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# Biotechnology Patent Law Top Ten of 2018 Broad Wins, Sovereignty Loses, and Patent Dance

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## **BIOTECHNOLOGY PATENT LAW TOP TEN OF 2018 BROAD WINS, SOVEREIGNTY LOSES, AND PATENT DANCE**

*Kevin E. Noonan\* and Andrew W. Torrance\*\**

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## ABSTRACT

*In this article, we discuss what we consider to be the ten important and influential biotechnology patent law judicial decisions of 2018. These hinged on a variety of patent doctrines. An abbreviated new drug application (ANDA) for the multiple sclerosis drug Ampyra set the stage for the Acorda Therapeutics, Inc. v. Roxane Laboratories, Inc. (Fed. Cir. 2018) decision, in which the Court of Appeals for the Federal Circuit (Federal Circuit) provided guidance on how to conduct an obviousness analysis (35 U.S.C. §103). The Berkheimer v. HP Inc. (Fed. Cir. 2018) decision, although addressing a software invention, provided valuable insight into how to determine if inventions fall within patent-eligible subject matter (35 U.S.C. §101). Widely-anticipated by the branded and generic pharmaceutical industries, sovereign Native American nations, and consumers alike, the Saint Regis Mohawk Tribe v. Mylan Pharmaceuticals Inc. (Fed. Cir. 2018) decision held that tribal sovereign immunity could not be used to shield patents covering the drug Restasis in an inter partes review (IPR) proceeding before the Patent Trial and Appeal Board (PTAB). In Regents of the University of California v. Broad Institute, Inc. (Fed. Cir. 2018), the Federal Circuit found there to be no interference-in-fact between patents and patent applications covering CRISPR gene editing owned by the Broad Institute and the University of California. The United States Supreme Court (Supreme Court), in Oil States Energy Services, LLC v. Greene’s Energy Group, LLC (2018), held that IPR proceedings violate neither Article III nor the Seventh Amendment of the United States Constitution, and, in SAS Institute Inc. v. Iancu (2018), further elaborated the law of IPRs by requiring the United States Patent and Trademark Office (“USPTO”) to produce a final written decision (FWD) on all claims challenged by a petitioner in an IPR petition. How to apply the written description requirement (35 U.S.C. §112) to patent claims covering monoclonal antibodies, as well as the requirements for granting a permanent injunction against infringing medicines or other therapeutic agents, were both the subject of the decision in Amgen Inc. v. Sanofi (Fed. Cir. 2017). The Supreme Court gave its first interpretation of the Biologics Price Competition and Innovation Act (BPCIA) for the approval of biosimilar drugs in Sandoz, Inc. v. Amgen, Inc. (2017), addressing, among other things, the disclosure and information exchange provisions of the statute, commonly known as the “patent dance” over Sandoz’ biosimilar of Amgen’s biologic, Neupogen. In contrast to cases where the Supreme Court deigned to act, the Court decided not to act in Regeneron*

*Pharmaceuticals v. Merus (2018), denying a petition for certiorari to consider the law of inequitable conduct. In a decision of considerable importance, the Supreme Court considered, in Life Techs. Corp. v. Promega Corp. (2017), whether the supply of a single component, Taq polymerase, of a multi-component toolkit for genetic testing by DNA amplification, for combination abroad, violates 35 U.S.C. § 271(f)(1), reversing the Federal Circuit's decision that it does, and remanding the case for further proceedings. Biotechnology patent law evolved in 2018 across a number of frontiers, and will certainly continue its doctrinal evolution in 2019.*

## I. INTRODUCTION

The year 2018 was a busy and exciting one for biotechnology patent law. The ownership odyssey of patents claiming mammalian CRISPR/Cas9 gene editing—perhaps the most important biotechnology innovation since the polymerase chain reaction (PCR)—was finally tested in Federal court. The Court of Appeals for the Federal Circuit (Federal Circuit) turned a distinctly cold shoulder to the Saint Regis Mohawk Tribe's invocation of tribal sovereign immunity to prevent *inter partes* review (IPR) of its drug patents. And the United States Supreme Court (Supreme Court) offered its views on the constitutional legitimacy of IPRs. In this article, we present a top ten list of the most important 2018 developments in biotechnology patent law. These top ten decisions offer insights about both the current and future state of biotechnology patent law.<sup>1</sup>

Admittedly, choosing the top ten judicial decisions suffers from an inevitable degree of subjectivity. However, we believe these decisions are among the most important decisions of the year in biotechnology patent law even if others might prefer to substitute a case or two for those on our list. Eight of the top ten decisions discussed in this article were delivered during the 2018 calendar year. Two constitute temporal anomalies, having been decided by the Supreme Court in 2017 but are included because of their great importance to biotechnology patent law.

We discuss the top ten biotechnology patent decisions below. These decisions are not presented in any particular order. After consideration of individual judicial decisions, we conclude by suggesting

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1. Much of the discussion of biotechnology law cases in this article is adapted, with full permission, from case summaries written by Dr. Kevin E. Noonan on his leading biotechnology patent law blog, [www.PatentDocs.org](http://www.PatentDocs.org).

what prospective impact these decisions may have on biotechnology patent law.

## II. THE 2018 TOP TEN IN BIOTECHNOLOGY PATENT LAW

- A. *Acorda Therapeutics, Inc. v. Roxane Laboratories, Inc.* (*Fed. Cir. 2018*) (*Panel: Circuit Judges Newman, Dyk, and Taranto; opinion by Judge Taranto; dissenting opinion by Judge Newman*).

Determining obviousness is always a reconstruction, imperfectly done, of a past that never was. The prior art is consulted and the question asked: Would a worker of ordinary skill in the art have been able to achieve the claimed invention with a reasonable expectation of success? Of course, this question is posed against a backdrop of the ordinarily skilled worker *not* having achieved the invention; that accomplishment was attained by the actual inventor(s). Nevertheless, the Supreme Court, since *Hotchkiss v. Greenwood*,<sup>2</sup> and the Patent Act, since 1952,<sup>3</sup> have recognized that sometimes the answer to the question must be no, if only to ensure satisfaction of the constitutional mandate that Congress only grant patents that will “promote the progress of . . . [the] useful arts.”<sup>4</sup>

In patent litigation, defendants have ample motivation to cast the imperfect past in a light most favorable to the claimed invention being obvious. To balance the rhetorical scales, defendants also bear the burden of establishing obviousness (as in all invalidity pleadings) by clear and convincing evidence. But what is clear and convincing to some is not to others, and the Federal Circuit’s split decision affirming the district court’s obviousness determination in *Acorda Therapeutics, Inc. v. Roxane Labs., Inc.* illustrates that point, while at the same time showing that even the objective indicia of nonobviousness identified by the Supreme Court in *Graham v. John Deere*<sup>5</sup> do not always provide a reliable, fact- and historically based shield against a finding of obviousness.<sup>6</sup>

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2. *Hotchkiss v. Greenwood*, 52 U.S. 248 (1851).

3. 35 U.S.C. §103 (2017) (“[A] claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.”).

4. U.S. CONST. art. I, § 8, cl. 8.

5. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

6. See generally *Acorda Therapeutics, Inc. v. Roxane Labs., Inc.*, 903 F.3d 1310 (Fed. Cir. 2018).

The lawsuit arose when Roxane Laboratories and co-defendants Mylan Pharmaceuticals, Inc. and Teva Pharmaceuticals USA, Inc. each filed an Abbreviated New Drug Application (ANDA) for Acorda's multiple sclerosis drug Ampyra and sent Paragraph IV letters to Acorda (and co-plaintiff Alkermes Pharma Ireland Ltd.) asserting that four Orange Book-listed patents (U.S. Patent Nos. 8,007,826; 8,663,685; 8,354,437; and 8,440,703) were invalid.<sup>7</sup> As the Federal Circuit panel stated, there was one additional patent, U.S. Patent No. 5,540,938, owned by Elan Corp. Plc and exclusively licensed to Acorda.<sup>8</sup> That patent broadly claimed therapeutic formulations of 4-aminopyridine (4-AP), while Acorda's patents were for narrower formulations having specific characteristics and properties that distinguished (undisputedly, for novelty purposes) these claims from the claims of the '938 patent.<sup>9</sup>

For the purposes of the appeal, all the asserted claims recited methods, dosing regimens, and sustained-release formulations for methods of administering to a patient with multiple sclerosis a sustained-release 4-AP formulation "(1) in a 10 mg dose twice a day (2) at that stable dose for the entire treatment period of at least two weeks (3) to achieve 4-AP serum levels of 15–35 ng/ml and (4) to improve walking."<sup>10</sup> The parties treated the following claims as representative:

Asserted claim seven (dependent from claim six) of the '826 patent:

6. A dosing regimen method for providing a 4-aminopyridine at a therapeutically effective concentration in order to improve walking in a human with multiple sclerosis in need thereof, said method comprising:

initiating administration of 4-aminopyridine by orally administering to said human a sustained release composition of 10 milligrams of 4-aminopyridine twice daily for a day without a prior period of 4-aminopyridine titration, and then,

maintaining administration of 4-aminopyridine by orally administering to said human a sustained release composition of 10 milligrams of 4-aminopyridine twice daily; without a subsequent period of 4-aminopyridine titration,

whereby an in vivo  $C_{\max SS}:C_{\min SS}$  ratio of 1.0 to 3.5 and a  $C_{av SS}$  of 15 ng/ml to 35 ng/ml are maintained in the human.

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7. *Id.* at 1313.

8. *Id.*

9. *Id.*

10. *Acorda Therapeutics, Inc.*, 903 F.3d at 1313.

7. The method of claim 6, whereby an increase in walking speed is obtained in said human.<sup>11</sup>

Asserted claim twenty-two of the '437 patent (dependent from claim eighteen, which depends on claim one):

A method of increasing walking speed in a human multiple sclerosis patient in need thereof comprising orally administering to said patient a sustained release composition of 10 milligrams of 4-aminopyridine twice daily for a time period of at least two weeks, wherein said 10 milligrams of 4-aminopyridine twice daily are the only doses of 4-aminopyridine administered to said patient during said time period.

...

18. The method of claim 1[,] wherein said sustained release composition is a tablet.

...

22. The method of claim 18[,] wherein said tablet exhibits a release profile to obtain a  $C_{avSS}$  of about 15 ng/ml to about 35 ng/ml.<sup>12</sup>

In the ensuing ANDA litigation,, the defendants stipulated to their infringement, but counterclaimed that all claims at issue were invalid for obviousness.<sup>13</sup> The district court found the '826, '685, '437, and '703 patents (but not the '938 patent) obvious and entered final judgment and an injunction that precluded final approval by the FDA of defendants' ANDAs until July 20, 2018 (the expiration date of the '938 patent).<sup>14</sup> This appeal ensued.

The Federal Circuit affirmed in an opinion by Judge Taranto joined by Judge Dyk; Judge Newman dissented vigorously.<sup>15</sup> The opinion set forth the extensive prior art asserted against Acorda's claims, evidence that Elan had tried (and failed) to produce a suitable 4-AP formulation, and evidence that Sanofi had also attempted making such a formulation without success.<sup>16</sup> Distinctions from the prior art included the need to titrate the dose of 4-AP, which (as the opinion concedes) had a "narrow

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11. U.S. Patent No. 8,007,826 col. 27 ll. 41–59 (filed Dec. 13, 2004).

12. U.S. Patent No. 8,354,437 col. 28 ll. 55–57 (filed Apr. 8, 2005).

13. *Acorda Therapeutics, Inc. v. Roxane Labs., Inc.*, No. 14-882-LPS, 2017 U.S. Dist. LEXIS 48479, at \*3 (D. Del. Mar. 31, 2017), *aff'd*, 903 F.3d 1310 (Fed. Cir. 2018).

14. *Id.* at \*199. The district court found the '938 patent not invalid and infringed, judgments not appealed to the Federal Circuit.

15. *See Acorda Therapeutics, Inc.*, 903 F.3d 1310.

16. *Id.*



toxic-to-therapeutic range.”<sup>17</sup> Also, the opinion noted variable reports of 4-AP efficacy and frequent reports of serious side effects (including seizures) from 4-AP administration in the prior art, and that Acorda’s methods, administration regimens, and sustained-release formulations were the only ones the FDA approved to improve walking speed in multiple sclerosis patients.<sup>18</sup>

Nevertheless, the majority affirmed based on finding the salient limitations (set forth above and numbered (1) through (4)) recited in the prior art, and that the skilled worker would have had a reasonable expectation of success in achieving the claimed invention in view of this extensive art.<sup>19</sup> The majority rejected Acorda’s three contentions: “that the district court erred in finding that a person of skill would have had a motivation to combine the prior art to arrive at the Acorda invention and a reasonable expectation of success in doing so”; “that the claim limitations relating to pharmacokinetics—i.e., achieving 4-AP serum levels of 15–35 ng/ml— are inherent in the claimed invention and therefore obvious”; and “that the court improperly applied a categorical rule that a blocking patent (the Elan patent) negates any findings in favor of Acorda on the objective indicia of commercial success, failure of others, and long felt but unmet need.”<sup>20</sup> While it may appear to some that the majority appears to have cherry-picked the prior art and reconstructed the invention using the claims as a roadmap (illustrating why the Supreme Court might have underestimated the pernicious effects of hindsight in obviousness determinations in *KSR Int’l. Co. v. Teleflex, Inc.*<sup>21</sup>), it is the majority’s rejection of Acorda’s third argument that makes this decision noteworthy.

The majority’s consideration of the so-called “secondary considerations” (otherwise termed the objective indicia of nonobviousness) is grounded in the question of whether the ‘938 patent is a “blocking patent” that itself provides the basis for the commercial success of Acorda’s Ampyra drug product (rather than any purported nonobviousness of the claimed invention).<sup>22</sup> The commercial success objective indication of nonobviousness requires a nexus between the success and the claimed invention; frequently, such assertions are rebutted, *inter alia*, by a patentee’s market power or other alternative

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17. *Id.* at 1316–17.

18. *Id.* at 1314–18.

19. *See Acorda Therapeutics, Inc.*, 903 F.3d at 1335.

20. *Id.* at 1328.

21. *See generally KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007).

22. *Acorda Therapeutics, Inc.*, 903 F.3d at 1336–37.

explanation for commercial success.<sup>23</sup> The majority opinion sets forth the court's precedent based on rebuttal of an assertion of commercial success as a basis for nonobviousness in *Merck & Co. v. Teva Pharmaceuticals USA, Inc.*, *Galderma Laboratories, L.P. v. Tolmar, Inc.*, and *Merck Sharp & Dohme Corp. v. Hospira, Inc.*<sup>24</sup> In each case, the court held that the asserted commercial success did not support nonobviousness due to the existence of another patent not at issue in the litigation that explained why others had not marketed a competing product.<sup>25</sup> Specifically, the majority noted that in *Merck Sharp & Dohme Corp. v. Hospira, Inc. (Merck II)* that “a blocking patent did not, all by itself, justify discounting evidence of commercial success, “calling it a “fact-specific inquiry.”<sup>26</sup> The court understood *Merck II*'s reasoning to reflect a common-sense recognition that, as a theoretical matter, a blocking patent may or may not deter innovation in the blocked space by commercially motivated potential innovators other than the owners or licensees of the blocking patent. Where the owner of the blocking patent or exclusive licensee is different from the owner of the patent in suit, the granting of a license may be a realistic possibility. Even where, as here, the owner of the patent-in-suit and the exclusive licensee of the blocking patent are the same, a potential innovator might or might not think it could successfully challenge the blocking patent. Such a potential innovator might or might not be willing to do research in the blocked space without a license to a blocking patent—even if the research itself is within the safe harbor provided by 35 U.S.C. § 271(e)(1)—and wait until the potential inventor has already developed and patented an aimed-at improvement to negotiate for a cross-license with the blocking patent's owner to share the profits from the improvement.<sup>27</sup> Besides the assessment of whether the blocking patent

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23. *Id.* at 1337.

24. *Acorda Therapeutics, Inc.*, 903 F.3d at 1337–38 (citing *Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364 (Fed. Cir. 2005); *Galderma Laboratories, L.P. v. Tolmar, Inc.*, 737 F.3d 731 (Fed. Cir. 2013); *Merck Sharp & Dohme Corp. v. Hospira, Inc.*, 874 F.3d 724 (Fed. Cir. 2017)).

25. *Id.*

26. *Id.* at 1338 (citing *Merck Sharp & Dohme Corp.*, 874 F.3d at 730).

27. The United States Code gives the definition of infringement:

It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

35 U.S.C. § 271(e)(1) (2010)

can be successfully challenged, a number of other variables appear to the Federal Circuit majority generally relevant to this calculus, including the following:

the costliness of the project; the risk of research failure; the nature of improvements that might arise from the project, and whether such improvements will be entirely covered by the blocking patent; the size of the market opportunities anticipated for such improvements; the costs of arriving at the improvements and getting them to market; the risk of losing the invention race to a blocking-patent owner or licensee; the risk that the blocking-patent owner (making its own economic calculations, perhaps in light of its own other products or research activities) will altogether refuse to grant a license to the improvement or will demand so large a share of profits that the whole project is not worthwhile for the potential innovator—all evaluated in light of other investment opportunities.<sup>28</sup>

Taking these factors and the prior art into consideration (including the fact that Acorda had been given an exclusive license to Elan’s ‘938 patent), the majority held that the district court had not erred in its analysis, given the deference due to the district court on the factual question of commercial success.<sup>29</sup> The same blocking effect was also fatal (to the panel majority) to the assertion of “long-felt need” and “failure of others” as objective indicia of nonobviousness.<sup>30</sup>

Not so for Judge Newman, whose dissent illustrates the pitfalls that exist in any obviousness determination.<sup>31</sup> Judge Newman considered exactly the same prior art and evidence that convinced the majority, and it convinced her of their error.<sup>32</sup> To Judge Newman, the history of the prior art was one of failure of many others to achieve the claimed invention.<sup>33</sup> She deemed the “new legal theory” regarding the almost plenary effect of blocking patents on the objective indicia not just inimical to the patentee, but also to “the afflicted public,” who would have lost the opportunity for Ampyra to have been developed if, in prescient retrospect, Acorda had foreseen the majority’s outcome.<sup>34</sup> Judge Newman cited the prior art as showing “decades of failure” to wrestle this unwieldy drug, with its

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28. *Acorda Therapeutics, Inc.*, 903 F.3d at 1338.

29. *See id.* at 1332.

30. *Id.* at 1341.

31. *Acorda Therapeutics, Inc.*, 903 F.3d. at 1342 (Newman, J., dissenting).

32. *Id.* at 1342–43.

33. *Id.* at 1343.

34. *Id.* at 1342–43.

“narrow toxic-to-therapeutic range[.]” associated with unpredictable and severe side-effects, to the reliable therapeutic uses achieved by Acorda:

The record shows that many scientists in many institutions studied and eventually abandoned 4-AP as a treatment prospect for multiple sclerosis. These abandoned studies constitute the prior art on which the district court and my colleagues rely for obviousness of the Acorda Patents. However, the experimentation with 4-AP shows just the opposite – it shows that work with 4-AP was abandoned due to the inability to balance the compound’s potential effectiveness with its toxicity.<sup>35</sup>

Over and over, through her litany of the prior art, she showed that the majority used prior art to support obviousness that revealed a failure to achieve the therapeutic goals without risking (and incurring) serious side effects.<sup>36</sup> Judge Newman set forth instances where the majority apparently ignored or downplayed evidence that prior art upon which their decision relied reported abandonment of research and development efforts on 4-AP due to “toxicity and seizures,” encephalopathy, hepatitis, or “dizziness, hypotension, or nausea” that accompanied the drug’s use.<sup>37</sup> The record shows that even Acorda, like all the other researchers, initially failed to develop a sustained release formulation and administration regimen effective at improving walking speed in multiple sclerosis patients, and that it was only when Acorda achieved an “analytical breakthrough” (i.e., a reevaluation of the clinical data) that its Ampyra product was successfully developed.<sup>38</sup>

In addition, with regard to the majority’s base determination of obviousness, Judge Newman asserted that:

[T]he question is not whether these four elements [as set forth above], if combined, would produce a successful treatment. The question is whether the prior art contains a suggestion or motivation to select these four elements from the decades of inconclusive prior art, with a reasonable expectation that the selection would eliminate the failures of the prior art.<sup>39</sup>

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35. *Id.* at 1343.

36. *See Acorda Therapeutics, Inc.*, 903 F.3d. at 1342–54 (Newman, J., dissenting).

37. *Id.* at 1347–50.

38. *See id.* at 1349–50.

39. *Id.* (citing *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litigation*, 676 F.3d 1063, 1068–69 (Fed. Cir. 2012)); Kevin E. Noonan, *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litigation* (Fed. Cir. 2012), PATENT DOCS (May 9, 2012), <https://www.patentdocs.org/2012/05/in-re-cyclobenzaprine-hydrochloride-extended-release-capsule-patent-litigation-fed-cir-2012.html> [<https://perma.cc/7NUN-FSSX>].

For Judge Newman, “[t]he years of studies and failures weigh heavily against the simplistic *post hoc* predictability accepted by the court.”<sup>40</sup> Judge Newman found no basis for the majority’s determination that the skilled worker would have had a reasoned basis *from the art* to make the selections Acorda did nor any reasonable expectation of success if the skilled worker had done so:

Acorda is correct that there was no suggestion in the prior art that the claimed combination should be tried, and there is no hint of a reasonable expectation of success. Acorda points to the decades of failure of others to develop a safe and effective treatment for multiple sclerosis using 4-AP, despite its known toxicity. The district court’s selection of separate limitations from separate sources, and retrospectively fitting them into the Acorda template, is achieved only with the hindsight knowledge of Acorda’s eventual success. Here, only the Acorda Patents teach the combination that successfully treats this multiple sclerosis impairment while avoiding toxicity and seizures.<sup>41</sup>

And with regard to commercial success, Judge Newman’s analysis provides a compelling argument that the district court and the majority made the wrong comparison in deciding that Elan’s blocking patent was relevant to the question:

Commercial success is measured against the products available for the same purpose, *not against infringing copies of the patented product*. Defendants do not contend that they are precluded from providing or developing other treatments for multiple sclerosis. The Acorda product met a long-felt need, for which the failure of others, despite decades of experimenting with the neurological properties of 4-AP, is evidence of the unobviousness of the Acorda achievement. Such evidence is an important aid to a court that is attempting to divine whether the patentee’s discovery was obvious in accordance with law.<sup>42</sup>

For good measure, Judge Newman ended her dissent by noting:

The district court was advised that the Patent Trial and Appeal Board sustained the validity of the Acorda Patents in *inter partes* review, at *Coalition for Affordable Drugs (ADROCA), LLC v. Acorda Therapeutics, Inc.* . . . . Although the majority reports this event, as did

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40. *Acorda Therapeutics, Inc.*, 903 F.3d at 1350 (Newman, J., dissenting).

41. *Acorda Therapeutics, Inc.*, 903 F.3d. at 1352–53 (Newman, J., dissenting); *see also Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1086 (Fed. Cir. 2008) (“The determination of obviousness is made with respect to the subject matter as a whole, not separate pieces of the claim.”).

42. *Acorda Therapeutics, Inc.*, 903 F.3d at 1353 (Newman, J., dissenting) (emphasis added).

the district court, its consequences are not explored, including issues of privity, estoppel, and finality.<sup>43</sup>

*B. Berkheimer v. HP Inc. (Fed. Cir. 2018) (Panel: Circuit Judges Moore, Taranto, and Stoll; Opinion by Judge Moore).*

This case arose from a patent infringement complaint by sole inventor Steven E. Berkheimer against HP alleging infringement of U.S. Patent No. 7,447,713.<sup>44</sup> HP moved for summary judgment under § 101 on claims construed by the district court in a *Markman* hearing, which the court granted, and this appeal followed.<sup>45</sup>

The ‘713 patent is directed to “digitally processing and archiving files in a digital asset management system” which “parses files into multiple objects and tags the objects to create relationships between them,” then compares these objects to “archived objects to determine whether variations exist based on predetermined standards and rules.”<sup>46</sup> The claimed method “eliminates redundant storage of common text and graphical elements, which improves system operating efficiency and reduces storage costs.”<sup>47</sup> Claims one and four of the ‘713 patent recite:

1. A method of archiving an item comprising in a computer processing system:

presenting the item to a parser;

    parsing the item into a plurality of multi-part object structures wherein portions of the structures have searchable information tags associated therewith;

    evaluating the object structures in accordance with object structures previously stored in an archive;

    presenting an evaluated object structure for manual reconciliation at least where there is a predetermined variance between the object and at least one of a predetermined standard and a user defined rule.<sup>48</sup>

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43. *Acorda Therapeutics, Inc.*, 903 F.3d. at 1354 (Newman, J., dissenting).

44. *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1362 (Fed. Cir. 2018); U.S. Patent No. 7,447,713 (filed Oct. 15, 2001).

45. *Id.* at 1362–63.

46. *Id.* at 1362.

47. *Id.* at 1362–63.

48. *Berkheimer*, 881 F.3d at 1366.

4. The method as in claim 1 which includes storing a reconciled object structure in the archive without substantial redundancy.<sup>49</sup>

The district court's decision granting summary judgment of patent ineligibility was grounded in the Supreme Court's *Alice Corp. v. CLS Bank Int'l* precedent, which set forth a two-part test to determine whether claims are directed to patent-eligible subject matter under § 101.<sup>50</sup> In the first prong of the test, a court must decide whether a claim is directed to one of the judicial exceptions (laws of nature, natural phenomena, and abstract ideas).<sup>51</sup> If so, then the court must further decide under the second prong of the *Alice/Mayo* test whether any element or combination of elements in the claim is sufficient to ensure that the claim amounts to significantly more than the judicial exception.<sup>52</sup> Several Federal Circuit cases have established that generic computer implementation of an otherwise abstract process does not qualify as "significantly more," but a claimed improvement to a computer or technological process can be patent-eligible.<sup>53</sup>

Regarding its § 101 analysis, the district court found that claim 1 satisfied the first prong of the *Alice/Mayo* test, being directed to "the abstract idea of 'using a generic computer to collect, organize, compare, and present data for reconciliation prior to archiving.'"<sup>54</sup> The Federal Circuit agreed, holding that "claims 1-3 and 9 are directed to the abstract idea of parsing and comparing data; claim 4 is directed to the abstract idea of parsing, comparing, and storing data; and claims 5-7 are directed to the abstract idea of parsing, comparing, storing, and editing data."<sup>55</sup> The court found analogies between Berkheimer's claims and those of *In re TLI Commc'ns LLC Patent Litig.* and *Content Extraction & Transmission LLC v. Wells Fargo Bank, Nat'l Ass'n.*, where claims directed to obtaining, processing, and storing data were found to be abstract.<sup>56</sup> The court rejected Berkheimer's argument that the claims were not abstract because "the 'parsing' limitation roots the claims in technology and transforms the data structure from source code to object code," saying

49. *Id.* at 1370; U.S. Patent No. 7,447,713 col. 47 ll. 8–30 (filed Oct. 15, 2001).

50. *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 218 (2014).

51. *Id.* at 217.

52. *Id.* at 217–18; *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66, 88 (2012).

53. *Alice Corp. Pty. Ltd.*, 573 U.S. at 225–26.

54. *Id.* at 1366.

55. *Berkheimer*, 881 F.3d at 1366.

56. *Id.* at 1366–67 (citing *In re TLI Commc'ns LLC Patent Litig.*, 823 F.3d 607, 613 (Fed. Cir. 2016); *Content Extraction & Transmission LLC v. Wells Fargo Bank, Nat'l Ass'n.*, 776 F.3d 1343, 1347 (Fed. Cir. 2014)).

“[t]hat the parser transforms data from source to object code does not demonstrate non-abstractness without evidence that this transformation improves computer functionality in some way.”<sup>57</sup>

Turning to the second prong of the § 101 inquiry, the court reiterated that “[t]he second step of the *Alice/Mayo* test is satisfied when the claim limitations ‘involve more than performance of well-understood, routine, and conventional activities previously known to the industry.’”<sup>58</sup> But the court then set forth its novel appreciation of how courts should apply the *Alice/Mayo* test that makes this case noteworthy:

The question of whether a claim element or combination of elements is well-understood, routine and conventional to a skilled artisan in the relevant field is a question of fact. Any fact, such as this one, that is pertinent to the invalidity conclusion must be proven by clear and convincing evidence. Like indefiniteness, enablement, or obviousness, whether a claim recites patent eligible subject matter is a question of law which may contain underlying facts.<sup>59</sup>

The panel found support for its interpretation in *Accenture Global Servs., GmbH v. Guidewire Software, Inc.*, as well as Justice Breyer’s statement from *Mayo v. Prometheus*, that the § 101 inquiry may overlap with fact-sensitive inquiries such as that for novelty under § 102.<sup>60</sup> This fact-based inquiry will not necessarily arise in every patent-eligibility challenge; some § 101 disputes may be resolved as a matter of law when there is no material issue of fact regarding whether one or more claim elements or combination thereof is well-understood, routine, or conventional to a person of ordinary skill in the art.<sup>61</sup> Applying these principles to the case at bar, the court stated:

While patent eligibility is ultimately a question of law, the district court erred in concluding there are no underlying factual questions to the § 101 inquiry. Whether something is well-understood, routine, and conventional to a skilled artisan at the time of the patent is a factual determination. Whether a particular technology is well-understood, routine, and conventional goes beyond what was simply known in the prior art. The mere fact that something is disclosed in a piece of prior

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57. *Id.* at 1367.

58. *Id.* (quoting *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 573 U.S. 208, 225 (2014)).

59. *Berkheimer*, 881 F.3d at 1368 (emphasis added).

60. *Id.*; see generally *Accenture Glob. Servs. GMBH v. Guidewire Software, Inc.*, 691 F. Supp. 2d 577 (D. Del. 2010); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012).

61. *Berkheimer*, 881 F.3d at 1368.



art, for example, does not mean it was well-understood, routine, and conventional.<sup>62</sup>

This reasoning implicates a distinction between whether a technology is “known” in the sense of § 102 (e.g., publicly available) and whether one of ordinary skill would find this technology to be well-understood, routine, and conventional (e.g., something that this person of ordinary skill would consider to be textbook knowledge or part of his or her ordinary course of activities).<sup>63</sup>

Despite enunciating this new interpretation of the *Alice/Mayo* test, the court concluded that claim 1 does not provide an inventive concept beyond that of the abstract idea therein.<sup>64</sup> On the other hand, the Court held that claims 4 through 7 recite “limitations directed to the arguably unconventional inventive concept described in the specification . . . that storing object structures in the archive without substantial redundancy improves system operating efficiency and reduces storage costs.”<sup>65</sup> This raised a genuine issue of material fact regarding these claims (i.e., “whether claims 4-7 archive documents in an inventive manner that improves these aspects of the disclosed archival system”).<sup>66</sup> Accordingly, the Federal Circuit remanded the matter to the district court to make such a determination.<sup>67</sup>

Prior to this decision, district courts considered questions of patent eligibility under § 101 as pure questions of law, typically on motions to dismiss early in litigation, and frequently without requiring claim construction on that basis. Part of these proceedings have been otherwise-unsubstantiated allegations that claim elements considered under the second prong of the *Alice/Mayo* test were “well-understood, routine, and conventional” without requiring any evidence to support the allegations.<sup>68</sup> Courts have not supported patentees’ supplications that evidence was required for this prong. The U.S. Patent and Trademark Office (Patent Office) has taken a similar stance: there has been little support for the notion that an examiner need supply facts in support of bald allegations of conventionality (albeit typically in the face of disclosure in the specification that supports the examiner’s position). This decision provides a basis for patentees and forewarned patent applicants to

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62. *Id.* at 1369.

63. *See Berkheimer*, 881 F.3d at 1369.

64. *Id.*

65. *Id.* at 1370.

66. *Id.*

67. *Id.* at 1371.

68. *See generally Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 573 U.S. 208 (2014).

challenge these broad statements of conventionality, and, at a minimum, get around presumptive decisions by courts and the Patent Office that have heretofore precluded the opportunity to address the factual underpinnings *vel non* of such arguments contrary to patent eligibility.

C. *Saint Regis Mohawk Tribe v. Mylan Pharmaceuticals Inc. (Fed. Cir. 2018) (Panel: Circuit Judges Dyk, Moore, and Reyna; Opinion by Judge Moore; concurring opinion by Judge Dyk).*

In *St. Regis Mohawk Tribe v. Mylan Pharmaceuticals*, the Federal Circuit affirmed the decision by the Patent Trial and Appeal Board (PTAB) of the Patent Office that tribal immunity could not be used to shield patents in IPR proceedings by denying the St. Regis Mohawk Tribe's motion to terminate Mylan's IPR proceedings on these grounds.<sup>69</sup>

The issue arose in IPR Nos. IPR2016-01127, IPR2016-01128, IPR2016-01129, IPR2016-01130, IPR2016-01131, and IPR2016-01132 (and parallel IPRs filed by Petitioners Teva Pharmaceuticals USA, Inc. and Akorn, Inc., which had been joined with Mylan's IPRs), instituted against U.S. Patent Nos. 8,685,930, 8,629,111, 8,642,556, 8,633,162, 8,648,048, and 9,248,191, respectively.<sup>70</sup> After the PTAB instituted IPRs against these six patents owned by Allergan, and directed to its Restasis product, Allergan assigned its rights in the patents to the St. Regis Mohawk Tribe (Tribe) in return for a license.<sup>71</sup> The Tribe argued unsuccessfully before the PTAB that, as the Tribe was the rightful owner of the patents, the PTAB lost jurisdiction based on tribal sovereign immunity.<sup>72</sup> The PTAB held that, as an issue of first impression, the Tribe had not borne its burden of showing it was entitled to the requested relief, and that the nature of the license left all substantive patent rights with

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69. *Saint Regis Mohawk Tribe v. Mylan Pharm., Inc.*, 896 F.3d 1322, 1325 (Fed. Cir. 2018).

70. U.S. Patent No. 8,685,930 (filed Aug. 7, 2013); U.S. Patent No. 8,629,111 (filed Aug. 14, 2013); U.S. Patent No. 8,642,556 (filed Aug. 14, 2013); U.S. Patent No. 8,633,162 (filed Aug. 14, 2013); U.S. Patent No. 8,648,048 (filed Aug. 14, 2013); U.S. Patent No. 9,248,191 (filed Mar. 21, 2014).

71. *Mylan Pharm. Inc. v. Saint Regis Mohawk Tribe*, IPR2016-01127, 5-6 (P.T.A.B. Feb. 23, 2018); Kevin E. Noonan, *Allergan Avails Itself of Sovereign Immunity*, PATENT DOCS (Sept. 13, 2017), <https://www.patentdocs.org/2017/09/allergan-avails-itself-of-sovereign-immunity.html> [<https://perma.cc/TV8F-VBSK>].

72. *Mylan Pharms. Inc. v. Saint Regis Mohawk Tribe*, IPR2016-01127, 18 (P.T.A.B. Feb. 23, 2018); Kevin E. Noonan, *Mohawk Nation Exercises Sovereign Immunity in Inter Partes Review*, PATENT DOCS (Sept. 25, 2017), <https://www.patentdocs.org/2017/09/mohawk-nation-exercises-sovereign-immunity-in-inter-partes-review.html> [<https://perma.cc/JQ8U-CNVA>].

Allergan, which company could thus amply represent the Tribe's rights, even in its absence.<sup>73</sup>

The Federal Circuit affirmed in an opinion by Judge Moore.<sup>74</sup> The opinion acknowledged the existence of tribal sovereign immunity affirmed by the Supreme Court, as described in the *Santa Clara Pueblo v. Martinez*<sup>75</sup> and *Oklahoma Tax Commission v. Citizen Band Potawatomi Indian Tribe of Oklahoma*, judicial decisions<sup>76</sup> but that this immunity “does not extend to actions brought by the federal government.”<sup>77</sup> In particular, tribal sovereign immunity “does not apply where the federal government acting through an agency engages in an investigative action or pursues an adjudicatory agency action.”<sup>78</sup> However, this exception to tribal sovereign immunity does not constitute a blanket rule regarding the application of tribal sovereign immunity.<sup>79</sup>

The Supreme Court's opinion in *Federal Maritime Commission v. South Carolina State Ports Authority (FMC)*<sup>80</sup> formed the basis of the panel's decision. This is appropriate seeing as the Tribe had itself cited this case to support its sovereign immunity assertion (even though that case involved state, not tribal, sovereign immunity).<sup>81</sup> The panel drew its distinction on the basis that it considered IPRs to be more akin to federal administrative proceedings (in which the federal government is the “superior sovereign,” and tribal immunity does not apply) than these proceedings are to a dispute between private parties, in which a government agency plays an adjudicatory role (as in the *FMC* precedent).<sup>82</sup> The opinion distinguished IPRs from the circumstances in *FMC* based on the hybrid nature of IPRs, as the Supreme Court characterized these proceedings in *Cuozzo Speed Technologies, LLC v.*

73. *Mylan Pharms. Inc. v. Saint Regis Mohawk Tribe*, IPR2016–01127, (P.T.A.B. Feb. 23, 2018); Kevin E. Noonan, *PTAB Denies St. Regis Mohawk Tribe's Motion to Terminate IPRs based on Sovereign Immunity*, PATENT DOCS (Feb. 25, 2018), <https://www.patentdocs.org/2018/02/ptab-denies-st-regis-mohawk-tribes-motion-to-terminate-iprs-based-on-sovereign-immunity.html> [https://perma.cc/S3FJ-PFFT.]

74. *Saint Regis Mohawk Tribe*, 896 F.3d at 1324.

75. *Santa Clara Pueblo v. Martinez*, 436 U.S. 49 (1978).

76. *Okla. Tax Comm'n v. Citizen Band Potawatomi Indian Tribe*, 498 U.S. 505 (1991).

77. *Saint Regis Mohawk Tribe*, 896 F.3d at 1325 (citing *E.E.O.C. v. Karuk Tribe Housing Authority*, 260 F.3d 1071, 1075 (9th Cir. 2001); *United States v. Red Lake Band of Chippewa Indians*, 827 F.2d 380, 383 (8th Cir. 1987)).

78. *Id.* (citing *Pauma v. NLRB*, 888 F.3d 1066 (9th Cir. 2018), and *Fed. Power Comm'n v. Tuscarora Indian Nation*, 362 U.S. 99, 122 (1960); *Karuk Tribe Hous. Auth.*, 260 F.3d 1071 (9th Cir. 2001)).

79. *Id.* (citing *Fed. Maritime Comm'n v. S.C. State Ports Auth.*, 535 U.S. 743, 754–56 (2002)).

80. *FMC v. S.C. State Ports Auth.*, 535 U.S. 743, 754–56 (2002).

81. *Saint Regis Mohawk Tribe*, 896 F.3d at 1326.

82. *Id.*

*Lee*.<sup>83</sup> The Federal Circuit’s opinion further relied upon the Supreme Court’s continuation of its explication of the nature of IPRs in its two recent decisions on these proceedings, *Oil States Energy Services v. Greene’s Energy Group, LLC* and *SAS Institute Inc. v. Iancu*.<sup>84</sup> Under these precedents, the panel concluded that there were sufficient similarities between IPRs and administrative agency proceedings (here, wherein the Patent Office reconsiders the propriety of granting the challenged patents) and sufficient differences from more adjudicatory proceedings (including the broad and complete discretion vested in the Director of the Patent Office on whether to institute an IPR, the absence of any requirement that either party continue to participate once an IPR has been instituted, and procedural differences relating to, *inter alia*, evidentiary and discovery rules) for tribal sovereign immunity not to apply.<sup>85</sup> The “government’s central role” in IPRs and the Director’s unreviewable discretion (rather than the insistence of a private party) in deciding whether to institute IPR proceedings were considerations leading to the panel’s conclusion that an “IPR is more like an agency enforcement action than a civil suit brought by a private party,” and tribal sovereign immunity could not shield the Tribe from the IPRs.<sup>86</sup> The opinion notes that the Director is politically accountable, *sub silentio*, acknowledging the public policy aspects of the question, both in controlling increased drug prices and in the ability of Native American tribes to participate in facets of the economy outside casinos and tourism.<sup>87</sup>

Also relevant to the panel’s opinion is the capacity of the PTAB to continue IPRs after institution even if the petitioner (as in *Cuozzo*) or patent holder declines to participate.<sup>88</sup> Finally, substantial differences in procedure between IPRs and district court litigation (wherein similarities between administrative agency action and district court litigation was used to support tribal sovereign immunity in *FMC*) was another basis for the Federal Circuit’s opinion.<sup>89</sup>

The opinion avoided Mylan’s other arguments, including that the assignment and re-licensing of these patents was a sham, intended by the parties to avoid reexamination of these patents, that would thwart

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83. *Id.*

84. *Id.* at 1326–27.

85. *Saint Regis Mohawk Tribe*, 896 F.3d at 1327.

86. *Id.*

87. *Id.*

88. *Reactive Surfaces Ltd., LLP v. Toyota Motor Corp.*, IPR2017-00572, 2 (P.T.A.B. July 13, 2017).

89. *Saint Regis Mohawk Tribe*, 896 F.3d at 1328 (“An IPR hearing is nothing like a district court patent trial.”).

congressional goals of improving patent quality via IPRs that provide a means to invalidate improvidently granted patents.<sup>90</sup> The panel also pointedly stated that its decision was limited to tribal sovereign immunity, and that the Court “leave[s] for another day” the question of whether States can assert their Eleventh Amendment immunity against IPR proceedings (which the court is scheduled to hear in the upcoming *Ericsson v. University of Minnesota* appeal).<sup>91</sup>

Judge Dyk wrote a concurring opinion, expressing his views that the history of reexamination proceedings before the Patent Office was consistent with the panel’s decision to uphold the PTAB’s refusal to recognize tribal sovereign immunity in this case.<sup>92</sup>

The Tribe thereafter filed a petition for *certiorari* to the Supreme Court,<sup>93</sup> which the Court denied.<sup>94</sup>

*D. Regents of the University of California v. Broad Institute, Inc. (Fed. Cir. 2018) (Panel: Chief Judge Prost and Circuit Judges Schall and Moore; Opinion by Judge Moore).*

In *Regents of the University of California v. Broad Institute, Inc.*, the Federal Circuit affirmed the PTAB in an appeal of the CRISPR<sup>95</sup> interference.<sup>96</sup> Because the Federal Circuit did not rehear this decision *en banc* (and the parties did not petition the Supreme Court for *certiorari*), the interference between the Broad Institute (Broad) and the University of California/Berkeley (UC) is now concluded.<sup>97</sup> The court affirmed the PTAB’s decision<sup>98</sup> that there is no interference-in-fact between Broad’s

90. *Id.*

91. *Saint Regis Mohawk Tribe*, 896 F.3d at 1329.

92. *Id.* at 1329–35 (Dyk, J., concurring).

93. Petition for Writ of Certiorari, *Saint Regis Mohawk Tribe, et al. v. Mylan Pharmaceuticals, Inc., et al.*, US\_\_ (No. 18-899).

94. Kevin E. Noonan, *Supreme Court Denied Certiorari Writ by St. Regis Mohawk Indian Tribe in Restatis® IPR*, PATENT DOCS (Apr. 15, 2019), <https://www.patentdocs.org/2019/04/supreme-court-denied-certiorari-writ-by-st-regis-mohawk-indian-tribe-in-restatis-ipr.html>.

95. CRISPR is an acronym for “clustered regularly interspaced short palindromic repeats”. In the context of “gene editing”, CRISPR often functions in conjunction with Cas9 (“CRISPR-associated protein 9”), and the combination of the two is also known as “CRISPR-Cas9.” There are other CRISPR-associated proteins in addition to type “9”.

96. *Regents of the Univ. of Cal. v. Broad Inst., Inc.*, 903 F.3d 1286, 1297 (Fed. Cir. 2018).

97. *See Regents of the Univ. of Cal.*, 903 F.3d at 1297.

98. *Id.* at 1289; Kevin E. Noonan, *PTAB Decides CRISPR Interference—No interference-in-fact*, PATENT DOCS (Feb. 15, 2017), <https://www.patentdocs.org/2017/02/ptab-decides-crispr-interference-no-interference-in-fact.html> [<https://perma.cc/HX9Y-NFRR>]; Kevin E. Noonan, *PTAB Decides CRISPR Interference in Favor of Broad Institute—Their Reasoning*, PATENT DOCS (Feb. 16, 2017), <https://www.patentdocs.org/2017/02/ptab-decides-crispr-interference-in-favor-of-broad-institute-their-reasoning.html> [<https://perma.cc/4959-PNPJ>].

twelve patents<sup>99</sup> and one application-in-interference and UC's pending patent application.<sup>100</sup>

To recap, the PTAB found that there was no interference-in-fact based on these requirements: In this proceeding, to prevail on its argument that there is no interference, Broad must show that the parties' claims do *not* meet at least one of the following two conditions:

1. that, if considered to be prior art to UC's claims, Broad's involved claims would not anticipate or render obvious UC's involved claims, or
2. that, if considered to be prior art to Broad's claims, UC's involved claims would not anticipate or render obvious Broad's claims.

Broad will prevail and a determination of no interference-in-fact will be made if a preponderance of the evidence indicates one of these conditions is not met.<sup>101</sup>

In considering the evidence before it, the PTAB gave great weight to contemporaneous, cautious statements in the art regarding whether the system would work in eukaryotic cells in view of inventor Doudna's disclosure of *in vitro* CRISPR activity.<sup>102</sup> Specifically, these statements convinced the PTAB that while the results "suggested the 'exciting possibility'" that CRISPR could be operative in eukaryotic cells: "it was not known whether such a bacterial system would function in eukaryotic cells"<sup>103</sup> and "[i]n another report, Doudna was quoted as stating that she had experienced 'many frustrations' getting CRISPR to work in human cells and that she knew that if she succeeded, CRISPR would be 'a profound discovery.'"<sup>104</sup> UC's assertion of other statements by their inventors that could be interpreted more positively did not convince the PTAB that there was a reasonable expectation of success in the art for getting CRISPR to work in eukaryotic cells,<sup>105</sup> with the PTAB stating "[a]lthough the statements express an eagerness to learn the results of

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99. *Regents of the Univ. of Cal.*, 903 F.3d at 1289–90 (citing U.S. Patent No. 8,697,359 (filed Oct. 15, 2013) as being representative).

100. *Id.* at 1289.

101. *Broad Inst., Inc., v. Regents of the Univ. of Cal.*, No. 106,048, 9 (P.T.A.B. Feb. 15, 2017), <https://e-foia.uspto.gov/Foia/RetrievePdf?system=BPAI&fINm=fd106048-02-15-2017-1> [<https://perma.cc/3T6M-6HQL>].

102. *Broad Inst., Inc., v. Regents of the Univ. of Cal.*, No. 106,048, 21 (P.T.A.B. Feb. 15, 2017); *Regents of the Univ. of Cal.*, 903 F.3d at 1293.

103. *Broad Inst., Inc., v. Regents of the Univ. of Cal.*, No. 106,048, 14 (P.T.A.B. Feb. 15, 2017).

104. *Id.* at 15.

105. *Id.*

experiments in eukaryotic cells and the importance of such results, none of them express an expectation that such results would be successful.”<sup>106</sup>

The PTAB swept aside UC’s arguments that this reasoning was flawed because the standard is not the inventor’s expectations, but those of the worker of ordinary skill. The PTAB stated that “if the inventors themselves were uncertain, it seems that ordinarily skilled artisans would have been even more uncertain.”<sup>107</sup> The PTAB also quoted UC’s expert as having said (contemporaneously with Professor Doudna’s report of *in vitro* CRISPR activity): “[t]here is no guarantee that [CRISPR] will work effectively on a chromatin target or that the required DNA-RNA hybrid can be stabilized in that context.”<sup>108</sup> The PTAB concluded that “[w]e fail to see how ‘no guarantee’ indicates an expectation of success.”<sup>109</sup>

Nor was the PTAB convinced based on the history of the development of CRISPR technology, which showed that many laboratories independent of the Doudna group quickly applied the new technology to manipulate eukaryotic cell genomic DNA<sup>110</sup>:

Regardless of how many groups achieved success in eukaryotic cells, we are not persuaded that such success indicates there was an *expectation* of success before the results from these experiments were known. The unpublished results of research groups are not necessarily an indication of whether ordinarily skilled artisans would have expected the results achieved. Instead of viewing such work as evidence of an expectation of success, we consider the number of groups who attempted to use CRISPR-Cas9 in eukaryotic cells to be evidence of the motivation to do so, an issue that is not in dispute. We agree with Broad’s argument that a large reward might motivate persons to try an experiment even if the likelihood of success is very low.<sup>111</sup>

The PTAB found that this evidence further supported its decision that there was insufficient evidence of a reasonable expectation of success to support UC’s allegation that their earlier work and publications would have rendered Broad’s invention obvious.<sup>112</sup> This evidence was that “differences in gene expression, protein folding, cellular compartmentalization, chromatin structure, cellular nucleases, intracellular temperature, intracellular ion concentrations, intracellular

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106. *Id.* at 17.

107. *Id.*

108. *Broad Inst., Inc., v. Regents of the Univ. of Cal.*, No. 106,048, 17 (P.T.A.B. Feb. 15, 2017).

109. *Id.* at 19.

110. *Id.* at 23.

111. *Id.*

112. *Id.* at 24.

pH, and the types of molecules in prokaryotic versus eukaryotic cells would contribute to this unpredictability [regarding whether the CRISPR-Cas9 system would be operative in eukaryotic cells].”<sup>113</sup> In response to UC’s allegations that these considerations turned out not to be an impediment to CRISPR’s activity in eukaryotic cells, the PTAB said “[t]he relevant question before us is whether those of skill in the art would have *expected* there to be problems *before* the experiments were done,” not whether it turned out that the experiments were successful once they were tried.<sup>114</sup>

Finally, the PTAB rejected UC’s citation of other prokaryotic genetic modification systems found to work in eukaryotes, finding that there was no commonality in these methods that would have refuted Broad’s evidence that the skilled worker would not have had any reasonable expectation of success.<sup>115</sup>

UC appealed, and on September 10, 2018, the Federal Circuit affirmed in an opinion by Judge Moore, joined by Chief Judge Prost and Judge Schall.<sup>116</sup> After providing a description of CRISPR<sup>117</sup>, and outlining substantive and procedural issues that had been before the PTAB, the court addressed the legal arguments proffered by UC in support of its argument against the PTAB’s decision of no interference-in-fact.<sup>118</sup> As stated in the opinion,

This case turns in its entirety on the substantial evidence standard. The [PTAB] found a person of ordinary skill in the art would not have had a reasonable expectation of success in applying the CRISPR-Cas9 system in eukaryotic cells. . . . Given the mixture of evidence in the record, we hold that substantial evidence supports the [PTAB]’s finding that there was not a reasonable expectation of success, and we affirm.<sup>119</sup>

The opinion then addressed UC’s two arguments aimed at refuting the PTAB’s decision, “that the [PTAB]: (1) improperly adopted a rigid test for obviousness that required the prior art contain specific instructions, and (2) erred in dismissing evidence of simultaneous

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113. *Broad Inst., Inc., v. Regents of the Univ. of Cal.*, No. 106,048, 29-30 (P.T.A.B. Feb. 15, 2017).

114. *Id.* at 32.

115. *Id.* at 39.

116. *Regents of the Univ. of Cal. v. Broad Inst., Inc.*, 903 F.3d 1286, 1288 (Fed. Cir. 2018).

117. See generally Kevin E. Noonan, *CRISPR Interference Declared*, PATENT DOCS (Jan. 28, 2016), <https://www.patentdocs.org/2016/01/crispr-interference-declared.html> [<https://perma.cc/MNK6-DEVY>].

118. *Regents of the Univ. of Cal.*, 903 F.3d at 1292.

119. *Regents of the Univ. of Cal.*, 903 F.3d at 1291.



invention as irrelevant.”<sup>120</sup> The court based its opinion on the evidence presented by one of Broad’s experts with regard to the difference between prokaryotic and eukaryotic cells (a distinction Broad recited extensively) “that rendered the application of the CRISPR-Cas9 system in eukaryotic cells unpredictable.”<sup>121</sup> These differences raised issues relevant to whether the skilled worker would have had a reasonable expectation of success in applying CRISPR to eukaryotic cells, and were also, according to the opinion, recognized by UC’s expert, including *inter alia* statements such as, “[t]here is no guarantee that Cas9 will work effectively on a chromatin target or that the required DNA-RNA hybrid can be stabilized in that context” and “whether the CRISPR-Cas9 system will work in eukaryotes ‘remains to be seen’ and ‘[o]nly attempts to apply the system in eukaryotes will address these concerns.’”<sup>122</sup> This evidence was supported, in the panel’s opinion, by UC’s own inventors (including Jennifer Doudna), “acknowledging doubts and frustrations about engineering CRISPR-Cas9 systems to function in eukaryotic cells and noting the significance of Broad’s success.”<sup>123</sup> In addition, the court noted evidence that other prokaryotic systems adapted to eukaryotic cells (“riboswitches, ribozyme systems, and group II introns”) “either [had] limited efficacy or the technology required a specific strategy to adapt it for use in eukaryotic cells.”<sup>124</sup> According to the court, this amounted to substantial evidence that the skilled worker would not have had a reasonable expectation of success in achieving CRISPR in eukaryotic cells.<sup>125</sup> The opinion recognized that UC had presented evidence in support of its position, but noted “[w]e are, however, an appellate body. We do not reweigh the evidence. It is not our role to ask whether substantial evidence supports fact-findings not made by the [PTAB], but instead whether such evidence supports the findings that were in fact made.”<sup>126</sup>

The opinion also rejected UC’s arguments that the PTAB had used a rigid test that required specific instructions in the prior art, and ignored the “inferences and creative steps” recognized as being relevant to an obviousness determination under the Supreme Court’s decision in *KSR Int’l Co. v. Teleflex Inc.*<sup>127</sup> With regard to “simultaneous invention”

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120. *Id.*

121. *Id.* at 1292.

122. *Id.*

123. *Id.* at 1293.

124. *Regents of the Univ. of Cal.*, 903 F.3d at 1293.

125. *Id.* at 1294.

126. *Id.*

127. *Id.* (citing *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418, 420 (2007)).

evidence (which UC argued the PTAB ignored), the opinion states that while “[s]imultaneous invention may serve as evidence of obviousness when considered in light of all of the circumstances,”<sup>128</sup> the existence of interferences means that simultaneous invention cannot, by itself, be evidence of obviousness.<sup>129</sup> The Federal Circuit rejected UC’s argument that evidence that six independent research groups applied CRISPR to eukaryotic cells “within a short period of time” after publication of its discovery on prokaryotes rendered Broad’s claims obvious, and approved the legal rationale used by the PTAB:<sup>130</sup>

The [PTAB] explained that “[e]ach case’s particular context, including the characteristics of the science or technology, its state of advance, the nature of the known choices, the specificity or generality of the prior art, and the predictability of results in the area of interest.” . . . (quoting *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1352 (Fed. Cir. 2008)). We do not see any error in this analysis.<sup>131</sup>

An important consequence of this decision is that the *status quo* will remain unchanged: Broad will maintain its extensive CRISPR patent portfolio and UC’s patent application (reciting claims broader than Broad’s and encompassing CRISPR without regard to the cells in which it is practiced) will have been granted by the Patent Office as a patent in due course.<sup>132</sup> Under these circumstances, a third party wishing to practice the technology in eukaryotic cells (encompassing everything from yeast to humans) would need a license from *both* UC and Broad (absent the parties coming to an agreement on how their overlapping technologies will be licensed). This situation of blocking patents could hinder commercial adoption of powerful new gene editing techniques. However, the prospect of holding back such a revolutionary and potentially beneficial new biotechnology should provide further impetus for some sort of co-licensing agreement between the parties to be forged.

*E. Oil States Energy Services, LLC v. Greene’s Energy Group, LLC (2018) (Opinion of the Court by Justice Thomas, joined by Justices Kennedy, Ginsburg, Breyer, Alito, Sotomayor, and Kagan; concurring opinion by Justice Breyer, joined by Justices Ginsburg*

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128. *Id.* at 1295 (citing *Lindemann Maschinenfabrik GmbH v. Am. Hoist & Derrick Co.*, 730 F.2d 1452, 1460 (Fed. Cir. 1984)).

129. *Id.*

130. *Regents of the Univ. of Cal.*, 903 F.3d at 1296.

131. *Id.*

132. U.S. Patent No. 10,266,850; see, Kevin E Noonan, *Another U.S. Patent Issued for CRISPR* (Apr. 28, 2019), <https://www.patentdocs.org/2019/04/another-us-patent-issued-for-crispr.html>.

and *Sotomayor*; dissenting opinion by Justice Gorsuch, joined by Chief Justice Roberts).

On April 24, 2018, the Supreme Court held in *Oil States Energy Services, LLC v. Greene's Energy Group, LLC* that IPR proceedings violate neither Article III nor the Seventh Amendment of the Constitution.<sup>133</sup> Justice Thomas, writing for the majority, explained that a grant of a patent is a matter involving a public right, not a private right, and falls within the public rights doctrine as involving the same considerations involved in a grant of a patent.<sup>134</sup> The majority noted that “[p]atent claims are granted subject to the qualification that the [Patent Office] has ‘the authority to reexamine—and perhaps cancel—a patent claim’ in an *inter partes* review” and this removes any constitutional infirmity for an Article I court (the PTAB) relieving a patentee of an improvidently granted patent right.<sup>135</sup> The majority opinion and the dissent both based their decisions on *McCormick Harvesting Machine v. Aultman*.<sup>136</sup> Justice Gorsuch’s dissent relied upon the broad language of that case that “[t]he only authority competent to set a patent aside, or to annul it, or to correct it for any reason whatever, is vested in the courts of the United States, and not in the department which issued the patent.”<sup>137</sup> However, the majority pointed out that this is “best read as a description of the statutory scheme that existed at that time,” and did not address whether Congress had authority to establish an entirely different scheme<sup>138</sup> (which it has done repeatedly since 1980 with passage of the amendment to the Patent Act authorizing *ex parte* reexamination).<sup>139</sup> In fact, before the 1870 change to the patent statute discussed in that case, Congress provided examiners with absolute discretion to cancel any reintroduced original claim in a reissue proceeding.<sup>140</sup> Congress withdrew this grant of authority before *McCormick Harvesting*, which made the Patent Office’s cancellation of original claims in reissue proceedings a violation of due process and an invasion on the then-exclusive jurisdiction of the judicial branch by the executive.<sup>141</sup>

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133. *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1379 (2018).

134. *Id.* at 1373.

135. *Id.* at 1374.

136. *See id.* at 1369 (citing *McCormick Harvesting Mach. Co. v. Aultman*, 169 U.S. 606 (1898)).

137. *Id.* at 1384 (Gorsuch, J., dissenting).

138. *Id.* at 1376 (majority opinion).

139. 35 U.S.C. § 302 (2012).

140. *Oil States Energy Servs.*, 138 S. Ct. at 1376.

141. *Id.*

The Court stressed, however, that its holding was limited to the question of the constitutionality of IPRs only.<sup>142</sup> For example, the Court pointed out that “Oil States [did] not challenge the retroactive application of *inter partes* review, even though that procedure was not in place when its patent issued.”<sup>143</sup> In addition, the Court noted that it was not determining that IPR proceedings could not raise due process concerns.<sup>144</sup> Finally, the Court emphasized that the holding should not be misconstrued to suggest that other constitutional challenges could not be made; for example, challenges related to the Due Process Clause or the Takings Clause.<sup>145</sup>

Justice Breyer wrote a concurrence that was joined by Justices Ginsberg and Sotomayor.<sup>146</sup> Even though he joined the Court’s opinion in full, Justice Breyer wrote to stress that the decision should not be read as stating that matters involving private rights could never be adjudicated outside of Article III courts.<sup>147</sup>

Justice Gorsuch’s dissent, joined by the Chief Justice,<sup>148</sup> explained that the history of the patent system and the prior case law required the finding that patents are private rights, and therefore must be adjudicated in Article III courts.<sup>149</sup>

*F. SAS Institute Inc. v. Iancu (2018) (Opinion of the Court by Justice Gorsuch, joined by Chief Justice Roberts and Justices Kennedy, Thomas, and Alito; dissenting opinion by Justice Ginsburg, joined by Justices Breyer, Sotomayor, and Kagan; dissenting opinion by Justice Breyer, joined by Justices Ginsburg and Sotomayor, and joined except as to Part III-A by Justice Kagan).*

The Supreme Court reversed the judgment of the Federal Circuit on April 24, 2018,, in *SAS Institute Inc. v. Iancu*.<sup>150</sup> In a rare close decision in a patent case, Justice Gorsuch (joined by the Chief Justice and Justices Kennedy, Thomas, and Alito) provided a textual explication of the IPR statute in deciding that the Patent Office was compelled to render a final written decision (FWD) on all claims challenged by a petitioner in an IPR

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142. *Id.* at 1379.

143. *Id.*

144. *Id.*

145. *Id.*

146. *Id.* at 1379–80 (Breyer, J., concurring).

147. *Id.* at 1379.

148. *Oil States Energy Servs.*, 138 S. Ct. at 1380 (Gorsuch, J., dissenting).

149. *Id.* at 1380–86.

150. *See generally SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348 (2018).

petition.<sup>151</sup> This decision overruled the Patent Office's practice that the Director (through the PTAB) could institute an IPR on less than all challenged claims and then limit the FWD to only the instituted claims.<sup>152</sup>

According to the majority, the decision to institute is binary (either the PTAB decides to institute or not), but once instituted, the PTAB must render a decision on all challenged claims.<sup>153</sup> Justice Gorsuch in his opinion set forth the relevant statutory language he believed supported the Court's opinion and the various procedures (one "inquisitorial" in nature, like *ex parte* reexamination, in contrast to the more adjudicatory IPR procedure).<sup>154</sup> IPRs "look[] a good deal more like civil litigation" and are governed by express provisions in the statute regarding the standards for instituting an IPR (§§ 311–14), conducting the IPR proceeding (§ 316), settlement (§ 317), and coming to a final decision on patentability (§ 318).<sup>155</sup>

Justice Gorsuch's interpretation of the language of the statute is based on earlier instances of statutory interpretation by the Court along with reference to dictionaries and legal scholarship.<sup>156</sup> Important terms in the statute include the use of the word "any" in 35 U.S.C. § 318(a) (that the Patent Office "shall issue a final written decision with respect to the patentability of *any* patent claim challenged by the petitioner") to mean "every," stating that "[t]he [Patent Office] cannot curate the claims at issue but must decide [the validity] of them all."<sup>157</sup> This interpretation is further supported by the use of the word "shall," which the opinion notes "generally imposes a nondiscretionary duty."<sup>158</sup> This language provides a "ready answer" to the question presented, the opinion stating that the language of § 318(a) is "both mandatory and comprehensive" with regard to the statutory requirement that the PTAB render a FWD on all claims challenged in an IPR petition.<sup>159</sup>

While stating that this analysis "would seem to make this an easy case," the opinion reviewed (and rejected) the Director's arguments to the contrary.<sup>160</sup> The majority found no basis in the statute for the Director to

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151. *Id.* at 1358.

152. 37 C.F.R. § 42.108(a) (2016), *abrogated by SAS Inst. Inc.*, 138 S. Ct. at 1360.

153. *SAS Inst. Inc. v. Iancu*, 138 S. Ct. at 1355.

154. *Id.* at 1353.

155. *SAS Inst. Inc. v. Iancu*, 138 S. Ct. at 1353–54.

156. *Id.* at 1354.

157. *Id.* at 1353.

158. *Id.* at 1354.

159. *Id.*

160. *Id.* at 1355.

have discretion regarding “partial institution.”<sup>161</sup> Indeed, the opinion noted that, unlike in *ex parte* reexamination, the IPR provisions of the statute do not permit the Director to initiate an IPR *sua sponte*.<sup>162</sup> “From the outset, we see that Congress chose to structure a process in which it’s the petitioner, not the Director, who gets to define the contours of the proceeding.”<sup>163</sup>

The Court majority also found interpretive meaning in further distinctions between IPR proceedings and *ex parte* reexamination.<sup>164</sup> In the latter proceedings, Congress chose “an inquisitorial approach” (analogous to *ex parte* examination in the first instance) and thus Congress “knew exactly how to” expressly give the Director the discretion he argues he has under the IPR provisions of the America Invents Act.<sup>165</sup> “Congress’s choice to depart from the model of a closely related statute is a choice neither we nor the agency can disregard.”<sup>166</sup>

Further, the Court’s opinion cited the language of § 314, which appears to provide either that the IPR proceedings be instituted or that they are not, based on the provision that the Director must decide “whether to institute an *inter partes* review . . . pursuant to the petition.”<sup>167</sup> Both the terms “whether” and “pursuant to the petition” had meaning to the Court majority. “Whether” to institute an IPR implies a “yes or no” option, and “pursuant to the petition” supports the earlier-stated view that *what* is instituted is an IPR on the claims challenged by the petitioner.<sup>168</sup> As stated in the opinion, “[n]othing suggests the Director enjoys a license to depart from the petition and institute a *different inter partes* review of his own design.”<sup>169</sup>

The majority also held that this portion of the statute, which the Director relied upon to imply discretion based on the language that the Director should institute if there is a “reasonable likelihood” that “at least 1 of the claims challenged in the petition” is invalid, implies exactly the opposite.<sup>170</sup> For the Court majority, “[o]nce that single claim threshold is satisfied, it doesn’t matter whether the petitioner is likely to prevail on any

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161. *Id.* at 1358.

162. *SAS Inst. Inc. v. Iancu*, 138 S. Ct. at 1355.

163. *Id.*

164. *Id.*

165. *Id.*

166. *Id.* at 1353 (citing *Univ. of Tex. Southwestern Med. Center v. Nassar*, 570 U.S. 338, 353–54 (2013)).

167. *Id.* (citing 35 U.S.C. § 314(b)).

168. *Id.* at 1355–56.

169. *SAS Inst. Inc. v. Iancu*, 138 S. Ct. at 1356 (emphasis in original).

170. *Id.*; 35 U.S.C. § 314(a) (2011).

*additional claims*”; the Director should institute the IPR on *all* challenged claims.<sup>171</sup> The opinion again references the *ex parte* reexamination statute to show that if Congress had intended to give the Director the discretion he claims, there was language available to do so.<sup>172</sup>

The opinion summarily rejected the Director’s reliance on his discretion under § 314 to institute an IPR to support his discretion to institute partially, once again characterizing the decision as binary.<sup>173</sup> This conclusion is supported, according to the opinion, by the language of the other provisions in the statute which reference “the petition” rather than challenged claims, the majority interpreting Congress not to have intended the Director to have discretion other than whether or not to institute an IPR against the claims the petitioner challenged.<sup>174</sup>

With regard to the ambiguity purported to be in the statute due to slight differences in the language of § 314 and § 318 (which forms the basis for the dissent’s position), the majority asserted that this is just a “slight linguistic discrepancy.”<sup>175</sup> Any differences between the claims challenged in the petition and the claims available for FWD can be explained by the patentee’s ability to cancel or amend claims, according to the opinion (terming it a “winnowing mechanism”).<sup>176</sup> The opinion states that “[w]e need not and will not invent an atextual explanation for Congress’s drafting choices when the statute’s own terms supply an answer.”<sup>177</sup>

Neither were the Director’s policy arguments persuasive (in contrast to the effects of these arguments on the dissenting Justices). Even though “[e]ach side offers plausible reasons why its approach might make for the more efficient policy[,] who should win that debate isn’t our call to make,” because “[p]olicy arguments are properly addressed to Congress, not this Court.”<sup>178</sup> And “[w]hatever its virtues or vices, Congress’ prescribed policy here is clear: the petitioner in an inter partes review is entitled to a decision on all the claims it has challenged” stated the Court, nicely closing the door on the basis for the dissenting Justices’ contrary opinion.<sup>179</sup>

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171. *SAS Inst. Inc.*, 138 S. Ct. at 1356 (emphasis in original).

172. *Id.*

173. *See id.* at 1355–56.

174. *Id.* at 1356–57.

175. *SAS Inst. Inc. v. Iancu*, 138 S. Ct. at 1357.

176. *Id.*

177. *Id.* (citing *U.S. v. Ron Pair Enterprises Inc.*, 489 U.S. 235, 240–41 (1989)).

178. *Id.* at 1357–58.

179. *Id.* at 1358.

Because the majority saw no ambiguity in the statutory language, deference to the agency's implementation decisions under *Chevron v. Natural Resources Defense Council* did not apply.<sup>180</sup> In an interesting side note (with regard to Justice Gorsuch's acknowledged antipathy to *Chevron*), the majority deigned to leave the continued vitality of the agency deference doctrine "for another day," merely holding that "we owe an agency's interpretation of the law no deference" if there is (as here, for these Justices) no ambiguity in the statute's mandate.<sup>181</sup>

And not surprisingly, the Court rejected the Director's final argument that the question before it was one regarding the institution decision, which Congress under § 314(d) put beyond judicial review.<sup>182</sup> The majority reminded the Director that *Cuozzo* recognized a "strong presumption" of judicial review of agency decisions, and that judicial review was necessary to preclude agency "shenanigans" that would "exceed its 'statutory bounds.'"<sup>183</sup>

Justice Breyer dissented, joined by Justices Ginsberg, Sotomayor, and Kagan.<sup>184</sup> These Justices perceived that there was an ambiguity in the statute resulting from differences in language (albeit slight) between § 314 and § 318 sufficient to support both the Director's application of the statute and entitlement to *Chevron* deference.<sup>185</sup> To the dissenters, the statutory language is far from being as clear as the majority believed: to them, the statute is "technical, unclear, and constitutes a minor procedural part of a larger administrative scheme."<sup>186</sup> The dissent expressly relied upon *Chevron*, characterizing it as "an interpretative technique that judges often use in such cases" where the statute contains an ambiguity (and perhaps setting the terms of a future dispute between the Justices on the question of *Chevron* deference).<sup>187</sup> Using this technique, the dissent found such an ambiguity, and, further, found that the Director's interpretation of the ambiguous statutory language is reasonable (and thus the dissenting Justices would have affirmed).<sup>188</sup> Helpful in considering the dissenting Justices' thinking in this regard, Justice Breyer set forth a hypothetical (as is his wont) in which a petitioner challenges sixteen claims and the PTAB

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180. See *Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984).

181. *SAS Inst. Inc.*, 138 S. Ct. at 1358.

182. *Id.* at 1360 (citing *Cuozzo Speed Technologies LLC v. Lee*, 136 S. Ct. 2131 (2016)).

183. *Id.*

184. *Id.* at 1360 (Breyer, J., dissenting).

185. *Id.* at 1361–65.

186. *Id.* at 1360.

187. *Id.*

188. See *SAS Inst. Inc.*, 138 S. Ct. at 1360.



institutes an IPR on one of them, and then used this hypothetical as a practical guidepost for his explication of the statutory language.<sup>189</sup>

The dissenting opinion performed its own brand of statutory exegesis and, unsurprisingly, found ambiguity between reference to claims challenged in the petition and claims surviving to FWD.<sup>190</sup> These Justices perceived that the majority relied on its own language that does not actually exist in the statute (specifically “any patent claim challenged by the petitioner’ *in the petitioner’s original petition*”) and, for them, “[w]hich reading we give the statute [their’s or the majority’s] makes a difference.”<sup>191</sup> Without expressly making the point, the dissent illustrated that, if these Justices could not agree on the meaning of the statutory language, such language is *prima facie* ambiguous and thus *Chevron* deference should attach to the Director’s interpretation.<sup>192</sup>

In addition, these Justices agreed with the Director’s argument that interpreting the statute as the majority did would impose tremendous inefficiencies on the PTAB, requiring the PTAB to provide a FWD on claims that the petitioner had not shown had a reasonable likelihood of being invalid.<sup>193</sup> This point was emphasized in a one-paragraph, separate dissent penned by Justice Ginsberg (joined by the other dissenting Justices), who saw “no cause to believe Congress wanted the [PTAB] to spend its time so uselessly.”<sup>194</sup>

One practical consequence of this decision (that Justice Breyer in his dissent fully appreciated) is that it provides a route for a petitioner, unhappy that the PTAB refused to institute IPR on any particular claim, to appeal the FWD and thus overcome the prohibition in the statute that the institution decision is at the Director’s discretion, and not appealable. This is clearly contrary to the legislative scheme (and Justice Sotomayor, one of the dissenting Justices here, at oral argument quizzed counsel aggressively on whether the entire exercise was a way to get around the Court’s *Cuozzo* decision).<sup>195</sup> This decision also raises the possibility that the PTAB, rather than issue an appealable FWD on claims that do not rise to the “reasonable likelihood” standard, will instead refuse to institute using language in the decision providing a roadmap for further petitions of more limited scope that it *will* institute. No matter how the PTAB

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189. *Id.* at 1361.

190. *Id.*

191. *Id.* at 1361–62.

192. *See id.* at 1360.

193. *See id.*

194. *See SAS Inst. Inc.*, 138 S. Ct. at 1360 (Ginsburg, J., dissenting).

195. Transcript of Oral Argument at 4–11, *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348 (2018) (No. 16-969).

adapts its practices to avoid the outcome mandated by this decision, the majority's clear holding provides the basis for the Patent Office and the public to petition Congress to intercede to change the statutory language to give the Director the discretion the Court majority could not find in the statute Congress enacted.

G. *Amgen Inc. v. Sanofi* (Fed. Cir. 2017) (Panel: Chief Judge Prost and Circuit Judges Taranto and Hughes; Opinion by Chief Judge Prost)

On October 5, 2017, the Federal Circuit rendered a decision in *Amgen Inc. v. Sanofi* that brought clarity to how the Court (and Patent Office) should apply the written description requirement in 35 U.S.C. § 112(a) to properly circumscribe the scope of claims to monoclonal antibodies.<sup>196</sup> As a bonus, the panel opined on the relationship between the various requirements for a court to grant a permanent injunction when the infringing article comprises a medicine or other therapeutic agent.<sup>197</sup>

Prior to the Supreme Court's recent focus on patent law questions (and the uncertainty and jurisprudential chaos that has arisen as a consequence), the Federal Circuit spent almost a decade refining application of the written description requirement to biotechnology patent claims. Arguably beginning with *Amgen v. Chugai*<sup>198</sup> and *Fiers v. Revel*,<sup>199</sup> the Court spoke most clearly in *University of California v. Eli Lilly & Co.*<sup>200</sup>; this jurisprudence matured in *University of Rochester v. G.D. Searle*<sup>201</sup> and *Enzo Biochem v. GenProbe*,<sup>202</sup> culminating in the Court's *Ariad v. Eli Lilly*<sup>203</sup> *en banc* decision that the written description and enablement requirements of 35 U.S.C. § 112, first paragraph (now, 35 U.S.C. § 112(a)), were separate and distinct and could be differentially satisfied on the same disclosure (i.e., enablement could be satisfied even though the written description requirement was not).<sup>204</sup>

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196. See generally *Amgen Inc. v. Sanofi*, 872 F.3d 1367 (Fed. Cir. 2017), *cert. denied*, *Amgen Inc. v. Sanofi*, 139 S. Ct. 787 (2019).

197. See *id.*

198. *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200 (Fed. Cir. 1991).

199. *Fiers v. Revel*, 984 F.2d 1164 (Fed. Cir. 1993).

200. *Regents of Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1562 (Fed. Cir. 1997).

201. *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2004).

202. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956 (Fed. Cir. 2002).

203. *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010) (*en banc*).

204. See generally *Amgen, Inc.*, 927 F.2d 1200; *Fiers*, 984 F.2d 1164; *Regents of the Univ. of California*, 119 F.3d 1559; *Univ. of Rochester*, 358 F.3d 916; *Enzo Biochem*, 323 F.3d 956; *Ariad Pharm.*, 598 F.3d 1336 (*en banc*).

These cases arose from the complexities of assessing the sufficiency of disclosure for claims to isolated nucleic acids (including cDNA molecules that remain patent-eligible after *AMP v. Myriad Genetics*).<sup>205</sup> Another complex class of important biomolecules, antibodies, and, in particular, monoclonal antibodies, have had a more murky course through § 112 jurisprudence; the issue in the few decided cases related to the requirements for producing humanized and ultimately human antibodies from (typically) mouse monoclonal progenitors rather than the scope of antibody claims as they relate to antigenic specificity.<sup>206</sup> The Federal Circuit's decision in this case provides some clarity in this regard.<sup>207</sup>

The case arose when Amgen sued Sanofi over its sales of Praluent (alirocumab) in competition with Amgen's Repatha (evolocumab) drug; Amgen's asserted patents, U.S. Patent Nos. 8,829,165 (165 patent) and 8,859,741 (741 patent), claim a genus of antibodies that encompass Sanofi's Praluent product.<sup>208</sup> As background, blood plasma contains low-density lipoproteins that bind cholesterol and are associated with atherosclerotic plaque formation.<sup>209</sup> Liver cells express receptors for LDL (LDL-R) wherein binding thereto reduces the amount of LDL cholesterol in blood and reduces the risk of plaque formation and cardiovascular disease.<sup>210</sup> PCSK9 (proprotein convertase subtilisin kexin type 9) is a molecule that binds to and causes liver cell LDL-R to be destroyed, thus reducing the capacity and effectiveness of the liver cell's ability to reduce serum LDL-cholesterol.<sup>211</sup> The antibodies at issue in this suit bind to PCSK9 and prevent PCSK9 from binding to LDL-R, causing their destruction and hence improving the capacity of the liver to clear the blood of serum cholesterol.<sup>212</sup> Claim 1 of the '165 patent is representative:

1. An isolated monoclonal antibody, wherein, when bound to PCSK9, the monoclonal antibody binds to at least one of the following residues: S153, I154, P155, R194, D238, A239, I369, S372, D374, C375, T377, C378, F379, V380, or S381 of SEQ ID

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205. See *Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1371 (Fed. Cir. 2017), cert. denied, *Amgen Inc. v. Sanofi*, 139 S. Ct. 787 (2019).

206. *Id.*

207. *Id.*

208. U.S. Patent No. 8,829,165 (filed Apr. 10, 2013); U.S. Patent No. 8,859,741 (filed Apr. 24, 2014).

209. *Sanofi*, 872 F.3d at 1371.

210. *Id.*

211. *Id.*

212. *Sanofi*, 872 F.3d at 1371.

NO:3, and wherein the monoclonal antibody blocks binding of PCSK9 to LDL[-]R.<sup>213</sup>

It is important to note that, while reciting the structure of the residues on PCSK9 that are bound by the claimed antibody, the claim does not recite any structural limitations of the antibody itself. The only antibody characteristic recited as a limitation is a functional one, i.e., the ability to bind (and not even specifically bind) to at least one of the recited PCSK9 residues.

Evidence at trial showed that Amgen had produced a plurality of anti-PCSK9 antibodies and screened them for the ability to inhibit PCSK9 binding to LDL-R in the liver.<sup>214</sup> This screening was done using a “trial and error” process that reduced 3,000 human monoclonal antibodies down to 85 antibodies that “blocked interaction between the PCSK9 . . . and the LDLR [at] greater than 90%,” of which the specification illustrated the three-dimensional binding arrangement for two (one of which became the Repatha™ antibody) by x-ray crystallography.<sup>215</sup> The specification of the Amgen patents in suit discloses amino acid sequence information for 22 human anti-PCSK9 antibodies able to compete for PCSK9 binding with these two more fully characterized antibodies.<sup>216</sup> Regeneron’s patents (not at issue here) recited antibody-specific amino acid sequences for its claimed anti-PCSK9 antibodies.<sup>217</sup>

The jury found Amgen’s patents not to be invalid; Sanofi stipulated to infringement.<sup>218</sup> The district court excluded Sanofi’s evidence relating to written description and enablement based on Praluent and other post-priority date antibodies (i.e., that were produced after Amgen’s earliest priority date).<sup>219</sup> The district court, relying on *Noelle v. Lederman*<sup>220</sup> as precedent, instructed the jury that an applicant can be entitled to claim scope encompassing generically described antibodies (as was the case for Amgen’s claims) *provided that* the applicant provided a full characterized, novel antigen.<sup>221</sup>

In the case of a claim to antibodies, the correlation between structure and function may also be satisfied by the disclosure of a newly

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213. *Id.* at 1372.

214. *Id.*

215. *Id.*

216. *Sanofi*, 872 F.3d at 1372.

217. *See id.*

218. *Id.*

219. *Id.*

220. *Noelle v. Lederman*, 355 F.3d 1343 (Fed. Cir. 2004).

221. *Sanofi*, 872 F.3d at 1376.

characterized antigen by its structure, formula, chemical name, or physical properties if you find that the level of skill and knowledge in the art of antibodies at the time of filing was such that production of antibodies against such an antigen was conventional or routine.<sup>222</sup>

The district court denied Sanofi's post-trial motion for judgment as a matter of law (JMOL) that Amgen's claims were invalid for failing the written description and enablement requirements of 35 U.S.C. § 112(a), and granted Amgen's motion for JMOL that the claims were nonobvious.<sup>223</sup> On this record, the district court also granted Amgen a permanent injunction preventing Sanofi from selling Praluent (which was stayed pending Sanofi's appeal).<sup>224</sup>

The Federal Circuit reversed in part, affirmed in part, vacated in part, and remanded, in an opinion by Chief Judge Prost, joined by Judges Taranto and Hughes.<sup>225</sup> The opinion distinguished two bases for a court to consider post-priority date evidence of failure to satisfy the written description requirement, and found that the district court misapplied the law in excluding Sanofi's evidence.<sup>226</sup> The first basis for considering post-filing evidence regarding written description is when the evidence is proffered to show whether there was sufficient disclosure in the specification as filed and for this purpose the panel stated that post-priority date evidence is improper.<sup>227</sup> Here, Sanofi's evidence was proffered under the second basis, which is whether the specification discloses a representative number of species in a claimed genus.<sup>228</sup> For such purposes, the opinion held that post-priority evidence is admissible, because such evidence can show that the genus is sufficiently diverse that the number of species disclosed in the specification is not representative.<sup>229</sup> As set forth in *Ariad*, an adequate written description of a genus requires the specification to disclose "a representative number of species falling within the scope of the genus *or* structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus."<sup>230</sup> The panel

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222. *Id.*; see also *Noelle*, 355 F.3d 1343.

223. *Sanofi*, 872 F.3d at 1371; see generally *Amgen Inc. v. Sanofi*, 227 F. Supp. 3d 333 (D. Del. 2017).

224. *Sanofi*, 872 F.3d at 1371, 1373.

225. *Id.* at 1371.

226. *Id.* at 1372.

227. *Id.* at 1373–74.

228. *Id.* at 1374.

229. *Id.* at 1375.

230. *Id.* at 1373 (citing *Ariad Pharm. Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010)).

distinguished prior precedent cited by Amgen, including *In re Koller*<sup>231</sup>, and *In re Hogan*<sup>232</sup>, because those cases were directed to the first basis for evaluating whether a specification satisfies the written description requirement.<sup>233</sup> (Another reason is that the second basis recognized by the opinion is arguably a creation of the Federal Circuit’s more recent written description jurisprudence.)<sup>234</sup>

The opinion acknowledged that the Court had not directly addressed this application of the law to date, but found it to be consistent with the Court’s earlier decision in *AbbVie*.<sup>235</sup> In *AbbVie*, the accused infringer used evidence from its own, later-developed antibodies to show that patentee AbbVie’s claims were not supported by an adequate written description of a representative number of species within the claimed antibody genus (although, as the opinion admits, defendant’s antibody “was a basis for the unrepresentativeness ruling without regard to whether it postdated the patent’s priority date”).<sup>236</sup> With regard to the *Hogan* precedent (which is binding on Federal Circuit panel opinions unless overturned by the *en banc* Court), the opinion states:

Appellees misread *In re Hogan* by conflating the difference between post-priority-date evidence proffered to illuminate the post-priority-date state of the art, which is improper, with post-priority-date evidence proffered to show that a patent fails to disclose a representative number of species. *In re Hogan* prohibits the former but is silent with respect to the latter.<sup>237</sup>

*Hogan* was based on the Patent Office requiring an applicant to disclose, at an application’s filing date, species that did not exist at that time.<sup>238</sup> The panel understood that not to be analogous to the case before it, and stated that as a consequence, the district court’s exclusion of Sanofi’s evidence relating to whether Amgen’s specification disclosed a representative number of species was error.<sup>239</sup> The Court remanded the matter to the district court for a new trial on this issue.<sup>240</sup>

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231. *In re Koller*, 613 F.2d 819, 825 (C.C.P.A. 1980).

232. *In re Hogan*, 559 F.2d 595, 605 (C.C.P.A. 1977).

233. *Sanofi*, 872 F.3d at 1373.

234. *Sanofi*, 872 F.3d at 1374–75; see *AbbVie Deutschland GmbH & Co. v. Janssen Biotech, Inc.*, 759 F.3d 1285 (Fed. Cir. 2014).

235. *Id.* at 1374.

236. *Id.*

237. *Id.* at 1374–75.

238. See generally *In re Hogan*, 559 F.2d 595 (C.C.P.A. 1977).

239. *Sanofi*, 872 F.3d at 1375.

240. *Id.*

The Court also found it to be error for the district court to have excluded evidence regarding enablement on the same grounds. This evidence related to the “lengthy and potentially undue experimentation” Amgen needed to employ to arrive at its antibodies that fell within the scope of the claims of the ‘165 and ‘741 patents.<sup>241</sup> This was relevant evidence not barred by its post-priority date origins, and the panel remanded for a new trial on enablement in light of this evidence.<sup>242</sup>

Perhaps the most significant portion of the opinion involves the jury instructions, which relied on *Noelle v. Lederman* for the proposition that characterizing a new antigen was sufficient to satisfy the statute for claims encompassing a broad genus of antibodies that could bind to the new antigen.<sup>243</sup> The panel found that this instruction “is not legally sound and [] not based on any binding precedent”, and then provided its legal analysis of *Enzo Biochem, Inc. v. Gen-Probe Inc.*,<sup>244</sup> *Noelle v. Lederman*,<sup>245</sup> and *Centocor Ortho Biotech, Inc. v. Abbott Labs*<sup>246</sup> in support of its conclusion.<sup>247</sup>

The basis for the instruction, according to the opinion, is in guidelines from the Patent Office discussed by the Court in *Enzo*.<sup>248</sup> There, the Court noted (in *dicta*, as characterized in this opinion), that the Patent Office would find claims to an antibody in compliance with Section 112 “notwithstanding the functional definition of the antibody, in light of the well-defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that the antibody technology is well developed and mature.”<sup>249</sup> The decision in *Noelle* was actually contrary (the claims were not entitled to priority to an earlier application because that application did not disclose “the structural elements of the antibody or antigen”) but (again in *dicta*) stated that “as long as an applicant has disclosed a ‘fully characterized antigen,’ either by its structure, formula, chemical name, or physical properties, or by depositing the protein in a public depository, the applicant can then claim an antibody by its binding affinity to that described antigen” based on the Court’s *Enzo* decision.<sup>250</sup> Finally, in *Centocor*, the Court questioned, as

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241. *Id.*

242. *Id.*

243. *See id.* at 1376.

244. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956 (Fed. Cir. 2002).

245. *Noelle v. Lederman*, 355 F.3d 1343 (Fed. Cir. 2004).

246. *Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341 (Fed. Cir. 2011).

247. *Sanofi*, 872 F.3d at 1376.

248. *Id.*

249. *Id.* (citing *Enzo Biochem*, 323 F.3d at 964).

250. *Id.* at 1377 (citing *Noelle*, 355 F.3d at 1349).

Amgen did here, the interpretation of its precedent that an applicant was entitled to a broad claim based solely on functional properties (e.g., binding affinity or specificity) of an antibody so long as the applicant provided a fully characterized, novel antigen.<sup>251</sup> As expressed in *Centocor*, one basis for skepticism over the “fully characterized antigen” test advocated there and here (by Amgen) was that instead of “analogizing the antibody-antigen relationship to a ‘key in a lock’, it was more apt to analogize it to a lock and ‘a ring with a *million* keys on it.’”<sup>252</sup> The panel emphasized that because the written description requirement is a question of fact, the value of these cases as precedent is “extremely limited.”<sup>253</sup>

The panel held this instruction to be improper because it effectively eliminated the written description requirement from the statute in favor of enablement, contrary to the Court’s *en banc* decision in *Ariad*, stating that “[b]y permitting a finding of adequate written description merely from a finding of ability to make and use, the challenged sentence of the jury instruction in this case ran afoul of what is perhaps the core ruling of *Ariad*.”<sup>254</sup> And the panel found that whether the relationship between the structure of the antigen, no matter how fully characterized, and any of its cognate antibodies is (here and hitherto) “hotly disputed” which precluded the Court from making any definitive finding.<sup>255</sup> The panel recited its abrogation of the “fully characterized antigen” test expressly:

Further, the “newly characterized antigen” test flouts basic legal principles of the written description requirement. Section 112 requires a “written description of the invention.” But this test allows patentees to claim antibodies by describing something that is not the invention, i.e., the antigen. The test thus contradicts the statutory “quid pro quo” of the patent system where “one describes an invention, and, if the law’s other requirements are met, one obtains a patent.” Indeed, we have generally eschewed judicial exceptions to the written description requirement based on the subject matter of the claims.<sup>256</sup>

For the same reasons the opinion affirmed the district court’s denial of JMOL that Amgen’s claims lack written description and enablement in

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251. *See id.* at 1377.

252. *Sanofi*, 872 F.3d at 1377 (emphasis in original) (citing *Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341, 1352 (Fed. Cir. 2011)).

253. *Id.* (citing *Centocor*, 636 F.3d at 1349).

254. *Id.* at 1378.

255. *Id.*

256. *Sanofi*, 872 F.3d at 1378–79 (citations omitted).



favor of those questions being decided on remand based on the facts properly permitted to be considered by the jury.<sup>257</sup>

Turning to the grounds for granting Amgen a permanent injunction, the panel found error in how the district court applied the standards enunciated by the Supreme Court in *eBay, Inc. v. MercExchange, L.L.C.*:<sup>258</sup>

[A] plaintiff seeking a permanent injunction *must satisfy* a four-factor test before a court may grant such relief. A plaintiff *must demonstrate*: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.<sup>259</sup>

Here, the district court granted the injunction despite finding that an injunction would “disserve” the public interest in the absence of plaintiff Amgen refuting this conclusion.<sup>260</sup> The panel’s plain reading of the Supreme Court’s mandate held this to be error.<sup>261</sup> In addition, the panel held to be error the district court’s finding that the public interest would be disserved because the effect of the injunction would be to “tak[e] an independently developed, helpful drug off the market.”<sup>262</sup> According to the opinion, using this standard a court would never be able to enjoin an infringing drug product because that would always involve taking a helpful drug off the market, contrary to both *eBay* and 35 U.S.C. § 271(e)(4)(B).<sup>263</sup>

This case is the latest application of the Federal Circuit’s written description doctrine, which is one of the few areas that the Supreme Court has not found it fit to question the Court’s application of U.S. patent law. On the one hand this is curious, because written description is perhaps the preeminent example of the Federal Circuit exercising its special expertise and Congressional mandate to provide a harmonized interpretation of patent law. On the other hand, how the Federal Circuit has developed this area of the law has, generally, limited the scope of biotechnology patent claims, consistent with the Supreme Court’s penchant for treating the patent grant parsimoniously. In any case, this decision makes the

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257. *See id.* at 1380.

258. *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006).

259. *Sanofi*, 872 F.3d at 1381 (emphasis added) (quoting *MercExchange* 547 U.S. at 391).

260. *Id.*

261. *See id.*

262. *Id.*

263. *Sanofi*, 872 F.3d at 1381 (citing *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317 (Fed. Cir. 2016)).

application of the written description requirement, as applied to antibody claims, more consistent with how the Court has applied § 112 to other biotechnological inventions, and, thus, is in keeping with past twenty years of the Court's jurisprudence. It is also more congruent with how the technology has developed since monoclonal antibodies were first disclosed (but not patented) by Kohler and Milstein in 1973. If such consistency is the proper role of the Federal Circuit, then this decision is an exemplar of it fulfilling that role.

*H. Sandoz, Inc. v. Amgen, Inc. (2017) (Opinion of the Court by Justice Thomas, joined by Chief Justice Roberts and Justices Alito, Breyer, Ginsburg, Gorsuch, Kagan, Kennedy, Sotomayor; concurring opinion by Justice Breyer)*

On June 12, 2017, the Supreme Court handed down its opinion in *Sandoz Inc. v. Amgen Inc.*, marking the first time the Court has interpreted the Biologics Price Competition and Innovation Act (BPCIA) for the approval of biosimilar drugs.<sup>264</sup> The Court described the statute as “a carefully calibrated scheme for preparing to adjudicate, and then adjudicating, claims of infringement” related to biosimilar applications.<sup>265</sup> This process begins with the disclosure by the biosimilar applicant of its an abbreviated Biologics License Application (aBLA) and related information in order to “enable the sponsor to evaluate the biosimilar for possible infringement of patents it holds on the reference product . . . .”<sup>266</sup> Nevertheless, the Court held that the reference product sponsor (RPS) cannot seek enforcement of the disclosure provision in 42 U.S.C. § 262(1)(2)(A) by injunction under federal law,<sup>267</sup> substantially agreeing with the Federal Circuit.<sup>268</sup> Nevertheless, the Supreme Court reversed and remanded for the Federal Circuit to consider the question whether the disclosure provision was enforceable under state law, or whether the BPCIA pre-empted any state law claim.<sup>269</sup> With regard to the 180-day notice-of-commercial-marketing provision of the statute, the Court reversed the Federal Circuit and held that the notice may be provided “either before or after receiving FDA approval.”<sup>270</sup>

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264. *Sandoz, Inc. v. Amgen, Inc.*, 137 S. Ct. 1664 (2017).

265. *Id.* at 1670.

266. *Id.* at 1670–71.

267. *Id.* at 1674.

268. *Id.*

269. *Id.* at 1676–77.

270. *Id.* at 1677.

In 2014 Sandoz became the first company to file an aBLA pursuant to the BPCIA's abbreviated pathway found at 42 U.S.C. § 262(k).<sup>271</sup> This application was for approval to market a biosimilar version of Amgen's Neupogen (filgrastim) biologic drug product.<sup>272</sup> Filgrastim is a 175 amino acid recombinant methionyl human granulocyte colony-stimulating factor (r-metHuG-CSF), and is often prescribed for cancer patients on chemotherapy at times when patients are at most risk of infection because their white blood cell count is low.<sup>273</sup> However, despite availing itself of this pathway for FDA approval, Sandoz refused to participate in the patent resolution component (the disclosure and information exchange provisions, also known colloquially as the "patent dance"), alleging that it was not a mandatory component.<sup>274</sup> Amgen responded by filing suit on October 24, 2014, requesting in part a preliminary injunction to prevent Sandoz from entering the market before the issues could be resolved by the Court.<sup>275</sup> The Northern District of California denied Amgen's motion, ruling that the disclosure and notice provisions of the BPCIA were not mandatory.<sup>276</sup> And, in a remarkably fractured decision, the Federal Circuit agreed.<sup>277</sup>

The first question considered by the Court addressed the patent dance:

Is an Applicant required by 42 U.S.C. § 262(l)(2)(A) to provide the Sponsor with a copy of its biologics license application and related manufacturing information, which the statute says the Applicant "shall provide," and, where an Applicant fails to provide that required information, is the Sponsor's sole recourse to commence a declaratory-

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271. *FDA accepts Sandoz application biosimilar filgrastim*, SANDOZ: A NOVARTIS DIVISION, (July 24, 2014), <https://www.sandoz.com/news/media-releases/fda-accepts-sandoz-application-biosimilar-filgrastim> [<https://perma.cc/LM72-GVX4>].

272. *FDA accepts Sandoz application biosimilar filgrastim*, SANDOZ: A NOVARTIS DIVISION, (July 24, 2014), <https://www.sandoz.com/news/media-releases/fda-accepts-sandoz-application-biosimilar-filgrastim> [<https://perma.cc/LM72-GVX4>].

273. *See Prescribing Information*, NEUPOGEN (FILGRASTIM), <https://www.neupogenhcp.com/important-safety-information/> [<https://perma.cc/9LBB-2WLQ>]; NEUPOGEN (FILGRASTIM), HIGHLIGHTS OF PRESCRIBING INFORMATION, 2, 14, [https://www.pi.amgen.com/~/\\_media/amgen/repositorysites/pi-amgen-com/neupogen/neupogen\\_pi\\_hcp\\_english.pdf](https://www.pi.amgen.com/~/_media/amgen/repositorysites/pi-amgen-com/neupogen/neupogen_pi_hcp_english.pdf) [<https://perma.cc/KV52-L5ZV>].

274. *Sandoz, Inc.*, 137 S.Ct. at 1676.

275. *Id.* at 1673.

276. *Amgen, Inc. v. Sandoz, Inc.*, No. 14-cv-04741-RS, 2015 WL 1264756, 10 (N.D. Cal. Mar. 19, 2015), *aff'd in part and vacated in part by* 794 F.3d 1347 (Fed. Cir. 2015).

277. *Amgen, Inc. v. Sandoz, Inc.*, 794 F.3d 1347, 1350 (Fed. Cir. 2015).

judgment action under 42 U.S.C. § 262(l)(9)(C) and/or a patent-infringement action under 35 U.S.C. § 271(e)(2)(C)(ii)?<sup>278</sup>

The Federal Circuit Court essentially sidestepped the question of whether the statutory commandment that a biosimilar applicant “shall provide” indicates that the requirement is mandatory, and, instead, held that an RPS cannot seek enforcement of this section by injunction under federal law.<sup>279</sup> The Supreme Court agreed with the Federal Circuit that the BPCIA provides the exclusive federal remedy for failure to disclose the required information by authorizing an RPS to bring an immediate declaratory-judgment action.<sup>280</sup>

If a subsection (k) applicant fails to provide the application and information required under paragraph (2)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of Title 28, for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.<sup>281</sup>

The Supreme Court continued, however, by concluding that the Federal Circuit erred in relying on 35 U.S.C. § 271(e)(4) as precluding state law remedies.<sup>282</sup> As the Supreme Court explained, failure to disclose the aBLA and related information is not part of the artificial act of infringement established in § 271(e)(2)(c).<sup>283</sup>

It shall be an act of infringement to submit—

(i) with respect to a patent that is identified in the list of patents described in section 351(l)(3) of the Public Health Service Act (including as provided under section 351(l)(7) of such Act), an application seeking approval of a biological product, or

(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug,

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278. *Sandoz, Inc.*, 137 S.Ct. at 1674.

279. *Id.*

280. *Id.*

281. 42 U.S.C. § 262(l)(9)(C) (2017).

282. *Sandoz, Inc.*, 137 S.Ct. at 1674.

283. *Id.*

veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.<sup>284</sup>

As the Court put it: “The flaw in the Federal Circuit’s reasoning is that Sandoz’s failure to disclose its application and manufacturing information was not an act of artificial infringement, and thus was not remediable under § 271(e)(4).”<sup>285</sup> Instead, the artificial infringement is the act of submitting the application.<sup>286</sup> The language in the statute regarding noncompliance with § 262(l)(2)(A) is not an element of infringement, but rather “merely assists in identifying which patents will be the subject of the artificial infringement suit.”<sup>287</sup> As a result, the exclusive remedies outlined in § 271(e)(4) for this artificial infringement do not apply.<sup>288</sup> Instead, the Supreme Court remanded this issue back to the Federal Circuit to determine whether an injunction is available under state law to enforce § 262(l)(2)(A), or whether state law enforcement is preempted by BPCIA.<sup>289</sup> If the Federal Circuit were to determine that state-law remedies are pre-empted (as it later did),<sup>290</sup> biosimilar applicants would be able to continue withholding information required by the BPCIA without threat of enforcement of that provision.<sup>291</sup>

The second question before the Court was whether a biosimilar applicant could give the 180-day Notice of Commercial Marketing prior to FDA approval, or whether such notice would not be effective until FDA approval (as the Federal Circuit held below).<sup>292</sup> This question was related to interpretation of another part of the statute, 42 U.S.C § 262(l)(8)(A): “The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k).”<sup>293</sup> Sandoz had provided this notice prior to obtaining FDA approval, and the district court agreed with Sandoz that this notice was effective.<sup>294</sup>

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284. 35 U.S.C. § 271(e)(2)(c) (2010).

285. *Sandoz, Inc.*, 137 S.Ct. at 1674.

286. *Id.*

287. *Id.*

288. *Id.* at 1675.

289. *Id.* at 1676.

290. *Amgen Inc. v. Sandoz Inc.*, 877 F.3d 1315, 1320 (Fed. Cir. 2017).

291. *Id.* The Federal Circuit later found that state law remedies were preempted by the BPCIA; see, *Amgen Inc. v. Sandoz Inc.* (Fed. Cir. 2017) -- One Last Dance . . . (December 14, 2017) (<https://www.patentdocs.org/2017/12/amgen-inc-v-sandoz-inc-fed-cir-2017-one-last-dance.html>)

292. *Sandoz, Inc.*, 137 S.Ct. at 1677.

293. 42 U.S.C. § 262(l)(8)(A) (2017) (emphasis added).

294. *Amgen, Inc. v. Sandoz, Inc.*, No. 14–cv–04741–RS, 2015 WL 1264756, \*8 (N.D. Cal. Mar. 19, 2015), *aff’d in part and vacated in part* by 794 F.3d 1347 (Fed. Cir. 2015).

Sandoz's biosimilar, under the brand name Zarxio, obtained FDA approval on March 5, 2015, and under the district court's interpretation of the statute Sandoz was free to enter the market (an outcome prevented by an injunction granted by the Federal Circuit pending its decision on appeal).<sup>295</sup> The Federal Circuit had agreed with Amgen that notice could only effectively be given after the biosimilar product has been approved by the FDA.<sup>296</sup> According to the Federal Circuit, while in other portions of the statute the biosimilar product is referred to as "the biological product that is the subject of the application," in subsection (l)(8)(A) the statute reads "the biological product licensed under subsection (k)."<sup>297</sup> The change in language indicated to the Federal Circuit that "[i]f Congress intended paragraph (l)(8)(A) to permit effective notice before the product is licensed, it would have used the 'subject of' language."<sup>298</sup> The appellate court appreciated that Congress made this distinction at least in part because it is only after licensure that "the product, its therapeutic uses, and its manufacturing processes are fixed," something that even the biosimilar applicant does not know with certainty when it applies for FDA approval.<sup>299</sup>

In addition, "[g]iving notice after FDA licensure, once the scope of the approved license is known and the marketing of the proposed biosimilar product is imminent, allows the RPS to effectively determine whether, and on which patents, to seek a preliminary injunction from the court."<sup>300</sup> This permits "a fully crystallized controversy" between the parties to have arisen when suit is filed, and "provides a defined statutory window during which the court and the parties can fairly assess the parties' rights prior to the launch of the biosimilar product."<sup>301</sup> Interpreting the statute as advanced by Sandoz would, on the contrary, result in a situation where "the RPS would be left to guess the scope of the approved license and when commercial marketing would actually begin."<sup>302</sup> Sandoz presented this question to the Court in its certiorari petition: "Whether notice of commercial marketing given before FDA approval can be effective and whether, in any event, treating Section 262(l)(8)(A) as a stand-alone requirement and creating an

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295. *Id.*

296. *Amgen, Inc.*, 794 F.3d at 1358.

297. *Id.* at 1357.

298. *Id.*

299. *Id.* at 1358.

300. *Id.*

301. *Id.*

302. *Id.*

injunctive remedy that delays all biosimilars by 180 days after approval is improper.”<sup>303</sup>

The Supreme Court reversed.<sup>304</sup> The Court’s analysis regarding the 180-day notice provisions of the statute was straightforward.<sup>305</sup> The Court held that the Federal Circuit had misinterpreted the statutory language by imposing a requirement for FDA approval before proper notice could be given.<sup>306</sup> According to the opinion, the reference in the statute to a licensed biosimilar product was to the term “commercial marketing” not “notice,” and thus just imposed the requirement that a product be licensed before it is marketed.<sup>307</sup> With this interpretation the notice was not tied to a product having been licensed before notice was given, as the Federal Circuit had held, but to the unremarkable reality that the product had to be licensed before it was sold.<sup>308</sup> The Supreme Court found only one timing requirement in the statute; that notice must be provided 180 days prior to marketing the biosimilar product.<sup>309</sup> The opinion recognized the Federal Circuit opinion to contain a second timing requirement, that FDA had approved the biosimilar.<sup>310</sup> This second requirement was not in the statute according to the Court and hence requiring approval was a misinterpretation of the statutory language by the Federal Circuit.<sup>311</sup> This conclusion was supported for the Court by the structure of subsection §262(l)(8)(B).<sup>312</sup> According to the opinion, Congress would have used this structure in its language for §262(l)(8)(A) if it intended the provision to have the interpretation applied by the Federal Circuit.<sup>313</sup>

Outside this question of statutory interpretation, the Court identified the policy arguments raised by the parties and the government and refused to be persuaded by the plausible contentions set forth therein.<sup>314</sup> Rather, the Court recommended that Congress is the appropriate body for making

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303. *Sandoz, Inc.*, 137 S. Ct. at 1677.

304. *Id.* at 1678.

305. *See id.* at 1677.

306. *Id.*

307. *Id.*

308. *Id.*

309. *Id.*

310. *Id.*

311. *Id.*

312. *Sandoz, Inc.*, 137 S. Ct. at 1677 (42 U.S.C. § 262(l)(8)(B) reads, in part, “[a]fter receiving the notice under subparagraph (A) and before such date of the first commercial marketing of such biological product, the reference product sponsor may seek a preliminary injunction. . . .” (emphasis added)).

313. *Id.*

314. *Id.* at 1678.

these policy distinctions and advised the parties to go there to effect a change in the law.<sup>315</sup>

Justice Breyer filed a brief concurring opinion, directed to his concerns (voiced during oral argument) that Congress had delegated responsibility to the FDA for interpreting the statute, based in part on its greater expertise.<sup>316</sup> The Justice thus invited the agency to “depart from, or to modify, today’s interpretation” under the appropriate circumstance, citing *National Cable & Telecommunications Assn. v. Brand X Internet Services*, to support his interpretation of the agency’s authority in this regard.<sup>317</sup>

*I. Regeneron Pharmaceuticals v. Merus (2018) (Denial of Certiorari by Supreme Court)*

On October 1, 2018, the Supreme Court denied *certiorari* to Regeneron Pharmaceuticals in its appeal of the Federal Circuit’s decision in *Regeneron Pharmaceuticals v. Merus* that affirmed the district court’s decision that the claims of Regeneron’s patent-in-suit were unenforceable due to inequitable conduct in the patent’s procurement.<sup>318</sup> In so doing, the Court passed up the opportunity to consider whether the split panel’s decision was consistent with the Federal Circuit’s own inequitable conduct jurisprudence, most recently handed down *en banc* in *Therasense, Inc. v. Becton, Dickinson and Co.*<sup>319</sup> The Court also passed up an opportunity to clarify, for the first time in over 70 years, a doctrine stemming directly from an ancient trio of its own decisions.<sup>320</sup> Under the circumstances, it is prudent for patent practitioners (prosecutors as well as litigators) to consider the lessons of the Federal Circuit’s *Regeneron* decision.

To recap, the case arose over Regeneron’s infringement suit against Merus involving U.S. Patent No. 8,502,018,<sup>321</sup> which is directed to transgenic mice expressing human variable domain immunoglobulin (Ig)

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315. *Id.*

316. *Id.*

317. *Id.* (Breyer, J., concurring) (citing *Nat’l Cable & Telecomm. Assn. v. Brand X Internet Serv.*, 545 U.S. 967, 982–84 (2005)).

318. *Regeneron Pharms., Inc. v. Merus N.V.*, 864 F.3d 1343, 1346 (Fed. Cir. 2017), *cert. denied*, 139 S. Ct. 122 (2018).

319. *Therasense, Inc. v. Becton, Dickinson and Co.*, 649 F.3d 1276 (Fed. Cir. 2011) (*en banc*).

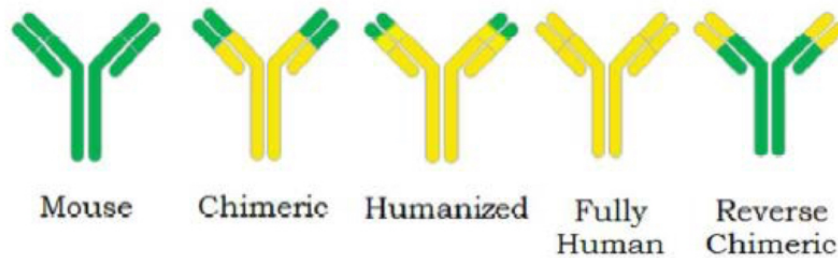
320. *See generally Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238, 250-51 (1944); *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814 (1945); *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240 (1933).

321. U.S. Patent No. 8,502,018 (filed June 20, 2011).



genes.<sup>322</sup> Claim 1 is representative: “1. A genetically modified mouse, comprising in its germline human unrearranged variable region gene segments inserted at an endogenous mouse immunoglobulin locus.”<sup>323</sup>

As explained in the Federal Circuit’s opinion, the types of antibody molecules that can be produced in mice using modern immunological and molecular biological techniques ranges from completely murine to completely human, and also include chimeric antibodies (encoded by human constant region genes and mouse variable domain genes) and “reverse” chimeric antibodies (encoded by human variable region genes and mouse constant region genes).<sup>324</sup> These possibilities are illustrated in the brief by a diagram (where green portions of the antibodies are encoded by mouse genes and yellow portions are encoded by human genes):<sup>325</sup>



Relevant to the issues before the Court was construction of the proper scope and meaning of the term “comprising in its germline human unrearranged variable region gene segments.”<sup>326</sup> Regeneron argued that this term was limited to inserting only human unrearranged variable regions genes, and thus only reverse chimeric antibodies would be encoded in the recombinant mouse genome; Regeneron argued its construction was supported by the plain meaning of the term and the ‘018 patent specification.<sup>327</sup> Merus, on the other hand, argued that the word “comprising” in the claim made the proper construction broader than just insertion of human unrearranged variable region gene segments, but also encompassed mice having genomes that encoded humanized, fully

322. *Regeneron Pharms., Inc.*, 864 F.3d at 1349.

323. *Id.* at 1348.

324. *Regeneron Pharms., Inc.*, 864 F.3d at 1348.

325. *Id.*

326. *Id.* at 1348–49.

327. *Id.* at 1352.

human, and reverse chimeric antibody embodiments.<sup>328</sup> The district court adopted Merus' construction, and the Federal Circuit agreed.<sup>329</sup>

This leads to the first lesson from the case: with regard to the but-for materiality prong of the *Therasense* test, the issue arises whether the standard of claim construction used by the examiner—broadest reasonable interpretation or BRI—is sufficient to prevent the district court from applying its own claim construction, consistent with *Phillips v. AWH Corp.*, to arrive at a different conclusion.<sup>330</sup> Here, whether the withheld references were but-for material depended on whether the interpretation of the phrase “comprising [human variable chain immunoglobulin genes]” was at least as broad before the Patent Office as it was before the district court.<sup>331</sup> (It is an unstated assumption that it should be, because the possibility that an applicant can amend the claims under the BRI test should make this the broadest construction.) If, as Regeneron contended, the claim language precluded embodiments wherein all or part of the human constant region genes were included, then the materiality of the undisclosed references may not have been as apparent to Regeneron or the examiner as it was to the district court and a majority of the Federal Circuit panel. This raises a serious issue of whether a district court must (or at least should) be bound by evidence of the context of prosecution to determine whether the examiner would have considered an uncited reference to satisfy the but-for materiality test (which reasonably should be the standard for whether an applicant or applicant's counsel withheld material references during prosecution). Under the Federal Circuit's *Regeneron* opinion the answer is no; this suggests that a patent prosecutor has two options for prudent practice: either make explicit (even if only by repeating any claim construction assertions made by the examiner) what the claims terms mean (contemporary practice avoids anything so potentially limiting) or expanding the scope of disclosure beyond either the applicant's or the examiner's understanding to preclude *any* interpretation from being broader than the one before the examiner.

Turning to the references, it was undisputed that during prosecution of the '018 patent, four references were known to Regeneron and its counsel that were not cited to the Patent Office. These references are:

1. Marianne Brüggemann & Michael S. Neuberger, “Strategies for Expressing Human Antibody Repertoires in Transgenic

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328. *Regeneron Pharms., Inc.*, 864 F.3d at 1350.

329. *Id.* at 1352.

330. *Id.* at 1353.

331. *Id.*

- Mice,” 17(8) *Review Immunology Today* 391 (1996) (Brüggemann);<sup>332</sup>
2. Shinsuke Taki et al., “Targeted Insertion of a Variable Region Gene into the Immunoglobulin Heavy Chain Locus,” 262 *Science* 1268 (1993) (Taki);<sup>333</sup>
  3. Yong–Rui Zou et al., “Cre-lox P-mediated Gene Replacement: A Mouse Strain Producing Humanized Antibodies,” 4(12) *Current Biology* 1099 (1994) (Zou);<sup>334</sup> and
  4. WIPO Patent Publication No. WO 91/00906 entitled “Chimeric and Transgenic Animals Capable of Producing Human Antibodies,” credited to Clive Wood et al. (Wood).<sup>335</sup>

These references were cited by a third party during prosecution of a related application after Regeneron received a Notice of Allowance for the ‘018 patent.<sup>336</sup> Regeneron did not submit these references to the Patent Office in the application that was granted as the ‘018 patent but did cite these references in all other pending related applications.<sup>337</sup>

This leads to the second lesson: cite *everything*, *particularly* references that are genuinely unknown to anyone under a Rule 56 duty, and when that art becomes known before allowed patent claims are permitted to issue. Any such reference will need to be cited, as Regeneron did, in all further related applications, and compliance with the duty of candor in those cases can be used (as it was here) as evidence supporting the materiality of the references. (These actions can also be used to support an inference of an intent to deceive; the district court’s application of an adverse inference, *infra*, prevented its decision from being an issue on appeal.)

The district court made the following findings of fact regarding the uncited references:

- Brüggemann was a review article that suggested replacing mouse Ig genes with human Ig genes in the mouse Ig locus. This specific “swapping” of the mouse and human genes would be an improvement over random integration (this was an argument Regeneron had made in support of its own invention). Regeneron’s basis for distinguishing this reference

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332. *Regeneron Pharms., Inc.*, 864 F.3d at 1349.

333. *Id.*

334. *Id.*

335. *Id.* at 1350.

336. *Id.* at 1349.

337. *Regeneron Pharms., Inc.*, 864 F.3d at 1350.

was that it does not teach reverse chimeric antibodies, but the district court's claim construction vitiated whatever force that argument may have had (or the significance of that argument on the materiality of the reference).<sup>338</sup>

- The Wood reference (according to the district court) also disclosed Ig locus targeting, based on expert testimony. The materiality of this reference was also based on its teaching that the constant region can be exogenous or endogenous, and thus encompasses insertion into the mouse Ig locus.<sup>339</sup>
- The Taki reference disclosed insertion of variable region genes from one *mouse* into another mouse, but the district court found the relevant consideration to be targeting exogenous Ig genes into an endogenous mouse Ig locus, not the mouse-human distinction. However, neither the district court nor the Federal Circuit addressed the distinction with the '018 patent claims that Taki discloses introduction of rearranged variable region genes and the '018 patent claims introduction of unrearranged human variable region genes.<sup>340</sup>
- The Zou reference disclosed modifying mouse constant region not variable region genes; but here again, the district court found the salient disclosure was targeting exogenous Ig genes into the mouse Ig locus.<sup>341</sup>

Although neither the district court nor the Federal Circuit found these references, alone or in combination, satisfied the requirements in the statute for invalidating the '018 patent claims (a fact noted in Judge Newman's dissent), the district court found that these references were but-for material, and this satisfied the first prong of the *Therasense* test for finding inequitable conduct.<sup>342</sup>

The district court also found that these references were not cumulative over the cited prior art, in particular U.S. Patent No. 6,114,598 to Kucherlapati, and a reference to Lonberg that had been overcome during prosecution of the '018 patent.<sup>343</sup> Regeneron argued that the Brüggemann reference was cumulative over Kucherlapati; the Wood reference was cumulative over Lonberg; and the Taki reference was

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338. *Id.* at 1353.

339. *Id.*

340. *Regeneron Pharms., Inc.*, 864 F.3d at 1354.

341. *Id.*

342. *Id.* at 1356.

343. *Id.* at 1355.

cumulative over the combination of Kucherlapati and Lonberg.<sup>344</sup> Specifically, Regeneron argued that Kucherlapati taught substitution of an exogenous (xenogeneic) locus at an endogenous target locus in the mouse genome, and that Lonberg taught a “knockout plus transgene” model, where the human antibody-encoding sequences are randomly inserted and the endogenous mouse Ig genes are disabled.<sup>345</sup> The district court distinguished the Kucherlapati reference from the Brüggemann reference by finding that Kucherlapati taught wholesale replacement of exogenous immunoglobulin (Ig) genes for the endogenous mouse Ig locus, and that such a replacement included mouse regulatory sequences whose removal could interfere with normal B-cell development and antibody production.<sup>346</sup> With regard to the Lonberg reference, the district court found that the Wood reference taught targeted insertion (as recited in the ‘018 patent claims) while Lonberg taught insertion at random sites in the mouse genome.<sup>347</sup> And the district court found that the combination of Kucherlapati and Lonberg was not cumulative to the Taki reference because Taki taught targeted insertion, and neither Kucherlapati nor Lonberg have these teachings.<sup>348</sup>

This is the third lesson: it can be challenging to apprehend the decisions a district court judge may make regarding whether uncited references are cumulative. A defendant’s expert will likely be the vehicle for introducing such evidence, which is directed to questions of fact, and the district court will be entitled to deference regarding not only the ultimate decision but also the credibility of contending expert witnesses. Thus, the prudent course is to consider *all* references not to be cumulative *unless* they are different versions of the same reference (e.g., a PCT/WIPO published application and its counterpart EPO publication of the same application).

With regard to the second prong of the *Therasense* test, intent to deceive, the Federal Circuit upheld (and the Supreme Court will not disturb) the district court’s drawing of an adverse inference based on the litigation misconduct catalogued by the district court in its opinion as not being an abuse of discretion.<sup>349</sup> The panel majority’s decision was supported by Regeneron’s failure to “meaningfully dispute any of the

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344. *Regeneron Pharms., Inc.*, 864 F.3d at 1355.

345. *Id.*

346. *Id.* at 1356.

347. *Id.*

348. *Id.*

349. *Regeneron Pharms., Inc.*, 864 F.3d at 1356.

factual findings underlying the district court’s decision,”<sup>350</sup> which included improperly withholding and citing on privilege logs documents clearly not privileged (such as experimental data); withholding as privileged information where the privilege had been waived; and withholding evidence of patent prosecution counsels’ reasoning and state of mind relevant to whether counsel had an intent to deceive.<sup>351</sup> The latter included, *inter alia*, the following cited in the Court’s opinion:

- *I firmly believed—and still believe today*—that Brüggemann, Taki, Zou and Wood were not material to patentability because they were substantially different from the mice claimed in the ‘176 application . . . and were cumulative of other information before the Patent Examiner.<sup>352</sup>
- [Counsel’s] description of his understanding of what a materiality analysis for inequitable conduct involves: “Regardless of whether I satisfied the minimum requirements of being an ordinary skilled artisan, I felt comfortable evaluating the art from that perspective during the prosecution of the ‘176 application. When I did have questions, however, I did not hesitate to reach out to those with more experience and knowledge.”<sup>353</sup>
- I routinely made Regeneron inventors aware of the foregoing obligations when providing them with invention declarations.<sup>354</sup>
- With regard to Brüggemann and Zou, “*I was generally familiar with the subject matter of those two references . . . [a]t no time did I consider these references to be material to patentability to the claims pending in the ‘176.*”<sup>355</sup>
- Because of this experience [prosecuting the ‘176 application as well as the ‘287 Patent], *I was readily familiar with both prior art that was before the Examiner in the ‘176 application and the pending claims of the ‘176 application.*<sup>356</sup>

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350. *Id.*

351. *Id.* at 1362.

352. *Id.* at 1360 (alteration in original).

353. *Regeneron Pharms., Inc.*, 864 F.3d at 1360 (alteration in original).

354. *Id.*

355. *Id.*

356. *Id.* at 1360–61

- I viewed the analysis [relating to the Withheld References] as straightforward.”<sup>357</sup> I concluded that [the Withheld References], alone or combined with other prior art of which I was aware, were cumulative of information already before the Examiner. Furthermore, *it was my view that* the skilled artisan would not have viewed them as teaching the reverse chimeric inventions that the Examiner had allowed in the ‘176 application.<sup>358</sup>

The tragedy for the patent prosecutors in this case is that this evidence not considered by the district court is the kind of evidence those prosecutors believed they would be able to present at trial, and that the contemporaneous record provided powerfully-exculpatory evidence regarding their subjective intent at the time they made the decision not to submit the references. Thus, the fourth lesson is: a patent prosecutor cannot have any reasonable basis for believing that they will have an absolute right, protected by due process, to present the evidence of their actual intent as a defense to an inequitable conduct charge. The extent to which the purported litigation misconduct deserved the sanction of an adverse inference is not the issue; what is important it that whether a patent prosecutor is exposed to an inequitable conduct determination can be, under the precedent established in this case, totally devoid of any deceptive intent on their part, no matter what evidence the prosecutor may have that would excuse a failure to disclose material prior art.

The Supreme Court’s decision not to review this case leaves a split between this decision and a pre-*Therasense* case, *Aptix Corp. v. Quickturn Design Systems, Inc.*, 269 F.3d 1369 (Fed. Cir. 2001), cited by Judge Newman in her dissent.<sup>359</sup> In that case, according to Judge Newman, “we held that courts may not punish a party’s post-prosecution misconduct by declaring the patent unenforceable” and cited multiple cases applying the principle that litigation misconduct can bar a litigant but does not render a patent unenforceable.<sup>360</sup> Yet that is what happened here, and thus any comfort *Therasense* may have given the patent bar regarding the need for evidence, inferential or otherwise, of a patent prosecutor’s intent to deceive, is greatly diminished by this decision.

Finally, because intent to deceive is personal (insofar as it applies only to those individuals who have a Rule 56 duty to disclose), it seems

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357. *Id.* at 1361.

358. *Id.*

359. *See Regeneron Pharms., Inc.*, 864 F.3d at 1365–74 (Newman, J., dissenting).

360. *Id.* at 1366 (citing *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238 (1944), *overruled on other grounds* by *Standard Oil Co. v. United States*, 429 U.S. 17, 18 (1976)).

inequitable to draw such an inference against the attorneys who prosecuted the '018 patent based on the conduct (bad or just misunderstood) of litigation counsel who did not have a Rule 56 duty of candor and were not involved in prosecuting the '018 patent to allowance. Inequitable conduct based on a practitioner's intent to deceive is a serious allegation having deleterious consequences to a patent prosecutor's reputation and can also have as negative repercussions an ethics inquiry by the Patent Office's disciplinary officials. Accordingly, it is not unreasonable for patent prosecutors to be placed in such jeopardy solely due to their own mis- or mal-feasance, rather than to be at the whim of conduct by litigation counsel taken for strategic reasons at trial (as the district court's decision and Federal Circuit opinion alleged here) that are found to be subject to sanction. The decision also perhaps raises questions of whether improperly rendering a patent unenforceable for inequitable conduct by a misapplication of the *Therasense* standard may amount to a 14th Amendment violation for taking property rights without due process. These issues were not enough for the Court to consider them worthy of its review, and thus remain somewhat uncertain.

*J. Life Techs. Corp. v. Promega Corp. (2017) (Decision by Justice Sotomayor, joined by Justices Alito, Breyer, Ginsburg, Kagan, Kennedy, Thomas; Concurrence by Justice Alito)*

The Supreme Court in this case decided whether the supply of a single component of a multi-component invention for combination abroad violates 35 U.S.C. § 271(f)(1).<sup>361</sup>

The patent-in-suit, known as the Tautz patent and exclusively licensed by Promega Corporation, claims a toolkit for genetic testing by DNA amplification.<sup>362</sup> There are five components to the patent: "(1) a mixture of primers that mark the part of the DNA strand to be copied; (2) nucleotides for forming replicated strands of DNA; (3) an enzyme known as *Taq* polymerase; (4) a buffer solution for the amplification; and (5) control DNA."<sup>363</sup> The patent was sublicensed to Life Technologies by Promega to manufacture and sell the toolkits worldwide.<sup>364</sup> Life Technologies manufactured all components except the *Taq* polymerase in the United Kingdom; the polymerase was manufactured in the United

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361. *Life Techs. Corp. v. Promega Corp.*, 137 S. Ct. 734, 739 (2017).

362. *Id.* at 738.

363. *Life Techs. Corp.*, 137 S. Ct. at 738.

364. *Id.*



States.<sup>365</sup> The polymerase was then shipped to the U.K. to be combined with the other four components.<sup>366</sup> Promega sued Life Technologies pursuant to 35 U.S.C. § 271(f)(1), which prohibits supply of all or a substantial portion of the components of a patented invention for combination abroad.<sup>367</sup> The jury in the district court found that Life Technologies willfully infringed the patent, and the district court granted Life Technologies motion for judgment as a matter of law.<sup>368</sup> The court agreed with Life Technologies that “all or a substantial portion” of an invention does not encompass the supply of a single component.<sup>369</sup> The Federal Circuit reversed the district court’s decision, concluding that “substantial” means “important”, and the Taq polymerase is an essential component for the invention.<sup>370</sup> On appeal to the Supreme Court, the question was “whether the supply of a single component of a multicomponent invention is an infringing act under U.S.C. § 271(f)(1).”<sup>371</sup>

The Court began its analysis by determining whether the use of the term “substantial” refers to a qualitative or quantitative measurement.<sup>372</sup> The statute does not provide a definition for the term, and the plain meaning of the term is ambiguous without context.<sup>373</sup> The Court construed the statute to mean that in context the phrase “all or a substantial portion” points toward a quantitative meaning.<sup>374</sup> “Portion” and “all” have quantitative meanings, and the Court provided several dictionary definitions for these terms.<sup>375</sup> Additionally, the fact that the phrase “substantial portion” is modified by “of the components of a patented invention” supported a quantitative interpretation in the Court’s view.<sup>376</sup> Therefore, the Court concluded that the text of the statute is correctly interpreted quantitatively.<sup>377</sup> The Court declined to adopt an interpretation that would require both quantitative and qualitative analyses.<sup>378</sup> A qualitative analysis would require determining which components of the

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365. *Id.*

366. *Id.*

367. *Id.*; 35 U.S.C. § 271(f)(1) (2010).

368. *Life Techs. Corp.*, 137 S. Ct. at 739.

369. *Id.*

370. *Id.*

371. *Id.*

372. *Life Techs. Corp.*, 137 S. Ct. at 739.

373. *Id.*

374. *Id.* at 740.

375. *Id.*

376. *See id.*

377. *Id.*

378. *Id.*

invention are more important than the others.<sup>379</sup> This complicates the duty of the factfinder due to its subjectivity, and is not supported by the text of the statute.<sup>380</sup>

Next, the Court determined “whether, as a matter of law, a single component can ever constitute a ‘substantial portion’ so as to trigger liability under §271(f)(1).”<sup>381</sup> The text of the statute consistently uses the term “components” in the plural when discussing the supply of a substantial number of components.<sup>382</sup> The Court compared the section to §271(f)(2), which refers to “any component” in the singular.<sup>383</sup> The Federal Circuit acknowledged that the two provisions encompass different scenarios, and the Supreme Court agreed.<sup>384</sup> However, the Supreme Court disagreed with the Federal Circuit’s conclusion that §271(f)(1) covers any single component.<sup>385</sup> The Supreme Court concluded that “component” is meant to reference a single component and “components” is meant to reference many components.<sup>386</sup> Due to this reading, the Court held that “all or a substantial portion” of a multicomponent invention cannot be a single component.<sup>387</sup> The Court did not attempt to define how many components in a multicomponent invention would count as “all or a substantial portion.”<sup>388</sup>

Based on this construction of the statutory language, the Supreme Court reversed the ruling of the Federal Circuit and remanded for further proceedings.<sup>389</sup> The immediate consequence of this decision is likely to be an increase in otherwise infringing activities abroad, wherein staple components are produced outside the U.S. and more complex or sophisticated components are made at home, thereby disadvantaging biotechnology or pharmaceutical patentees who manufacture or assemble their products in the U.S. in favor of competitors who do so overseas.

### III. CONCLUSIONS

Several implications for patent law doctrine, as applied to biotechnology, emerge from the top ten judicial decisions surveyed above.

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379. *Id.* at 741.

380. *Id.*

381. *Id.*

382. *Life Techs. Corp.*, 137 S. Ct. at 741.

383. *Id.* at 741–42.

384. *Id.* at 742.

385. *Id.*

386. *Id.*

387. *Id.* at 743.

388. *Id.*

389. *Id.*

Although only the passage of time and application by the courts will reveal the full topography of these implications, several lessons may already be drawn.

A. *Obviousness*

The *Acorda* decision suggests that the Federal Circuit is likely to continue a fairly broad interpretation of nonobviousness doctrine. This includes allowing challengers of patent validity to infer a generous amount of information from prior art references, and to combine such information relatively easily in order to make successful showings of nonobviousness. In particular, the existing of a blocking patent seems likely to make reliance on secondary indications of nonobviousness more difficult, leading to more invalidity findings.

B. *Statutory Subject Matter*

The *Berkheimer* decision appears to herald a change in direction for §101 subject matter doctrine. Here, the court suggested that a patentee or patent applicant may have an heretofore unavailable opportunity to rebut findings of invalidity due to unpatentable subject matter. Under *Berkheimer*, facts matter in a § 101 analysis and disputed facts can make it more difficult to invalidate patents on the pleadings, as well as at the summary judgment stage.

C. *Tribal Sovereign Immunity as a Patent Shield*

The issue of whether Native American tribes may use their tribal sovereign immunity to prevent challenges to their patents' validity may ultimately be decided by the Supreme Court. In the meantime, however, the Federal Circuit has ruled that tribal sovereign immunity may not shield tribe-owned patents from invalidity proceedings like IPRs, and the Supreme Court has declined to grant *certiorari* in the first case squarely to present it with this issue.

D. *DNA Interference*

Whoever ultimately owns patents successfully claiming the application of the CRISPR/Cas9 (and other forms of Cas) in mammals is likely to benefit from a windfall on the order of magnitude of the PCR patent estate in the 1980s. Thus far, it appears that the Broad Institute (and co-assignees), and its now-famous biologist, Feng Zhang, will control fundamental patents claiming uses of CRISPR/Cas9 in mammals and

other eukaryotes, and will be big players in the gene editing stakes alongside the University of California/Berkeley (and co-assignees) and its own celebrity biologist, Jennifer Doudna.

*E. Continued viability of the PTAB and IPR*

The Supreme Court, in *Oil States*, decided that the Constitution does not prohibit the Patent Office from resolving issues of validity post issuance outside of an Article III Court. Whether one sees the PTAB as a patent death court or a judicious and efficient gatekeeper of patent quality, it now appears that IPRs are here to stay, at least in the medium term. They are likely to continue to play an outsized role in testing and invalidating biotechnology patents.

*F. Scope of PTAB Institutions and Written Decisions*

In light of the resilience of IPRs, the Supreme Court, in *SAS Institute*, also decided that the PTAB would have to provide written reasons for the decisions they make. This burden will add to the workload of administrative patent judges, but should also help to clarify the procedures and arguments the PTAB use in this innovative, relatively inexpensive, and quite rapid proceeding.

*G. Written Description of Antibodies*

In *Amgen*, the Federal Circuit harmonized the application of the written description requirement as applied to antibody claims with the manner in which it is applied to other biotechnological inventions, such as nucleotide sequences. This seems to bring antibody inventions into the fold of the generally stricter written description requirement that has been applied to biotechnology inventions for several decades.

*H. BPCIA implementation*

The Supreme Court's put its imprimatur on Sandoz's interpretation of the BPCIA *not* to require a biosimilars applicant to submit to the reference product sponsor its application and any manufacturing information, despite the usually mandatory "shall" in the express language of the statute (42 U.S.C. §262(k)(2)). This decision has disrupted patent litigation under the Act to an extent that only Congress can repair.

### I. *The Inequitable Road to Inequitable Conduct*

The *Regeneron* denial of *certiorari* provides a warning to those involved in prosecuting patents to be extremely careful in how they act and what prior art reference they cite to the examiner. Inequitable conduct in the antibody context appears to be relatively easy to demonstrate. For example, patent attorneys would be advised to err on the side of submitting more prior art, rather than less, in order to maximize the probability that a court will not find that any prior art references had been impermissibly withheld from the Patent Office. Abundance of prosecutorial caution may increase the volume of prior art examiners need to consider, with potential consequences for prosecution timing and Patent Office backlogs.

### J. *Infringement Via Component Sales*

The Supreme Court used the *Life Techs* decision to interpret the meaning of a “substantial portion” of a claimed invention. It clarified that the approach should rely on quantitative, not qualitative, interpretation to determine whether or not patent infringement has occurred. The result is an inquiry into whether that number constitutes a substantial portion of a claimed invention. The Supreme Court held that a single component, as a matter of law, cannot constitute a “substantial portion” of a multicomponent invention. Overseas biotechnology manufacturing and assembly of products is likely to benefit.

### K. *Issues on the Horizon*

Biotechnology shows no signs of slowing down. Quite to the contrary, the pace of innovation in the field, encompassing myriad new approaches to therapeutics, diagnostics, and even human enhancement, appears to be accelerating, diversifying, and increasingly affecting people as part of their ordinary lives. Biotechnology patent law will have to try to keep pace, with many significant judicial decisions expected in the future. It seems likely that biotechnology and the law of biotechnological patents will continue to provoke robust interest and heated controversy. However, discussion of these developments will have to await the “BIOTECHNOLOGY PATENT LAW 2019 REVIEW.”