fed. Cir. 2019).
1059. *Id.*
1060. *Id.* at 1350.
1061. *Id.* at 1351–52 (quoting Antares Pharma, Inc. v. Medac Pharma, Inc., 771 F.3d 1354, 1362 (Fed. Cir. 2014)).