Top Ten Biotechnology Patent Cases of 2023: Antibodies Unenabled, Extrinsic Evidence Excluded, and Double Patenting Prohibited

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Abstract

The prospect for future innovation is evident in biotechnology, including great medical, agricultural, and industrial promises that genome editing, antibody drugs, mRNA vaccines, and other biological technologies offer. These possibilities also seem to be evident in how courts, including the Supreme Court, were involved in deciding biotechnology questions in 2023. In addition to Supreme Court consideration of the scope and requirements of enablement, the Federal Circuit applied Supreme Court rubrics on this issue and also decided questions of utility, enablement, written description, anticipation, obviousness, and standing. But all is not rosy for supporters of stronger patent laws—judicial limitations on subject matter eligibility under 35 U.S.C. § 101 for diagnostic inventions and patenting natural products, including DNA molecules, continue to frustrate those hoping to patent such subject matter. And, the U.S. Congress did not appear to have the will or interest to reform these or other patent law issues, leaving any changes to the courts, at least for now. These trends in judicial decisions were not unique to 2023, and the year provided a furtherance and continuation of issues having arisen during the time of this series of law review articles since 2018.

Table of Contents

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I. Introduction

Stock prices of biotechnology and pharmaceutical companies swooned in 2023, some reaching perilous lows. Nevertheless, it was a boom time for biotechnology patent law decisions, with even the United States Supreme Court deciding a biotechnology patent law case. Perhaps the close attention courts paid to this area of technology is a harbinger of better times to come, not just on the stock markets but also in the realization of the great medical, agricultural, and industrial promises that genome editing, antibody drugs, mRNA vaccines, and other biological technologies hold for the world. The courts are certainly busying themselves with the patent doctrines that underpin these beneficial inventions.

In addition to a major decision by the Supreme Court, *Amgen v. Sanofi*, the top ten biotechnology patent cases of 2023 include two cases—*Medytox, Inc. v. Galderma S.A.* and *Baxalta Inc. v. Genentech, Inc.*—that apply *Sanofi*, as well as seven other decisions relating to a miscellaneous variety of biotechnology patent law issues.[1] These include utility, enablement, written description, anticipation, obviousness, and standing issues. However sharply the courts hone patent doctrine, two dark clouds linger over biotechnology patent law: the patentability of diagnostic methods and patenting natural product, including DNA molecules discovered within genomes. The U.S. Congress continues to agitate regarding amending the Patent Act to restore the patentability of these areas of subject matter.[2] Yet, thus far, these initiatives have been "full of sound and fury, [s]ignifying [less than] nothing."[3]

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1 Medytox, Inc. v. Galderma S.A., 71 F.4th 990 (2023); Baxalta Inc. v. Genentech, Inc., 81 F.4th 1362 (Fed. Cir. 2023); Amgen v. Sanofi, 598 U.S. 594 (2023).

2 Patent Eligibility Restoration Act of 2022, S. 4737, 117th Cong. (2022); Patent Eligibility Restoration Act of 2023, S. 2140, 118th Cong. (2023).

3 WILLIAM SHAKESPEARE, MACBETH act 5, sc. 5, l. 27–28 (Open Road Integrated Media, 2020).

What is not nothing is the set of biotechnology patent decisions discussed below. They indicate a legal field in rude health and an industry just waiting for the market winds to shift to a more favorable direction. They will, and they will soon, as the biotechnologies that the cases cover are extraordinary and getting more so by the day.

II. Decisions

1. *Amgen v. Sanofi*, 598 U.S. 594 (2023)

The Supreme Court handed down its decision in *Amgen v. Sanofi* this year, affirming the Federal Circuit's decision below in a unanimous opinion by Justice Gorsuch that did little to change the status quo.

a. Details of the Case

The case arose when Amgen sued Sanofi and Regeneron over sales of Praluent® (alirocumab), which allegedly competes with Amgen's Repatha™ (evolocumab).[4] Amgen's asserted patents, U.S. Patent Nos. 8,829,165 and 8,859,741, claim a genus of antibodies that encompass Praluent®.[5] As background, blood plasma contains low-density lipoproteins that bind cholesterol and are associated with atherosclerotic plaque formation.[6] Liver cells express receptors for LDL (LDL-R), wherein binding thereto reduces the amount of LDL cholesterol in the blood, reducing the risk of plaque formation and cardiovascular disease.[7] 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.[8] The antibodies at issue in this suit bind to PCSK9 and prevent PCSK9 from binding to LDL-R, preventing their destruction and resulting in lower serum cholesterol.[9]

The following claims were recited in the opinion as being relevant to the issues before the Court:

> Claims of the '165 patent:
>
> 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 NO:3, and wherein the monoclonal antibody blocks binding of PCSK9 to LDL[-]R.
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> 19. The isolated monoclonal antibody of claim 1 wherein the isolated monoclonal antibody binds to at least two of the following residues S153, I154, P155, R194, D238, A239, I369, S372, D374, C375, T377, C378, F379, V380, or S381 of PCSK9 listed in SEQ ID NO:3.
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> 29. A pharmaceutical composition comprising an isolated monoclonal antibody, wherein the isolated monoclonal antibody binds to at least two of the following residues S153, I154, P155, R194, D238, A239, I369, S372, D374, C375, T377, C378, F379, V380, or S381 of

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4 Amgen v. Sanofi, 598 U.S. 594, 602–03 (2023).
5 *Id.*
6 *Id.* at 601.
7 *Id.*
8 *Id.*
9 *Id.* at 599.

> PCSK9 listed in SEQ ID NO: 3 and blocks the binding of PCSK9 to LDLR by at least 80%.[10]

Claims of the '741 patent:

> 1. An isolated monoclonal antibody that binds to PCSK9, wherein the isolated monoclonal antibody binds an epitope on PCSK9 comprising at least one of residues 237 or 238 of SEQ ID NO: 3, and wherein the monoclonal antibody blocks binding of PCSK9 to LDLR.
> 2. The isolated monoclonal antibody of claim 1, wherein the isolated monoclonal antibody is a neutralizing antibody.
> 7. The isolated monoclonal antibody of claim 2, wherein the epitope is a functional epitope.[11]

It is important to note that, while reciting the structure of the residues on PCSK9 (the *antigen*) that are bound by the claimed antibody, the claim does not recite *any* structural limitations on the antibody.[12] The only antibody characteristics recited as limitations are functional, i.e., the ability to bind (and not even specifically bind) to at least one of the recited PCSK9 residues and block PCSK9's interaction with the LDL-R.[13]

Evidence at a first trial between the parties showed that Amgen had produced a plurality of anti-PCSK9 antibodies and screened them for the ability to inhibit PCSK9 binding to LDL-R.[14] This screening was done using a "trial and error" process that reduced 3,000 human monoclonal antibodies 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.[15] The specification of the Amgen patents in suit disclose amino acid sequence information for twenty-two human anti-PCSK9 antibodies able to compete for PCSK9 binding in addition to these two more fully characterized antibodies.[16] Regeneron's patents (not at issue here) recited antibody-specific amino acid sequences for its claimed anti-PCSK9 antibodies.[17]

The jury in the earlier case found Amgen's patents not to be invalid.[18] The district court, relying on *Noelle v. Lederman* 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 disclosed a fully characterized, novel antigen.[19] The Federal Circuit reversed in part, affirmed

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10 U.S. Patent No. 8,829,165.
11 U.S. Patent No. 8,859,741.
12 *Amgen*, 598 U.S. at 602.
13 *Id.*
14 *Id.* at 603–04.
15 Amgen v. Sanofi, 872 F.3d 1367, 1372 (Fed. Cir. 2017) (alteration in original) (quoting U.S. Patent No. 8,829,165).
16 *Id.*
17 *Id.*
18 *Id.* at 1371.
19 *Id.* at 1375–77 (citing Noelle v. Lederman, 355 F.3d 1343 (Fed. Cir. 2004)).

in part, vacated in part, and remanded.[20] With regard to the written description question, the court vacated and remanded, on the grounds that the district court had instructed the jury based solely on the court's *Noelle v. Lederman* precedent, which was inconsistent with the court's later *en banc* decision in *Ariad v. Eli Lilly & Co*.[21] The court also found it to be an error for the district court to have excluded evidence regarding enablement, 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.[22] The Federal Circuit ordered a new trial to consider post-priority-date evidence for enablement.[23] On remand, the jury found that claim 7 of the '741 patent and claims 19 and 29 of the '165 patent were not invalid.[24] The district court granted Sanofi's motion for JMOL with regard to enablement for these claims.[25]

In the resulting appeal, the Federal Circuit affirmed that the claims were not enabled.[26] The panel based its decision on the principle that "[t]he claimed antibodies are defined by their function: binding to a combinations of sites (residues) on the PCSK9 protein, in a range from one residue to all of them; and blocking the PCSK9/LDLR interaction."[27] The panel referred (as it must) to its decision in *In re Wands* (and its famous "*Wands* factors"), the dispositive factor in the court's decision being the amount of experimentation required to encompass the full scope of the claims at issue.[28] Albeit being a question of law, enablement depends particularly on the facts from which conclusions of law are based. The opinion is sensitive to the requirement for patenting that the specification enable practice of the claimed invention throughout its full scope, and with the *Wands* rubrics, that the scope of the claims can determine the extent of experimentation required and whether such experimentation is undue.

Amgen's arguments were grounded in the disclosure in the specification regarding the type of experimentation required and the guidance provided therein on the extent of such experimentation, while Defendants argued that the scope of these claims encompassed "millions of antibody candidates," that antibody production was unpredictable, and that the specification lacked sufficient guidance because, *inter alia*, "practicing the full scope of the claims requires substantial trial and error."[29] Defendants emphasized not the antibodies Amgen had actually made but "the number of candidates that must be made and tested to determine whether they satisfy the claimed function."[30]

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20 *Id.* at 1371.
21 *Id.* at 1376–77.
22 *Id.* at 1375.
23 *Id.*
24 Amgen v. Sanofi, 987 F.3d 1080, 1084 (Fed. Cir. 2021).
25 *Id.*
26 *Id.* at 1082.
27 *Id.* at 1083.
28 *Id.* at 1084.
29 *Id.* at 1085.
30 *Id.*

Calling *In re Wands* the Federal Circuit's "go to" precedent, the opinion stated that while itself a monoclonal antibody case, "*Wands* did not proclaim that all broad claims to antibodies are necessarily enabled."[31] The panel considered the findings of invalidity in more recent cases, including *Wyeth & Cordis Corp. v. Abbott Laboratories*,[32] *Enzo Life Sciences, Inc. v. Roche Molecular Systems, Inc.*,[33]and *Idenix Pharmaceuticals LLC v. Gilead Sciences Inc*.[34] In all these cases, the Federal Circuit found that the claims were not enabled due to the broad scope of embodiments the claims in these cases encompassed and the amount of undue experimentation required to satisfy the enablement requirement throughout its full scope.[35] The panel set forth its synthesis of the Federal Circuit's analysis regarding satisfaction of the enablement requirement arising from these cases:

> What emerges from our case law is that the enablement inquiry for claims that include functional requirements can be particularly focused on the breadth of those requirements, especially where predictability and guidance fall short. In particular, it is important to consider the quantity of experimentation that would be required to make and use, not only the limited number of embodiments that the patent discloses, but also the full scope of the claim.[36]

This precedent was controlling here: "[w]hile functional claim limitations are not necessarily precluded in claims that meet the enablement requirement, such limitations pose high hurdles in fulfilling the enablement requirement for claims with broad functional language."[37] As applied to Amgen's claims, the panel recognized each of them to be "a composition claim defined, not by structure, but by meeting functional limitations."[38] This outcome is consistent with *Wands*, according to the opinion, because the "functional breadth" of these claims is "indisputably broad" and "the claims are far broader in functional diversity than the disclosed examples."[39] Taking a real property analogy from *AbbVie Deutschland GmbH & Co. v. Janssen Biotech, Inc*., the opinion stated that "[i]f the genus is analogized to a plot of land, the disclosed species and guidance 'only abide in a corner of the genus.'"[40] The opinion also referenced the unpredictability of the antibody arts as a relevant (and supportive) *Wands* factor in favor of invalidity.[41] The *Wands* quantum of guidance factor was also deficient, according to the opinion, because "any reasonable factfinder would conclude that the patent does not provide significant guidance or direction to a person of ordinary skill in the art for the full scope of the claims."[42]

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31 *Id.* at 1086.
32 720 F.3d 1380 (Fed. Cir. 2013).
33 928 F.3d 1340 (Fed. Cir. 2019).
34 *Amgen*, 987 F.3d at 1086; Idenix Pharm. LLC v. Gilead Sci., Inc., 941 F.3d 1149 (Fed. Cir. 2019).
35 *Amgen*, 987 F.3d at 1087.
36 *Id.* at 1086.
37 *Id.* at 1087.
38 *Id.*
39 *Id.*
40 *Id.* (citing AbbVie Deutschland GmbH & Co. v. Janssen Biotech, Inc., 759 F.3d 1285, 1299–300 (Fed. Cir. 2014)).
41 *Id.* at 1087–88.
42 *Id.* at 1088.

Importantly, the panel cabined its decision by stating that while the "substantial amount of time and effort" required to produce the scope of antibodies claimed here is undue, "[w]e do not hold that the effort required to *exhaust* a genus is dispositive."[43] The court struck a balance: "[t]he functional limitations here are broad, the disclosed examples and guidance are narrow, and no reasonable jury could conclude under these facts that anything but 'substantial time and effort' would be required to reach the full scope of claimed embodiments."[44] The facts here (which distinguish this decision from *Wands*) are that "the evidence showed that the scope of the claims encompasses millions of candidates claimed with respect to multiple specific functions, and that it would be necessary to first generate and then screen each candidate antibody to determine whether it meets the double-function claim limitations."[45] Under these facts, the substantialness of such time and effort was sufficient to be considered undue experimentation by the court.

The Supreme Court granted Amgen's petition for certiorari on the second of the questions presented in its petition:

> 2. Whether enablement is governed by the statutory requirement that the specification teach those skilled in the art to "make and use" the claimed invention, 35 U.S.C. §112, or whether it must instead enable those skilled in the art "*to reach the full scope* of claimed embodiments" without undue experimentation—i.e., to cumulatively identify and make all or nearly all embodiments of the invention without substantial "'time and effort,'" Pet.App. 14a.[46]

This question, and how the court has been petitioned to address it, directly concerns the scope of disclosure necessary to satisfy the statutory requirements of 35 U.S.C. § 112(a), a question of particular importance for genus claims in pharmaceutical and biotechnology patents.[47] In its petition for certiorari, Amgen's argument regarding the second question presented was that it was contrary to ancient Supreme Court precedent.[48] Amgen argued that the Federal Circuit's standard for statutorily compliant enablement, what it termed cumulative disclosure that reached the full scope (even to the most remote corners of the claimed invention), is "a standard of its own devising" that is "impossible to satisfy."[49] This standard requires the claims to be enabled throughout their full scope even if there is no evidence that there is any particular species that would require undue experimentation to achieve,

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43 *Id.*

44 *Id.*

45 *Id.*

46 Amgen v. Sanofi, 143 S. Ct. 399 (2022) (emphasis added) (quoting Petition for Writ of Certiorari at i, Amgen v. Sanofi, 598 U.S. 594 (2023) (No. 21-757)). The Court did not deign to consider the first question, regarding whether enablement should be a question of law for the court, as it is under current Federal Circuit precedent, or a question of fact for the jury.

47 *See* Dmitry Karshtedt, Mark A. Lemley & Sean B. Seymore, *The Death of the Genus Claim*, 35 HARV. J. L. & TECH. 1, 15, 16, 21, 30 (2021).

48 Petition for Writ of Certiorari, Amgen v. Sanofi, 598 U.S. 594 (2023) (No. 21-757) (citing Mowry v. Whitney, 81 U.S. 620, 644–45 (1871); The Telephone Cases, 126 U.S. 1, 536 (1888); Minerals Separation, Ltd. v. Hyde, 242 U.S. 261, 271 (1916); Schriber-Schroth Co. v. Cleveland Tr. Co., 305 U.S. 47, 57 (1938); Universal Oil Prods. Co. v. Globe Oil & Refin. Co., 322 U.S. 471, 484 (1944)).

49 *Id.* at 13 (citing Karshtedt et. al., *supra* note 47).

Amgen argued.[50] The proper standard, according to Amgen—consistent with the statutory text, the history of how enablement has been considered, and Supreme Court precedent—is whether disclosure is sufficient to be able to make and use the invention, which does not require disclosure throughout the entire scope of the claim.[51] "The Federal Circuit identified no reason why patent validity should depend on the *cumulative* effort required to ferret out *every* conceivable implementation of the invention," Amgen argued in its petition, asserting that the requirement was contrary to *Minerals Separation, Ltd. v. Hyde*.[52] The test creates an impossibility that prevents a patentee from protecting her invention because a claim can be avoided by an infringer who makes a minor (structural) change, according to Amgen.[53] And as a consequence, "[t]he Federal Circuit routinely lays waste to innovative patents that juries upheld at trial" by imposing its test, according to the petition.[54]

The reaction to this certiorari grant was submission of nearly three dozen amicus briefs on both sides of the issue.

For petitioner Amgen (12 amici and their arguments):

- National Association of Patent Practitioners: the Federal Circuit's "full-scope" test is unworkable, and the Court's "reasonableness" standard from *Materials Separation v Hyde* is the proper enablement test.[55]
- Alliance of U.S. Startups and Inventors for Jobs (USIJ) and Innovation Alliance (IA): some inventions can only be protected by genus claims.[56]
- Diversified Researchers and Innovators (which includes the Association of University Technology Managers (AUTM), Bavarian Nordic, Biogen, Bristol Myers Squibb, Corning, Merck, and 3M): *Materials Separation v. Hyde* applies the proper enablement standard.[57]
- Intellectual Property Professors (Mark A. Lemley et al.): "The central feature of patent law in the life sciences industries is the genus claim" because without it, "a competitor could make a minor change to the chemical the patentee invented and avoid liability while capturing the heart of the invention."[58]

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50 *Id.*

51 *Id.* at 1–2.

52 *Id.* at 3; *see also* Minerals Separation, Ltd. v. Hyde, 242 U.S. 261, 271 (1916).

53 Petition for Writ of Certiorari, *Amgen*, 598 U.S. at 30.

54 *Id.* at 24.

55 Brief of National Association of Patent Practitioners, Inc. as Amicus Curiae in Support of Petitioner at 4, 11–12, Amgen v. Sanofi, 598 U.S. 594 (2023) (No. 21-757).

56 Brief of Alliance of U.S. Startups and Inventors for Jobs ("USIJ") and Innovation Alliance ("IA") as Amicus Curiae in Support of Petitioners at 12, Amgen v. Sanofi, 598 U.S. 594 (2023) (No. 21-757).

57 Brief of Diversified Researchers and Innovators as Amicus Curiae in Support of Petitioners at 12, Amgen v. Sanofi, 598 U.S. 594 (2023) (No. 21-757).

58 Brief of Intell. Prop. Professors as Amici Curiae in Support of Petitioners at 1–2, Amgen v. Sanofi,

- AbbVie: this brief is directed at the consequences of the Federal Circuit opinion that "chill[] investment . . . and innovation" for subject matter like chemistry, pharmaceuticals, and biotechnology.[59]
- GlaxoSmithKline (GSK): claims often are directed to "major scientific breakthroughs, establish first-in-class medicines, and encourage downstream improvements that can themselves be patented." The importance of genus claims, GSK explains, is that they encompass "closely related species or modifications" that can be exploited by competitors to expropriate "the heart of the invention" unless the innovator has a genus claim that prevents such expropriation.[60]

For respondent Sanofi (17 amici and their arguments):

- Another group of law professors (Joshua D. Sarnoff et al.): the patent applicant must disclose sufficient information for the skilled worker to be able to make and use the invention, and the Court must establish "*how much* of a structural-functional relationship must be disclosed to validly support a genus claim without improperly shifting the burden of inventing to skilled artisans?" and "for an already invented and properly disclosed genus, how much *additional* information must an applicant provide to "enable" skilled artisans to "make and use" the claimed genus?"[61]
- Esteemed scientists: filed to "provide[] information and scientific perspectives concerning several issues at the heart of this case" and explain that the structural complexities of antibodies make it difficult to enable a broad scope.[62]
- Fresenius Kabi: enablement provides a balance to the public, and overbroad patents upset that balance and "negatively affect competition."[63]
- Eli Lilly & Co., Ipsen Bioscience, Inc., and Innovent Biologics, Inc.: claims directed to purely functional results would be "indisputably detrimental to the public."[64]

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598 U.S. 594 (2023) (No. 21-757). This brief relies on Dmitry Karshtedt, Mark A. Lemley & Sean B. Seymore, *The Death of the Genus Claim*, 35 HARV. J. L. & TECH. 1, 23–35 (2021).

59 Brief of AbbVie Inc. as Amicus Curiae in Support of Petitioners at 5–6, Amgen v. Sanofi, 598 U.S. 594 (2023) (No. 21-757).

60 Brief of GSK plc in as Amicus Curiae Support of Petitioners at 1–2, Amgen v. Sanofi, 598 U.S. 594 (2023) (No. 21-757).

61 Brief of Law Professors Joshua D. Sarnoff et al. as Amici Curiae in Support of Respondents at 2, Amgen v. Sanofi, 598 U.S. 594 (2023) (No. 21-757).

62 Brief of Sir Gregory Paul Winter and Interested Scientists as Amici Curiae in Support of Respondents at 6–7, Amgen v. Sanofi, 598 U.S. 594 (2023) (No. 21-757).

63 Brief of Fresenius Kabi USA, LLC as Amicus Curiae in Support of Respondents at 2, Amgen v. Sanofi, 598 U.S. 594 (2023) (No. 21-757).

64 *See* Brief of Eli Lilly and Co., Ipsen Bioscience, Inc. and Innovent Biologics, Inc. as Amicus Curiae in Support of Respondents at 2–3, n.2, Amgen v. Sanofi, 598 U.S. 594 (2023) (No. 21-757)

- Pfizer: "the undue breadth of the claims and the exclusive rights [Amgen] seek[s] to encompass" is "a naked attempt to preempt future innovation and an unwarranted extension of the patent monopoly."[65]
- Genentech, AstraZeneca Pharma, Bayer AG, Gilead Sciences, and Johnson & Johnson: the Federal Circuit upholds genus claims that are supported by disclosure and that have appropriate scope using a flexible standard that is consistent with Supreme Court and its own precedent, unlike the claim at issue here ("one species is not enough to enable a genus," at least for antibody claims).[66]
- Small and Medium Biotechnology Companies: "[t]he longstanding enablement standard is consistent with text and precedent. The balance it strikes promotes innovation and saves lives."[67]
- Law professors (Tu, Rai, Litvak, Collins, Chao): claims should be limited to what is disclosed because that is what is invented, and "[t]rial-and-[e]rror [i]nventing[,]" like Amgen's here, in their view, "is inherently narrow" and the scope of the claim should be commensurate thereto.[68]
- Professor Robin Feldman: the brief presents the most extreme position, that *Wood v. Underhill* and *Consolidated Electric Light Co. v. McKeesport Light Co*. "hold that the correct standard here is not *undue* experimentation but rather *any* experimentation."[69]
- AIPLA: enablement does not require disclosure of all embodiments and *Wands* is the correct legal and analytical framework.[70]
- Association for Accessible Medicines: Federal Circuit's decision aligns with statutory text and with the structure and purpose of the Patent Act, and Amgen's theory will inhibit competition in the pharma industry.[71]

(discussing regimes where a company can control all antibody therapeutics to a particular target as stifling competition and harming patients).

65 Brief of Pfizer Inc. as Amicus Curiae in Support of Respondents at 3, 19, Amgen v. Sanofi, 598 U.S. 594 (2023) (No. 21-757).

66 Brief of Genentech, Inc., Astrazeneca Pharms. LP, Bayer AG, Gilead Sciences, Inc., and Johnson & Johnson as Amici Curiae in Support of Respondents at 4–5, Amgen v. Sanofi, 598 U.S. 594 (2023) (No. 21-757).

67 Brief for Small and Medium Biotechnology Companies as Amici Curiae in Support of Respondents at 4, Amgen v. Sanofi, 598 U.S. 594 (2023) (No. 21-757).

68 Brief of Intell. Prop. L. Professors and Scholars as Amici Curiae in Support of Respondents at 7, Amgen v. Sanofi, 598 U.S. 594 (2023) (No. 21-757).

69 *See* Brief of Professor Robin Feldman as Amicus Curiae in Support of Respondents at 2, 7, Amgen v. Sanofi, 598 U.S. 594 (2023) (No. 21-757) (first citing Wood v. Underhill, 46 U.S. (5 How.) 1, 4 (1847); and then citing Consolidated Electric Light Co. v. McKeesport Light Co., 159 U.S. 465, 474–75 (1895)).

70 Brief for the Am. Intell. Prop. L. Ass'n as Amicus Curiae Suggesting Affirmance, Amgen v. Sanofi, 598 U.S. 594 (2023) (No. 21-757).

71 Brief of the Ass'n for Accessible Med. as Amicus Curiae in Support of Respondents, Amgen v. Sanofi, 598 U.S. 594 (2023) (No. 21-757).

- Arnold Ventures, National Centers for Health Research, and Certain Medical Doctors: perceived negative consequences on innovation and competition in pharma, citing reports about high drug costs.[72]
- Unified Patents: concerns the enablement issue raised for patentees outside the biotech and pharma industries, functional claims impede innovation regardless of technology, and that the "full scope" test is needed to prevent this negative outcome. [73]

The Supreme Court heard oral argument in an extended session with arguments from the parties and the U.S. government. Petitioner was represented by Jeffrey Lamken, respondents by Paul Clement, and the Government by Colleen Sindak.[74]

The Justices showed a great deal of interest, albeit with some difficulty, in making sure that they properly understood the complexity of the genus at issue. Justice Thomas, for example, began the Court's questioning by asking how many antibodies were invented, suggesting it was 26 and after Mr. Lamken explained that Amgen contended the actual number was about 400, the Justice said, "in other words, you can't say how many?"[75] Justice Jackson also queried Mr. Lamken, who expanded on his answer to Justice Thomas by saying "we got 3,000 [antibodies], which were filtered down to 384. The 26 [antibodies] are something different. The 26 are the ones where we went through and figured out the exact amino acid sequence and then listed them in the patent."[76] He then drew the distinction that "there's a reason why you don't go and do 384 amino acid sequences for every one of them in the patent. . . . patent law has never required all of [the] embodiments in there."[77]

The answers to the question (depending on who was answering) was the 26 expressly disclosed by the respondent to nearly 400 disclosed by the petitioner based on the number Amgen isolated, with respondent emphasizing the "millions and millions" allegedly falling within the scope of the claims (saying "the numbers don't lie").[78] Petitioner reminded the Court that these estimates included antibodies having "conservative substitution[s]" in the amino acid sequence expected to yield equivalent antibodies in structure and claimed function (calling them the "swapped amino acid species," Mr. Lamken said they were "99.99% similar" and "routine" to make).[79] Regarding the conservative substitution species, Mr. Clement challenged the assertion that antibodies differing from the disclosed sequences by any amino acid sequence change could be assumed to be functional, saying "[y]ou have to go through

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72 Brief of Arnold Ventures, The Nat'l Ctr. for Health Rsch., and Certain Med. Doctors as Amicus Curiae in Support of Respondents, Amgen v. Sanofi, 598 U.S. 594 (2023).

73 Brief of Unified Patents, LLC as Amicus Curiae in Support of Respondents, Amgen v. Sanofi, 598 U.S. 594 (2023) (No. 21-757).

74 Oral Argument, Amgen v. Sanofi, 598 U.S. 594 (2023) (No. 21-757), https://www.supremecourt.gov/oral_arguments/audio/2022/21-757.

75 *Id.* at 3:33.

76 *Id.* at 41:18.

77 *Id.* at 41:28.

78 *Id.* at 41:58.

79 *Id.* at 4:48.

that whole experimental process again to confirm that it binds in the right place" and referring the Court to Sir Gregory Winter's amicus brief in this regard.[80] When asked by Justice Gorsuch, Mr. Clement stated that only the 26 identified antibodies were enabled.[81] The Government agreed, stating that the only antibodies that were enabled were those for which Amgen had provided the amino acid sequence (indeed, when asked by Justice Roberts whether there was anything in Mr. Clement's argument the government disagreed with, Ms. Sindzak said there wasn't).[82]

Missing from the argument was a reminder that, to the extent Amgen's genus claims can be analogized to a conventional pharmaceutical genus claim, any particular, undisclosed antibody that is patentably distinct from the genus can be independently patentable and Amgen does not "own" those antibodies (although Amgen's patent may be a dominating patent).

The Justices asked both parties' counsel whether this was at root a factual issue, Justice Gorsuch specifically asking Mr. Lamken whether there were any disagreements of law other than the appropriateness of the cumulative effort test, and if not, "why isn't this just a fact-bound dispute?"[83] Justice Kagan asked Mr. Clement whether there was any dispute on the law (as opposed to the law's application to the facts at the Federal Circuit).[84] Justice Kagan also asked Mr. Lamken, "do you understand the parties now all to agree on the appropriate legal test, and are we simply arguing now about how that test applies in this case?" to which Mr. Lamken replied, "I think the parties all agree that the cumulative effort, the idea of reach the full scope, that that cannot be sustained."[85] Mr. Clement was less sanguine on the scope of the parties' agreement, telling Justice Kagan that there "must be" disagreement on the law because Amgen's assessment is that it is enough to "consign people skilled in the art to Sisyphean tasks forever" in making the antibodies falling within the scope of the claim; "what skilled artisans want[,]" Mr. Clement argued, "is not to randomly generate something within the broad range that's claimed, but they want to be able to pick a specific embodiment, not a hypothetical one, but a specific one" contrary to petitioner's position.[86]

As often happens in arguments before the Court, analogies abounded, with petitioner arguing that James Watt did not need to disclose every possible embodiment of a steam engine to enable claims to one.[87] Mr. Lamken's argument motivated Justice Thomas to remark that this case was perhaps more akin to claiming

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80 *Id.* at 49:10.
81 *See id.* at 1:04:30.
82 *See id.* at 1:26:55.
83 *Id.* at 19:49. Mr. Lamken responded in the negative, based on the Federal Circuit's "full scope" test wherein "it would be necessary to first generate and then screen each candidate antibody to determine whether it meets the double function limitations, that's a statement saying [you've] got to be able to make them all. That can't be right." *Id.*
84 *Id.* at 52:28.
85 *Id.* at 18:18.
86 *Id.* at 52:55.
87 *See id.* at 25:12.

the use of steam pressure to produce mechanical work (much like Claim 8 in the Morse patent invalidated in *O'Reilly v. Morse* (i.e., using electricity to produce "writing at a distance")).[88] Mr. Clement used as an analogy claims to paints of different colors, where if robin's egg blue paint was disclosed it would be enabled, whereas it would not if the public needed to make mixtures of different dyes and wait to find one that produced that color.[89] Even the Court, through Justice Kavanaugh, raised the government's analogies in its brief to recipes for cake, bread, and stew.[90] And later the government's lawyer Ms. Sindzak analogized to knowledge by a skilled artisan that pine was not a suitable type of wood from which to make a baseball bat and thus a claim to making bats from wood would not be invalidated due to this one, art-recognized exception.[91]

Two amicus briefs were discussed, one by Professor Lemley and the other by Sir Gregory Winter. The latter brief being so sufficiently (potentially) persuasive on the underlying scientific facts that Mr. Lamken characterized it as "the functional equivalent of an expert report," while Ms. Sindzak noted that in footnotes to two recent papers Professor Lemley had suggested that Amgen's claims could be invalid for non-enablement.[92] Mr. Clement dismissed the Lemley brief by telling the Court the Federal Circuit had not invalidated all biotechnology claims on enablement grounds and said the Justices should rely on the Winter brief "for the science."[93] Mr. Clement posited that "it may be that in this particular area of antibody science given the current state of the science that you may not have an ability to functionally claim a genus, and that's kind of at some level nobody's fault, it's just the way the science works."[94]

Mr. Clement also reiterated a line of argument from the Winter brief, in suggesting to the Court that these claims could be considered an effort to make an "end run" around the Court's precedent in *Assoc. Molec. Pathol. v. Myriad Genetics*, insofar as the "sweet spot" in PCSK9 could not itself be patented under that precedent because it was naturally occurring (a clever way of persuading the Court against the claims outside the strict bounds of enablement law itself).[95] Mr. Clement also took from the Winter brief the argument that the "roadmap" purportedly provided by Amgen's specification does not facilitate identifying antibodies falling within the scope of the claim because, in addition to the routine experiments required to produce them, it then "adds additional steps that somebody skilled in the art wouldn't want to do and are just basically an additional step, additional test they have to run to see

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88 *Id.* at 32:59; *see also* O'Reilly v. Morse, 56 U.S. 62 (1853).

89 Oral Argument at 50:28, Amgen v. Sanofi, 598 U.S. 594 (2023) (No. 21-757), https://www.supremecourt.gov /oral_arguments/audio/2022/21-757.

90 *Id.* at 37:15.

91 *Id.* at 1:23:03.

92 *Id.* at 1:34:05, 1:18:28.

93 *Id.* at 1:06:36 (citing, as discussed in Sanofi's briefing, Bayer Healthcare LLC v. Baxalta Inc, 989 F.3d 964 (Fed. Cir. 2021)).

94 *Id.* at 1:06:38.

95 *Id.* at 55:30.

whether they infringe, because the people skilled in the art don't really care where it binds. They care that it blocks."[96] These steps "slow down others in the field" accordingly.

In his only engagement at any length, Justice Alito asked Mr. Lamken whether there was something unique in this decision or whether the Federal Circuit has been doing this all along, and if so, why now?[97] The response was that the Federal Circuit has shown a "basic hostility to the breadth of claims, and [that] this is basically the apogee, we've reached an endpoint where, frankly, the industry can't take it any longer because you can't invest $2.6 billion if the breadth of your claims is such that it means you can't get adequate protection because, if you cover everything you invented, then it's invalid because it's too hard to make them all."[98] The Justice challenged this answer by asking whether the Federal Circuit's decisions had been inhibiting research for antibody-based pharmaceuticals and Mr. Lamken cited Professor Lemley's article in support of the assertion.[99] Justice Alito also inquired whether the "roadmap" disclosed in the patents was not just a research plan to which Mr. Lamken responded the patent disclosed "these two new antibodies that didn't exist before our invention" and "they allow you to find everything that will bind to the sweet spot in PCSK9 because they cover it completely."[100]

Justice Jackson evinced an appreciation regarding the burdens of proof below and the issue of whether the district court and the Federal Circuit had properly overruled the jury determination that respondents had not satisfied the clear and convincing evidence standard.[101] Mr. Lamken stated that the respondents had not shown even one antibody falling within the scope of the claim that could not have been made using the "roadmap" in Amgen's specification.[102] In reply Mr. Clement relied on the "millions and millions" of antibodies that fall within the scope of Amgen's claims and the amount of trial-and-error experimentation needed to produce them.[103] In this regard Justice Gorsuch expressed agreement with Mr. Clement that the cumulative effort needed to produce all species in a claimed genus is not dispositive but a relevant consideration.[104]

With regard to the relevance of the amount of effort it takes to practice the invention, Justice Sotomayor asked whether Mr. Lamken agreed with the statement in the Federal Circuit opinion that "[i]t was 'appropriate' to look at the amount of

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96 *Id.* at 54:21.
97 *Id.* at 26:57.
98 *Id.* at 27:13.
99 *Id.* at 27:47 (citing Dmitry Karshtedt, Mark A. Lemley & Sean B. Seymore, *The Death of the Genus Claim*, 35 HARV. J. L. & TECH. 1, 23–35 (2021)).
100 *Id.* at 30:00
101 *Id.* at 39:56.
102 *Id.* at 44:09.
103 *Id.* at 48:42.
104 *Id.* at 51:20.

effort needed to obtain embodiments outside the scope of the disclosed examples."[105] The eventual answer from Mr. Lamken was that:

> [I]f it said *an* embodiment, that would be correct. Embodiments means that you're looking at . . . what [the Federal Circuit] called reaching the full scope, and I think that is incorrect. . . . So the effort to make every single embodiment within the invention simply means that if you have an invention of any scope, it's not going to be enabled. There may be millions of ways to make the James Watt steam engine, but you're not invalidated simply because it would take a long time to make all of those different variants of the steam engine.[106]

Several of the Justices asked what remedy the parties wanted (e.g., Justice Jackson frankly asking "you said we can do one thing beyond that, and what is that?") and how the Court would provide clarification in the law, with the Chief Justice inquiring on the amount of disclosure that would be considered reasonable under the Court's *Minerals Separation, Ltd. v. Hyde* decision, Justice Gorsuch asking counsel about the continuing relevance of the *Wands* factors, and Justices Jackson, Alito, and Barrett inquiring on what could be considered undue experimentation.[107] Mr. Lamken responded to Justice Gorsuch that "at the very least, we should have a remand so that we try again under the proper standard without the reach the full scope standard or try to hypothesize how long it takes to make millions of antibodies and then test each of them."[108] Justice Barrett asked why, and Mr. Lamken stated that "the Federal Circuit could not possibly have gotten it right because of what I just read to you from [the record], where it looks at the effort to make each and every antibody of the potential millions" and "somebody who's trying to overturn a PTO-issued patent and two jury verdicts should at least say here's an actual antibody, an actual embodiment, that is difficult to make. It requires undue experimentation to get there."[109] Justice Kavanaugh in a similar vein asked Mr. Lamken whether there was disagreement with any of the Court's precedents.[110]

Regarding the question of the undue experimentation standard, Justice Gorsuch asked Mr. Lamken whether he agreed that "a patent fails the enablement test if it would force a person skilled in the art to undertake undue experiment to produce the claimed invention?" (answer: "yes") and if the *Wands* factors were valuable in making an undue experimentation assessment.[111] To this latter question Mr. Lamken responded that "the *Wands* factors can be useful in particular cases when properly applied," but they have "become something of a checklist that's abstracted and therefore replaces the ultimate statutory standard."[112] To the Justice's question "do you agree that the broader the patent the more difficult it is to prove enablement" Mr. Lamken responded, "not necessarily" because "'harder' and 'broader' are not

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105 *Id.* at 23:48.
106 *Id.* at 25:12.
107 *See generally id*.
108 *Id.* at 22:36.
109 *Id.* at 22:51.
110 *Id*. at 36:29.
111 *Id.* at 8:01.
112 *Id.* at 8:36.

necessarily synonymous."[113] And to Justice Jackson's question on finding undue experimentation as to a species, Mr. Lamken responded "if you just have a one-off that doesn't mean anything to skilled artisans, you're not going to invalidate the patent."[114] The Justice then asked, "How many of these 'one-offs' can you have?" to which Mr. Lamken stated, "if you have so many that it means that you're searching for a needle in a haystack and you don't have instructions on how to do it so that it's —it is that trial and error for years on end, it's *Edison* and *Consolidated Electric*."[115]

In his responses Mr. Clement gave full-throated voice to the opinion that "functional claims are terrible because they retard science," using Morse claim 8 and the patentee's position in *Consolidated Electric v. Edison,* but he also said he did not think the test should be "zero-tolerance" regarding at least "some" experimentation.[116] In responding to Justice Alito, he stated that both "time and effort" and the nature of the effort were relevant and that if the claims had recited the amino acid sequences of the disclosed sequences there would have been no need for experimentation.[117]

Ms. Sindzak spoke at considerable length compared with the brief expository remarks both Mr. Lamken and Mr. Clement made in their presentations. While the government's argument paralleled the respondent's, the assistant solicitor general emphasized the amino acid sequence as the "recipe" for an antibody, without which a claim is not properly enabled (noting, "it really is that simple").[118] Ms. Sindzak asserted that it was dangerous to relax the enablement rules because the antibody field is unpredictable and there may be other unknown antibodies that "work[] better than everything else, or the one that's going to be tolerated by more patients or the one that's going to be cheaper to manufacture" (not considering independently patentable species).[119] The government also referred to the doctrine of equivalents as the proper way under the statute to protect antibodies structurally indistinct enough from the expressly recited antibodies to be deemed infringing (a position advocated by at least one amicus brief).[120] The Chief Justice posited that the doctrine might be less protective (something Mr. Lamken asserted in rebuttal) to which Ms. Sindzak responded that, to the extent a patentee has not invented something, "I don't think the doctrine of equivalents is going to get them things they haven't invented yet."[121]

With regard to *In re Wands,* Ms. Sindzak stated that precedent cannot be relied upon because at the time antibodies were not defined by amino acid sequence but by

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113 *Id.*
114 *Id.* at 15:13.
115 *Id.*
116 *Id.* at 1:11:17.
117 *Id.*
118 *Id.* at 1:15:59.
119 *Id.* at 1:16:44.
120 *Id.* at 1:18:18.
121 *Id.*

functional properties and satisfied the enablement requirement by deposit.[122] The government also agreed with Justice Kavanaugh that an affirmance would quell arguments that the Federal Circuit had erred and leave any further remedy to Congress.[123] In response to Justice Gorsuch asking if you could, for example, every single time get a winner, then the fact that it would require a long time to get them all wouldn't—wouldn't necessarily defeat a patent, would it?"[124] Ms. Sindzak said:

> It can be relevant, and I think it can particularly be relevant if, for example, you figure out that . . . there's a million types of ammonia in the world and 10 of them . . . can be used instead of gasoline to run superefficient cars, right? But you don't know which 10, so you just claim the genus of ammonia that can be used to run cars, and then what you're saying is you have to go out there and try them. And you may actually have to try all a million of them so—to get to those 10. And so there the cumulative effort is relevant because you're going to be there testing and testing and testing.[125]

On rebuttal Mr. Lamken reasserted petitioner's most straightforward argument, that a " key fact for this case is that Sanofi has not identified one antibody that would require undue experimentation to make."[126]

Both the respondent's counsel (jokingly) and the assistant solicitor general (more earnestly) suggested that the Court dismiss the certiorari writ as having been improvidently granted.[127]

The Court's unanimous opinion relies heavily on its own precedent that was extensively cited by both parties in their briefs and arguments, including *O'Reilly v. Morse*,[128] *The Incandescent Lamp Patent*,[129] and *Holland Furniture Co. v. Perkins Glue Co*.[130] In the Court's view, the statute plainly requires that "[i]f a patent claims an entire class of processes, machines, manufactures, or compositions of matter, the patent's specification must enable a person skilled in the art to make and use the entire class."[131] The Court is careful to address some of the concerns raised by Amgen and its amici regarding the burdens the disclosure requirements would impose: if taken to its extreme, disclosure requirements could inhibit innovation in the biotech and pharma arts.[132] In this regard, the Court states "[a]ll this is not to say a specification always must describe with particularity how to make and use every single embodiment within a claimed class."[133] But the enablement requirement requires, for

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[122] *Id.* Unmentioned was the fact that had Amgen deposited the 384 antibodies they would have been enabled at least those antibodies.
[123] *Id.* at 1:32:42.
[124] *Id.* at 1:23:35.
[125] *Id.* at 1:24:24.
[126] *Id.* at 1:33:37.
[127] *See id.* at 52:23, 1:31:19.
[128] 56 U.S. 62 (1853).
[129] 159 US. 465 (1895).
[130] Amgen v. Sanofi, 598 U.S. 594, 605 (2023); *see also* Holland Furniture Co. v. Perkins Glue Co., 277 U.S. 245 (1928).
[131] *Amgen*, 598 U.S. at 610.
[132] *See id.* at 613–16.
[133] *Id.* at 610–11.

example, that the specification also disclose "some general quality . . . running through" the class that gives it "a peculiar fitness for the particular purpose," as in *Incandescent Lamp*, and situations where some adaptation or testing is needed does not make the disclosure "necessarily inadequate," as in *Wood v. Underhill*.[134] Under *Minerals Separation, Ltd. v. Hyde*, the opinion states that "[a] specification may call for a reasonable amount of experimentation to make and use a claimed invention, and reasonableness in any case will depend on the nature of the invention and the underlying art."[135]

Amgen's claims fail this test, the Court holding that the scope of the claims at issue were much broader than the 26 expressly disclosed antibodies.[136] The Court sees these claims as being like ("bear more than a passing resemblance") the claims in *Morse, Incandescent Lamp*, and *Holland Furniture* that were held to be invalid.[137] The Court understands Amgen's claims as an attempt to "monopolize an entire class of things defined by their function" even though that class was much broader ("a vast number") group of antibodies.[138] Nor was Amgen's disclosure of a "roadmap" for obtaining other antibodies or reference to "conservative substitutions" persuasive, as the Court considered these to "amount to little more than two research assignments."[139]

The decision certainly solidifies the Federal Circuit's trend of limiting claim scope much more closely to what is expressly disclosed, and the Court's affirmance of the insufficiency of relying on conservative substitutions will have consequences extending much more broadly beyond antibody claims.

b. Consequences of the Decision

On January 10, 2024, the U.S. Patent and Trademark Office published a notice in the Federal Register regarding proposed guidance on how the Office will apply the enablement requirement under 35 U.S.C. § 112(a) in light of the Supreme Court's decision last year in *Amgen v. Sanofi*.[140] In a nutshell, the Office announced that it will do so by continuing to use the rubrics established by the Federal Circuit in *In re Wands*.

The notice sets forth the Office's understanding of the Supreme Court's decision and its substantial adherence to existing law, particularly *Wands*. But the Office is also cognizant (as the past fifteen to twenty years have illustrated) that Supreme Court precedent is certainly (if not the only) the most relevant source of interpretation on how the patent statute should be understood and applied. The notice cites *O'Reilly* v.

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134 *Id.* at 611 (citing Wood v. Underhill, 46 U.S. 1, 4–5 (1847)).
135 *Id.* at 612 (citing Minerals Separation, Ltd. v. Hyde, 242 U. S. 261, 270–271 (1916)).
136 *Id.* at 614.
137 *Id.* at 613.
138 *Id.*
139 *Id.* at 613–14.
140 Guidelines for Assessing Enablement in Utility Applications and Patents in View of the Supreme Court Decision in Amgen Inc. et. al. v. Sanofi Inc. et. al., 89 Fed. Reg. 1563 (Jan. 10, 2024).

Morse,[141] *The Incandescent Lamp Patent*,[142] and *Holland Furniture Co.* v. *Perkins Glue Co*.,[143] in this regard.[144] The Office also recognizes more recent Federal Circuit precedent, including *McRO, Inc. v. Bandai Namco Games Am. Inc.*,[145] *Wyeth & Cordis Corp. v. Abbott Laboratories*,[146] *Enzo Life Sciences, Inc. v. Roche Molecular Systems, Inc.*,[147] *Idenix Pharmaceuticals LLC v. Gilead Sciences Inc.*,[148] the Supreme Court's holding in *Amgen*, based on *Wood v. Underhill*,[149] and *Minerals Separation, Ltd.* v. *Hyde*,[150] as stating that a "specification is not necessarily inadequate just because it leaves the skilled artisan to perform some measure of adaptation or testing."[151]

This is where the *Wands* factors come into play by providing the framework for determining the "reasonableness of experimentation." The notice acknowledges that the Court did not expressly address or rely on the *Wands* factors but finds support for their continued analytical vitality in the Court's emphasis that "the specification may call for a reasonable amount of experimentation to make and use the full scope of the claimed invention," the *Wands* factors being probative thereof.[152] The notice cites post-*Amgen* decisions, specifically *Baxalta Inc.* v. *Genentech Inc.*,[153] *Medytox, Inc.* v. *Galderma S.A.*,[154] and *In re Starrett*,[155] for reference to or reliance upon *Wands*.[156] Returning to the Federal Circuit's decision in *Amgen* (affirmed by the Supreme Court), the notice cites the determination in that decision that "the scope of the claims was far broader in functional diversity than the disclosed examples, that the invention was in an unpredictable field of science with respect to satisfying the full scope of the functional limitations, and that there was not adequate guidance in the specification," all of which tracks with the *Wands* factors.[157] Similar assessments are provided for in the *Baxalta* (district court litigation), *Medytox* (PTAB decision in a PGR proceeding), and *Starrett* (PTAB decision in an *ex parte* appeal) Federal Circuit decisions.[158]

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141 56 U.S. 62 (1854).
142 159 U.S. 465 (1895).
143 277 U.S. 245 (1928).
144 Guidelines for Assessing Enablement in Utility Applications and Patents in View of the Supreme Court Decision in Amgen Inc. et. al. v. Sanofi Inc. et. al., 89 Fed. Reg. at 1565.
145 959 F.3d 1091 (Fed. Cir. 2020).
146 720 F.3d 1380 (Fed. Cir. 2013).
147 928 F.3d 1340 (Fed. Cir. 2019).
148 941 F.3d 1149 (Fed. Cir. 2019).
149 46 U.S. 1 (1846).
150 242 U.S. 261 (1916).
151 Guidelines for Assessing Enablement in Utility Applications and Patents in View of the Supreme Court Decision in Amgen Inc. et. al. v. Sanofi Inc. et. al., 89 Fed. Reg. 1563, 1565–66 (Jan. 10, 2024).
152 *Id.* at 1565.
153 81 F.4th 1362 (Fed. Cir. 2023).
154 71 F.4th 990 (Fed. Cir. 2023).
155 2023 WL 3881360 (Fed. Cir. 2023) (non-precedential).
156 Guidelines for Assessing Enablement in Utility Applications and Patents in View of the Supreme Court Decision in Amgen Inc. et. al. v. Sanofi Inc. et. al., 89 Fed. Reg. at 1565–66.
157 *Id.* at 1565.
158 *Id.* at 1565–66.

The notice and proposed guidance falls within the statutory interpretive protocol wherein the Supreme Court provides broad interpretation of the limits the statute imposes on what is patentable. The Federal Circuit applies those standards to individual cases cabined by their particular facts, and the Office, as an administrative agency, applies both layers of precedential interpretation in examining patent applications for compliance with the statutory standards as enacted by Congress and interpreted by the courts. The notice particularly specifies that it will apply the *Wands* factors "to ascertain whether the experimentation required to enable the full scope of the claimed invention is reasonable . . . regardless of technology" under M.P.E.P § 2164.04.[159]

2. *United Therapeutics Corp. v. Liquidia Technologies, Inc.*, 74 F.4th 1360 (Fed. Cir. 2023)

In earlier times, the Federal Circuit, responding to efforts by the U.S. Patent and Trademark Office to reject patent applications directed to biotechnology-related inventions, held that the utility of such inventions did not require demonstration of therapeutic effectiveness, those determinations being the purview of the FDA.[160] Among other things, that apportionment of responsibilities was reaffirmed, albeit under different procedural circumstances, in the earlier of two Federal Circuit decisions this year in *United Therapeutics Corp. v. Liquidia Technologies, Inc*.[161]

The case arose in litigation between NDA holder United Therapeutics Corp. (UTC) and Liquidia, who filed its own NDA (under § 505(b)(2) of the Food, Drug, and Cosmetic Act).[162] Both regulatory approval applications were directed towards inhaled formulations of treprostinil for treating pulmonary hypertension (UTC's Tyvaso®, Liquidia's Yutrepia™).[163] Relevant to the proceedings before the Federal Circuit, pulmonary hypertension (PH) presents in five subgroups, as explained in the opinion:

> Group 1, pulmonary arterial hypertension ("PAH"); Group 2, pulmonary venous hypertension, i.e., pulmonary hypertension related to left-heart disease; Group 3, pulmonary hypertension associated with disorders damaging the lungs; Group 4, pulmonary hypertension caused by chronic thrombotic or embolic disease, including chronic blood clots in the lungs; and Group 5, a miscellaneous category for conditions that do not fit well into the other four subgroups.[164]

A distinction between Group 2 and the remaining groups is that this malady arises due to cardiac issues (postcapillary PH) while the rest of the groups are caused

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159 *See id.* Much of the argument is taken from S. Sean Tu & Christopher M. Holman, *Antibody Patents: Use of the Written Description and Enablement Requirements at the Patent & Trademark Office*, 38 BERKELEY TECH. L. J. 1, 18 fig. 8 (2023).

160 *In re* Brana, 51 F.3d 1560 (Fed. Cir. 1995).

161 United Therapeutics Corp. v. Liquidia Techs., Inc., 74 F.4th 1360 (Fed. Cir. 2023).

162 *Id.* at 1360.

163 *Id.* at 1363–64.

164 *Id.* at 1363.

by pathologies in pulmonary capillaries (precapillary PH).[165] Both parties' treprostinil formulations act by reducing pulmonary blood pressure by vasodilation.[166]

UTC owns the Orange-Book-listed patents at issue, U.S. Patent Nos. 9,593,066 and 10,716,793; representative claims of each patent are set forth in the opinion.

The '793 patent:

> Claim 1. A method of treating pulmonary hypertension comprising administering by inhalation to a human suffering from pulmonary hypertension a therapeutically effective single event dose of a formulation comprising treprostinil or a pharmaceutically acceptable salt thereof with an inhalation device, wherein the therapeutically effective single event dose comprises from 15 micrograms to 90 micrograms of treprostinil or a pharmaceutically acceptable salt thereof delivered in 1 to 3 breaths.[167]

The '066 patent:

> Claim 1. A pharmaceutical composition comprising treprostinil or a pharmaceutically acceptable salt thereof, said composition prepared by a process comprising providing a starting batch of treprostinil having one or more impurities resulting from prior alkylation and hydrolysis steps, forming a salt of treprostinil by combining the starting batch and a base, isolating the treprostinil salt, and preparing a pharmaceutical composition comprising treprostinil or a pharmaceutically acceptable salt thereof from the isolated treprostinil salt, whereby a level of one or more impurities found in the starting batch of the treprostinil is lower in the pharmaceutical composition, and wherein said alkylation is alkylation of benzindene triol.
> Claim 6. The pharmaceutical composition of claim 1, wherein the isolated salt is stored at ambient temperature.
> Claim 8. A process of preparing a pharmaceutical product comprising treprostinil or a pharmaceutically acceptable salt thereof, comprising alkylating a triol intermediate of the formula:
>
> > hydrolyzing the resulting compound to form treprostinil, forming a salt of treprostinil stable at ambient temperature, storing the treprostinil salt at ambient temperature, and preparing a pharmaceutical product from the treprostinil salt after storage, wherein the pharmaceutical product comprises Treprostinil or a pharmaceutically acceptable salt thereof.[168]

UTC brought suit asserting claims 1, 4, and 6–8 of the '793 patent and claims 1–3, 6, 8, and 9 of the '066 patent.[169] UTC alleged that Liquidia's product, which has not been approved by the FDA and hence not marketed, would directly infringe the asserted claims of the '793 patent under 35 U.S.C. § 271(a) and induce infringement under 35 U.S.C. § 271(b).[170] Liquidia counterclaimed that all asserted claims were invalid for failure to satisfy the written description and enablement requirements of 35 U.S.C. § 112(a).[171] The district court held that the asserted claims of the '793 patent were not invalid and that UTC had established by a preponderance of the evidence

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165 *Id.*
166 *Id.*
167 *Id.* at 1364.
168 *Id.* at 1365–66.
169 *Id.* at 1366.
170 United Therapeutics Corp. v. Liquidia Techs., Inc., 624 F. Supp. 3d 436, 443 (D. Del. 2022).
171 *Id.* at 458, 465.

that Liquidia's product would infringe these claims directly and by inducement to infringe, rejecting Liquidia's argument that it lacked specific intent for the latter species of infringement.[172] In this regard, the district court found that administration instructions on Liquidia's label would "inevitably lead to the administration of a therapeutically effective single event dose" as recited in the asserted claims.[173] Concerning Liquidia's counterclaims of invalidity, despite the art-recognized differences between PH Group 2 and the other groups of PH (and the putative differences in safety and efficacy resulting therefrom), the district court held that these considerations did not require undue experimentation by the skilled artisan because the claims did not require a showing of safety and efficacy.[174] And the district court found no failure to satisfy the written description requirement because the specification taught that "treprostinil would effectively vasodilate the pulmonary vasculature, improve hemodynamics, and treat a patient's elevated pulmonary blood pressure."[175] Accordingly, the district court pursuant to the statute stayed FDA approval until expiration of the '793 patent.[176] In a separate *inter partes* review proceeding brought by Liquidia, all claims of the '793 patent were found invalid—that decision being appealed to the Federal Circuit.[177]

The district court held that asserted claims 1–3, 6, and 9 of the '066 patent were invalid due to anticipation by a prior art reference (Moriarty, which "discloses the synthesis of analogues of benzindene prostacyclins, including treprostinil") and that claims 1–3 would be infringed by Liquidia's treprostinil product but that claims 6, 8, and 9 would not be infringed (because Liquidia's product did not satisfy the "ambient temperature" limitation).[178] Liquidia's counterclaims of invalidity for failure to satisfy the written description requirement, on the other hand, failed.[179] This appeal followed.

The Federal Circuit affirmed the district court's decision in all respects in an opinion by Judge Lourie joined by Judges Dyk and Stoll; in so doing, the opinion illustrates the difficulty appellants have in overcoming factual issues under the "clear error" standard in bench trials, as the Federal Circuit repeatedly states that the panel did not discern clear error in the district court's factual findings.[180] With regard to the '793 patent, the Federal Circuit rejected Liquidia's challenge to the district court's claim construction of the term "treating pulmonary hypertension" not to require that such treatment be safe and efficacious based on the skilled artisan interpreting the claim to have these characteristics.[181] This argument focused on treatment of Group

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172 *Id.* at 463.
173 *Id.*
174 *Id.* at 467–68.
175 *Id.* at 469.
176 *Id.* at 469.
177 *See infra* note 199.
178 *Id.* at 449, 452–53, 457.
179 *Id.* at 459.
180 United Therapeutics Corp. v. Liquidia Techs., Inc., 74 F.4th 1360, 1367–68 (Fed. Cir. 2023).
181 *Id.* at 1368.

2 PH patients, wherein both parties' experts recognized that treprostinil would not benefit them (implicating efficacy at least for such treatments).[182] While agreeing with the district court that the phrase "treating pulmonary hypertension" included treating Group 2 PH patients (based on disclosure in the specification that did not distinguish between the PH groups in this regard), the district court's construction of the phrase "a therapeutically effective single event dose of a formulation comprising treprostinil" (unchallenged by Liquidia), according to the Federal Circuit, did not incorporate into the claims "any additional efficacy limitations or any safety limitations."[183] Without such a construction, the opinion asserted, "Liquidia's argument concerning the safety and efficacy of treating Group 2 PH patients is not before us" because "[q]uestions of safety and efficacy in patent law have long fallen under the purview of the FDA."[184] Accordingly, the court refused to draw the distinctions Liquidia argued, and thus the Federal Circuit affirmed the district court's determination that Liquidia's treprostinil product would infringe the asserted claims of the '793 patent.[185]

On similar bases, the Federal Circuit affirmed the district court's determination that Liquidia did not establish by clear and convincing evidence that UTC's asserted claims were invalid for failing to satisfy either the written description or enablement requirements of 35 U.S.C. § 112(a).[186] The panel held that the district court had properly relied on expert testimony that "a skilled artisan would understand that the claimed administration of treprostinil would vasodilate the pulmonary vasculature, improve hemodynamics, and in this way for a single dose, treat a patient's elevated pulmonary blood pressure independent of the type (i.e., group) of pulmonary hypertension patient" and thereby satisfy the recited limitations in the asserted claims of the '793 patent.[187] The court sets forth these additional reasons for its decision regarding the § 112(a) requirements:

> Liquidia essentially asks us to treat Group 2 PH as a claimed species within a larger genus (i.e., all five groups of pulmonary hypertension). But analogizing a subset of patients having a variant of a particular disease to traditional genus and species claims is inapt. It would be incorrect to fractionate a disease or condition that a method of treatment claim is directed to, and to require a separate disclosure in the specification for each individual variant of the condition (here, an individual group of pulmonary hypertension patients) in order to satisfy the enablement and written description provisions of 35 U.S.C. § 112, unless these variants are specified in the claims.[188]

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182 *Id.*
183 *Id.*
184 *Id.* at 1369 (first citing *In re* Brana, 51 F.3d 1560, 1567 (Fed. Cir. 1995); then citing Scott v. Finney, 34 F.3d 1058, 1063 (Fed. Cir. 1994); and then citing *In re* Anthony, 414 F.2d 1383, 1395 (C.C.P.A. 1969)).
185 *Id.* at 1363, 1369.
186 *Id.* at 1370–71.
187 *Id.*
188 *Id.* at 1371.

Further:

> Disease-specific treatment requirements are matters for the FDA and medical practitioners. They are best suited to make these determinations because practitioners are informed by the findings of the regulatory agency to avoid treatment of patients who will not properly respond. And every claim to a method of treatment of an ailment has refinements. That is, for any given method of treatment claim, there may be a subset of patients who would not benefit from or should not take the claimed treatment. That does not mean that such claims are not sufficiently enabled or supported by written description. A subset of unresponsive patients is not analogous to unsupported species in a generic claim to chemical compounds.[189]

On the question of inducement to infringe, the panel summarily rejected Liquidia's reliance on the PTAB's decision in a parallel IPR (that all claims of the '793 patent are invalid) because that decision is not yet final, distinguishing *Commil USA, LLC v. Cisco Systems, Inc.*, 575 U.S. 632, 644 (2015).[190] On the merits, the panel agreed with UTC that all Liquidia's eventual label needs to provide are instructions to administer a therapeutically effective amount of treprostinil in a single event dose as required by the asserted '793 patent claims.[191]

Turning to the '066 patent, the Federal Circuit deigned not to consider the parties' arguments regarding infringement based on the district court's determination that the asserted claims were invalid for anticipation by the Moriarty reference.[192] UTC argued that the district court erred in this determination because the evidence was insufficient that Moriarty's pharmaceutical product contained the pattern of impurities in UTC's treprostinil formulation due to alkylation and hydrolysis steps in its preparation.[193] The panel agreed with the district court that the asserted claims were product-by-process claims that were evaluated for anticipation purposes as product claims and that the Moriarty reference showed the same level of impurities as found in UTC's treprostinil product.[194] Finally, the Federal Circuit affirmed the district court's finding that Liquidia's product did not infringe claims 6, 8, or 9 based on evidence that the product was stored at 2°–8°C and not ambient temperature as required by these claims.[195]

For those keeping score, Liquidia is free of liability under the asserted claims of the '066 patent either because these claims are invalid (claims 1–3) or not infringed (claims 6, 8, and 9). While Liquidia had been precluded from obtaining FDA approval by the district court's infringement determination of the asserted claims of the '793

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189 *Id.*

190 *Id.* at 1371–72. This seems a sound application of judicial economy principles, because should the Federal Circuit affirm, as it did, *see infra*, that PTAB determination Liquidia has a remedy in asking the district court (as it has) to lift the stay on FDA approval of its commercial product..

191 *Id.* at 1372.

192 *Id.*

193 *Id.* at 1373.

194 *Id.*

195 *Id.* at 1374.

patent, the existing stay on approval was lifted when the Federal Circuit affirmed the PTAB determination that these claims are invalid.[196]

The court's decision regarding safety and effectiveness appears somewhat paradoxical (at least with regard to efficacy) for claims reciting methods of treatment, particularly when further limited to a "single event dose."[197] Some of the logic devolves to claim construction and Liquidia's failure to challenge the "therapeutically effective single event dose" limitation while maintaining a bright line between the purviews of patent and regulatory law provide another reason. Further considerations involve the distinction the panel chose to draw between "unsupported species in a generic claim to chemical compounds" and "a subset of unresponsive patients" in a method of treatment claim.[198] Whether these distinctions provide an avenue for applicants of the former class of claims to expand the scope of such claims to generic chemical compounds is of course uncertain but perhaps provides a basis for the "clever draftsman" to work semantic magic (or legerdemain) to such ends.

Turning to the Federal Circuit's affirmance of the PTAB's invalidation of the '793 patent, all claims of the '793 patent were challenged in the IPR, with claim 1 being representative (see above) and setting forth as relevant dependent claims 4, 6, and 7:

> 4. The method of claim 1, wherein the inhalation device is a dry powder inhaler.
>
> 6. The method of claim 4, wherein the formulation is a powder.
>
> 7. The method of claim 6, wherein the powder comprises particles less than 5 micrometers in diameter.[199]

Liquidia's IPR petition asserted obviousness of all '793 patent claims based on U.S. Patent No. 6,521,212 ("the '212 patent") in combination with two scientific abstracts to Voswinckle (termed "JESC" and "JAHA").[200] The '212 patent described methods for delivering benzindene prostaglandins (of which treprostinil sodium is one) by inhalation to treat pulmonary hypertension, while the Voswinckle references described studies using various amounts of treprostinil (16, 32, 48, and 64 μg/mL) (JESC) and wherein patients in the study were administered the drug in three breaths (JAHA).[201] UTC responded to Liquidia's obviousness allegation by challenging the status of the Voswinckle references as prior art.[202] The basis for this assertion was that Liquidia had not established that the Voswinckle references were printed publications under pre-AIA 35 U.S.C. § 102(b).[203] Liquidia relied upon the Voswinckle references having been stored in libraries but it had not (according to UTC) shown that "both [had] been available at the library and sufficiently indexed or

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196 United Therapeutics Corp. v. Liquidia Techs. Inc., 2023 WL 8794633, at *6 (Fed. Cir. 2023).
197 *United Therapeutics Corp.*, 74 F.4th at 1370.
198 *Id.* at 1371.
199 *United Therapeutics Corp.*, 2023 WL 8794633, at *1.
200 *Id.*
201 *Id.*
202 *Id.*
203 *Id.*

categorized by priority date."[204] In rejecting this challenge, the PTAB noted that each of the Voswinckle references were presented at a public conference attended by 20,000 people (including "scientists, physicians, and nurses, *as well as* journalists").[205] In addition, the Board recognized that the Voswinckle references were cited in other documents available to the public prior to the '793 patent's priority date.[206] On these grounds the Board concluded that the combination of the Voswinckle references and the '212 patent rendered obvious the invention claimed in the '793 patent.[207] The Board also held that the objective indicia asserted by UTC ("unexpected results, copying, and long-felt and unmet need") did not overcome their *prima facie* obviousness determination.[208]

UTC petitioned for rehearing (including an appeal to the PTO's Precedential Opinion Panel, or POP) on the question of whether the Voswinckle references were prior art.[209] While the Panel did not agree to review the decision, it did direct the Board panel to reconsider because in its judgment the Board had failed to determine whether the "other publications" (identified as "research aids") that purportedly disclosed the Voswinckle references had themselves had been available to the public before the critical date.[210] In addition, the POP determined that the Board had not "adequately addressed" whether the Voswinckle references "were publicly accessible by way of their presentation and/or inclusion in distributed materials, such as at a conference or library."[211] The Board dutifully reconsidered the evidence and maintained its decision that the references were prior art.[212] Admitting it had not recognized that the research aids had *not* been publicly available before the priority date, the Board nevertheless found that the Voswinckle references had been distributed at conferences prior to that date (including in an "abstract book" provided to attendees).[213] Having dispensed with any deficiencies in its reasoning on this issue, the Board held the asserted claims of the '793 patent to be invalid for obviousness and UTC appealed.[214]

The Federal Circuit affirmed, in an opinion by Judge Lourie joined by Judges Prost and Reyna. With regard to the prior art status of the Voswinckle references, the court first addressed whether the Board's analysis "improperly exceeded the prior art theories set forth in Liquidia's petition" under 35 U.S.C. § 312(a)(3) as interpreted by the Supreme Court in *SAS Inst. Inc. v. Iancu*.[215] UTC argued that the Board's reasoning regarding the prior art patency of the Voswinckle references that depended

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204 *Id.* at *2; *see In re* Hall, 781 F.2d 897, 898–99 (Fed. Cir. 1986).
205 *United Therapeutics Corp.*, 2023 WL 8794633, at *4.
206 *Id.* at *1.
207 *Id.* at *5.
208 *Id.*
209 *Id.* at *2.
210 *Id.*
211 *Id.*
212 *Id.*
213 *Id.*
214 *Id.*
215 *Id.* at *3; *see also* SAS Inst. Inc. v. Iancu, 138 S. Ct. 1348, 1357 (2018).

on their inclusion of the abstract books at conferences exceeded Liquidia's arguments in its petition.[216] The panel held that Liquidia's position in its petition was that the Voswinckle references were prior art because they had been publicly disclosed, and that the Board properly found Liquidia's later arguments in its reply to be timely under the statute because they were asserted "in direct response" to UTC's contrary arguments first raised in its response.[217] This reasoning was not an abuse of discretion, according to the Federal Circuit panel, under *inter alia*, *Anacor Pharms., Inc. v. Iancu*[218] because Liquidia's arguments in its reply were not inconsistent with its position in its petition (i.e., that the Voswinckle references were prior art under pre-AIA 35 U.S.C. § 102(b)).[219]

The panel also agreed with the Board's substantive determination that the Voswinckle references were prior art.[220] UTC argued that the Board's reasoning regarding the references was entirely "hypothetical" and only supported by "conclusory expert testimony."[221] In this regard, the court rejected UTC's assertion that "evidence of *actual* existence or dissemination" was required, saying this was "not the proper standard."[222] Rather, the opinion asserts that "[o]ur cases have consistently held that the standard for public accessibility is whether a person of ordinary skill in the art *could*, after exercising reasonable diligence, access a reference."[223] But once such public accessibility has been established "'there is no requirement to show that particular members of the public *actually received* the information,'" according to the opinion.[224] On this basis, the panel held that the Board relied on substantial evidence that the Voswinckle references were prior art.[225]

Turning to the ultimate question of obviousness for sole independent claim 1, the court held that the Board had relied on substantial evidence in concluding that, while no one reference explicitly taught the recited administered range of a therapeutically effective single event dose that comprises from 15 micrograms to 90 micrograms of treprostinil, the skilled worker would have understood that the JESC reference disclosed solutions within this range.[226] This reference taught administration of treprostinil in various concentrations (16, 32, 48, and 64 μg/mL) but did not disclose explicitly recited administered dosage volumes.[227] However, according to the Federal Circuit, the Board properly relied on expert testimony

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216 *United Therapeutics Corp.*, 2023 WL 8794633, at *3.
217 *Id.*
218 889 F.3d 1372, 1380–82 (Fed. Cir. 2018)
219 *United Therapeutics Corp.*, 2023 WL 8794633, at *3.
220 *Id.*
221 *Id.* at *4.
222 *Id.*
223 *Id.* at *4 (citing Samsung Elecs. Co. v. Infobridge Pte. Ltd., 929 F.3d 1363, 1374 (Fed. Cir. 2019)).
224 *Id.* at *4 (emphasis in original) (citing Jazz Pharms., Inc. v. Amneal Pharms., LLC, 895 F.3d 1347, 1356 (Fed. Cir. 2018)) (quoting Constant v. Adv. Micro-Devices, Inc., 848 F.2d 1560, 1569 (Fed. Cir. 1988)).
225 *Id.* at *4.
226 *Id.*
227 *Id.*

regarding such volumes (ranging from at least 1 mL and up to 5 mL of solution), which would deliver 16–80, 32–160, 48–240, or 64–320 μg, each of which contained a value falling within the dose recited in claim 1.[228] The panel considered UTC's challenges to these calculations on technical grounds, finding that the Board had heard and rejected these same arguments. Accordingly, the panel accepted the Board's conclusions to be supported by substantial evidence on the obviousness question.[229]

Regarding the objective indicia of nonobviousness, the panel found that the Board's rejection of UTC's arguments was also supported by substantial evidence (noting that UTC's assertions regarding unexpected results were included in "only a single paragraph in UTC's opening brief, [which] borders on waiver").[230] On the merits, the court held that UTC provided assertions but not evidence of any such unexpected results.[231]

Finally, the Federal Circuit upheld the Board's obviousness determination of dependent claims 4, 6, and 7.[232] UTC's arguments regarding these claims were that the recitation therein of dry power administration of treprostinil was a "separate invention" not disclosed in any of the asserted prior art references.[233] Thus, UTC argued that the Board failed to explain how the ordinarily skilled worker would have had any reasonable expectation of success in administering treprostinil as a dry powder.[234] The panel first held that UTC had waived this argument because it had not raised it (at least in this form) before the Board.[235] And on the merits, the panel held that as with independent claim 1 the Board's decision on these dependent claims was supported by substantial evidence (including the unrebutted testimony of Liquidia's experts) and thus affirmed.[236]

One of the most notable consequences (intended or not, for good or ill) of the Leahy-Smith America Invents Act (AIA) has been the possibility (now likelihood, if only in frequency) that the decisions of the Patent Trial and Appeal Board and district courts will be different (typically to the detriment of patent holders). This outcome is at least in part the result of differences in the burdens of proof between the two fora, specifically the preponderance of the evidence standard before the Board and the clear and convincing evidence standard in district court. These circumstances have raised concerns (most notably by now-suspended Federal Circuit Judge Pauline Newman) regarding the constitutional propriety of an Article I court being able to overrule an Article III court on separation of powers grounds.[237] This case provides another

228 *Id.*
229 *Id.* at *5.
230 *Id.*
231 *Id.*
232 *Id.*
233 *Id.*
234 *Id.*
235 *Id.*
236 *Id.* at *5–6.
237 *See* XY, LLC v. Trans Ova Generics, L.C., 890 F.3d 1282 (Fed. Cir. 2018).

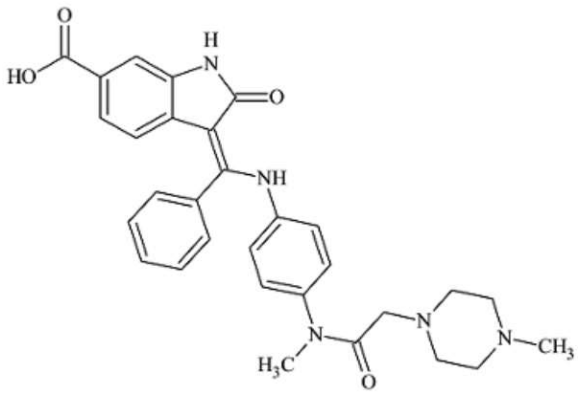
example of such an outcome, resulting in Liquidia now having the ability to enter the marketplace with its treprostinil drug product almost four years earlier than the expiration date (May 14, 2027) of the '793 patent prior to its invalidation by the PTAB.

3. *Allgenesis Biotherapeutics, Inc. v. Cloudbreak Therapeutics, Inc.*, 85 F.4th 1377 (Fed. Cir. 2023)

The Federal Circuit dismissed an appeal from an unsuccessful challenger in an *inter partes* review (IPR) proceeding based on failure to satisfy the standing requirements for such an appeal, in *Allgenesis Biotherapeutics Inc. v. Cloudbreak Therapeutics, Inc.*

The case arose in an IPR over U.S. Patent No. 10,149,820, directed to compositions and methods for treating pterygium, "an eye condition in which a tumor-like growth extends from the nasal or temporal side of the eye to the cornea."[238] Surgery was the recognized treatment, and also recognized was the likelihood of tumor recurrence.[239] The '820 patent claims use of multikinase inhibitors including nintedanib, pazopanib, and sunitinib.

Figure 1
Nintedanib



Claims 4 and 5 were the only claims remaining after the IPR; claim 4 was set forth as representative:

> 1. [disclaimed] A method for reducing hyperemia or symptoms thereof in pterygium in an affected eye of a subject in need of such treatment, without surgically excising a pterygium, comprising administering to the affected eye of the subject a therapeutically effective amount of a multikinase inhibitor.
>
> 3. [disclaimed] The method of claim 1, wherein the multikinase inhibitor is administered to the affected eye in the form of topical ocular formulation or ocular implant.

[238] Allgenesis Biotherapeutics, Inc. v. Cloudbreak Therapeutics, Inc., 85 F.4th 1377, 1378–79 (Fed. Cir. 2023).
[239] *Id.* at 1378.

> 4. The method of claim 3, wherein the multikinase inhibitor is nintedanib and the nintedanib is administered to the affected eye in the form of a topical ocular formulation and is administered topically to the affected eye.
>
> 5. The method of claim 4, wherein the topical ocular formulation further comprises one or more pharmaceutically acceptable excipients.[240]

Relevant to the issues on appeal, the Board held that Allgenesis had not shown the remaining (not disclaimed) claims of the '820 patent were invalid for anticipation or obviousness over its own PCT application because the earliest priority date for the '820 patent (June 5, 2015) was earlier than the priority date of the PCT application (June 22, 2015) and Cloudbreak's provisional application provided sufficient written description support for claims 4 and 5 of the '820 patent.[241] The Board also determined that the '820 patent claims were not obvious in view of the combination of two other references because of the '820 patent's disclosure of unexpected results of improved efficacy and safety.[242] Allgenesis appealed both grounds of the Board's determination of nonobviousness.[243]

The Federal Circuit dismissed the appeal based on Allgenesis's failure to satisfy Article III requirements, in a decision by Chief Judge Moore joined by Judges Stoll and Cunningham.[244] The opinion set forth the basis for Allgenesis's deficiency as being rooted in the requirement for standing of "injury-in-fact" under *Spokeo, Inc. v. Robins*.[245] This requirement, while not arising for standing to *file* an IPR petition,[246] is required to *appeal* the Board's decision.[247] Allgenesis asserted standing based on "(1) its potential infringement liability and (2) the Board's priority determination."[248] Neither assertion was sufficient, according to the opinion, because Allgenesis's allegations of injury were speculative and insufficiently concrete to establish injury-in-fact.[249] With regard to *potential* liability for infringement, the opinion states that the evidence, a declaration from Allgenesis's Vice President of Finance, relied on a Phase II clinical trial in 2020 and vague assertions of future plans to produce a nintedanib commercial product.[250] The opinion found these assertions to be unconvincing, saying that they "fail[] to identify any specific, concrete plans for Allgenesis to develop a nintedanib product that might implicate claims 4 and 5 of the '820 patent."[251] Nor did Allgenesis provide testimony regarding plans for further development such as a Phase III trial.[252] Instead, according to the panel, Allgenesis

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240 *Id.* at 1379.
241 *Id.*
242 *Id.*
243 *Id.* at 1380.
244 *Id.* at 1378.
245 *Id.* at 1380; *see also* Spokeo, Inc. v. Robins, 578 U.S. 330, 338 (2016).
246 *See* Cuozzo Speed Techs., LLC v. Lee, 579 U.S. 261, 279 (2016).
247 *Allgenesis*, 85 F.4th at 1380.
248 *Id.*
249 *Id.* at 1380–81.
250 *Id.*
251 *Id.* at 1380.
252 *Id.* at 1381.

provided "generic" statements that it had not abandoned plans for a commercial product.[253] However, according to the opinion, "[s]uch conclusory testimony is insufficient to establish that Allgenesis has any concrete plans to develop and bring to market a nintedanib treatment for pterygium."[254] Nor did Allgenesis assert any threat from Cloudbreak to file suit for infringement.[255] The panel concludes that "Allgenesis has failed to establish it has nonspeculative, concrete plans for future activity that creates a substantial risk of future infringement."[256]

Allgenesis was no more successful in its second assertion of injury-in-fact: that the Board's decision on priority of invention in favor of Cloudbreak would impair its ability to obtain its own patent on using nintedanib to treat pterygium.[257] Once again, the Federal Circuit found Allgenesis's evidence and argument to be insufficient to support its injury-in-fact claim.[258] The opinion analogizes the circumstances with the court's earlier decision in *Best Medical International, Inc. v. Elekta Inc*.[259] What the cases had in common, in the Federal Circuit's view, was reliance on collateral estoppel as the basis for the injury, and, as the court notes, "[c]ollateral estoppel will not attach to the Board's non-appealable priority determination."[260] And again the court states that "Allgenesis has, based on these quite vague allegations, failed to establish a concrete injury."[261] Even when eschewing estoppel arguments, the panel opined that Allgenesis "failed to articulate with any specificity how the Board's priority determination will impact its issued patents or pending continuation applications which claim priority to its PCT application," those articulations being found in "a single paragraph containing only vague allegations in its opening brief and reply brief, respectively."[262]

Having decided that Allgenesis failed to establish injury-in-fact as required for standing, the Federal Circuit dismissed the appeal without reaching the merits.[263]

4. *Actelion Pharms. Ltd. v. Mylan Pharms. Inc.*, 84 F.4th 1167 (Fed. Cir. 2023)

Proper construction of claim limitations reciting the chemical property of pH, which denotes the concentration of hydrogen ions in a solution as an indication of acidity, has arisen several times in district court and Federal Circuit opinions, perhaps the most notable being in *Warner-Jenkinson v. Hilton Davis Chemical*, which

253 *Id.*
254 *Id.*
255 *Id.* at 1382.
256 *Id.* at 1381.
257 *Id.*
258 *Id.*
259 *Id.*; *see also* Best Medical International, Inc. v. Elekta Inc., 46 F.4th 1346 (Fed. Cir. 2022).
260 *Allgenesis*, 85 F.4th at 1381 (citing SkyHawke Techs., LLC v. Deca Int'l Corp., 828 F.3d 1373, 1376 (Fed. Cir. 2016)).
261 *Id.*
262 *Id.*
263 *Id.* at 1383.

revitalized the doctrine of equivalents.[264] The issue arose this year before the Federal Circuit in *Actelion Pharmaceuticals Ltd. v. Mylan Pharmaceuticals Inc*., with the court vacating and remanding the district court's claim construction for failure to consider extrinsic evidence. The opinion illustrates the difficulties posed and considerations considered by the court when addressing claim constriction for terms comprising pH.

The case arose in ANDA litigation related to Actelion's Flolan® (epoprostenol) product, used for treatment of cardiovascular disease.[265] As described in the opinion, the compound is unstable in water and prepared by Actelion as a freeze-dried or lyophilized powder for reconstitution in commercially available IV fluids prior to use (intravenous administration to a patient) without needing refrigeration (sold by Actelion as Veletri®).[266] The patents-in-suit were U.S. Patent Nos. 8,318,802 and 8,598,227, with claim 11 of the '802 patent being set forth as representative:

> 11. A lyophilisate formed from a bulk solution comprising:
> (a) epoprostenol or a salt thereof;
> (b) arginine;
> (c) sodium hydroxide; and
> (d) water,
> wherein the bulk solution has *a pH of 13 or higher*, and wherein said lyophilisate is capable of being reconstituted for intravenous administration with an intravenous fluid.[267]

The opinion also notes that the inventor's discovery that epoprostenol formulations "in the presence of an alkalinizing agent, and high pH (>11) is very stable compared to Flolan" was unexpected.[268] Litigation ensued when Mylan sent Actelion a Paragraph IV letter under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with Actelion asserting claims 1, 6, 8, 10, 11, 16, 18, 20, and 22 of the '802 patent and claims 1–3, 8, 10, 12, 14, 16, 18–22, and 24–42 of the '227 patent under 35 U.S.C. § 271(e)(2).[269]

Both parties argued that the pH limitation should be construed by its ordinary and customary meaning but differed as to what that meaning was. Actelion argued that the term "a pH of 13 or higher" should be construed as giving the acidity value of the solution as an order of magnitude subject to conventional rounding rules, wherein the term would include a pH of 12.5 (which would be rounded up to 13).[270] Mylan, on the other hand, argued that the term cannot properly be construed to include any pH value less than 13 and, if interpreted as a range, must be between pH 12.995 and 13.004 based on the concept of significant figures (or digits) in view of the logarithmic nature of pH values.[271] Both parties asserted chemical textbooks to support their claim construction arguments.[272]

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264 Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17 (1997).
265 Actelion Pharms. Ltd. v. Mylan Pharms. Inc., 85 F.4th 1167 (Fed. Cir. 2023).
266 *Id.* at 1168.
267 *Id.* (emphasis in original) (italicizing the limitation that was at issue).
268 *Id.*
269 *Id.* at 1169.
270 *Id.*
271 *Id.*
272 *Id.*

The district court declined the parties' invitations to consider the proffered textbook definitions as extrinsic evidence and construed the limitation according to Actelion's plain meaning definition based solely on the intrinsic evidence.[273] According to the district court, the plain meaning of a numerical value included two significant figures and thus "a pH of 13" would ordinarily encompass values from 12.5 to 13.4.[274] Neither the specification nor the prosecution history contained any disclosure that would implicate any "increased degree of precision" according to the district court.[275] The parties stipulated infringement in favor of Actelion, the district court entered judgment, and this appeal followed.[276]

The Federal Circuit vacated the judgment and remanded to the district court for further claim construction in light of extrinsic evidence, in an opinion by Judge Stoll joined by Judges Reyna and Stark. After reciting the standard of review (*de novo* for claim construction relying solely on intrinsic evidence, clear error for claim construction relying on extrinsic evidence, and *de novo* on the "ultimate interpretation of the claim"), the panel turned to the "narrow question" of the proper meaning of "a pH of 13" in the context of the '802 and '227 patents.[277] Put simply, the court found the intrinsic evidence to be "equivocal" and the extrinsic evidence asserted by the parties and not considered by the district court to be "highly relevant to how a person of ordinary skill would understand the [disputed claim] language."[278] The opinion then reviewed the conventional sources of claim construction (the "plain and ordinary meaning" of the claim language, the specification, and the prosecution history) to explicate their conclusion that the intrinsic evidence was equivocal.[279] Regarding the "plain and ordinary meaning" of the claim language, the panel disagreed with Mylan's construction involving the range from pH 13 to the upper range of pH 14, stating that such cases are "not of great significance to our analysis here" and "there is no blanket rule that ranges, or specifically open-ended ranges, must foreclose rounding."[280] The opinion also noted that while the claims lack any conventional "approximation language" such as "about" the panel did not agree with Mylan's argument that as a consequence the term "a pH of 13" must be construed to mean exactly pH 13.[281] The opinion states that this absence of approximation language is not dispositive and that the court is not interested in promulgating a "bright line rule" on this question.[282]

Regarding the specification, the panel found the language therein to be inconsistent.[283] In some sections the pH of the "bulk solution" are described as being

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273 *Id.* at 1170.
274 *Id.*
275 *Id.*
276 *Id.*
277 *Id.*
278 *Id.*
279 *Id.*
280 *Id.* at 1171.
281 *Id.*
282 *Id.* The opinion further notes the panel finds both parties' arguments to be "equally plausible." *Id.*
283 *Id.* at 1172.

"adjusted to about 12.5–13.5, most preferably 13" (and also distinguished pH 12.5 from pH 13 and the range of pH 12.5–13.5 from pH 13) while elsewhere pH 13 is described as "pH 13.0," which would indicate a more restricted scope for this limitation.[284] Mylan argued (unsuccessfully before the district court as well as the panel) that these disclosures precluded the claim term "pH 13" from encompassing a range and in particular pH 12.5.[285] These arguments, and Actelion's responses, convinced the panel that "the specification supplies the same clarity as to the desired level of precision as muddied water" and thus could not be relied upon to provide intrinsic evidence of the meaning of pH 13 in the claims.[286] Further, while the significance of the pH term was in the stability of the drug compound epoprostenol in the formulation, the opinion found no evidence in the specification that stability was tested in the range of pH 12–13 upon which the claim term could be definitively construed.[287]

Finally, regarding the prosecution history, the court considered several amendments to the claims involving the pH limitation and statements by the examiner that evidence regarding formulations at pH 12 did not distinguish over the prior art but those at pH 13 did so.[288]

Under these circumstances the panel decided that:

> We find that this case is one where the proper claim construction cannot be reached without the aid of extrinsic evidence, and that the district court should have considered, at minimum, the textbook excerpts offered and addressed by the parties.[289]

This decision was supported by Supreme Court precedent[290] and Federal Circuit case law[291] cited in the opinion.

Accordingly, the panel decided to vacate and remand, because:

> It is not for this court to make those findings [regarding extrinsic evidence] in the first instance. We decline to decide, for example, how many significant figures "a pH of 13" has or what it would mean for a number—either for a pH value or for the concentration of hydrogen ions—to have zero significant figures. Instead, we leave those and other relevant factual questions that might arise based on the extrinsic evidence, including the three textbooks, for the district court to address in the first instance.[292]

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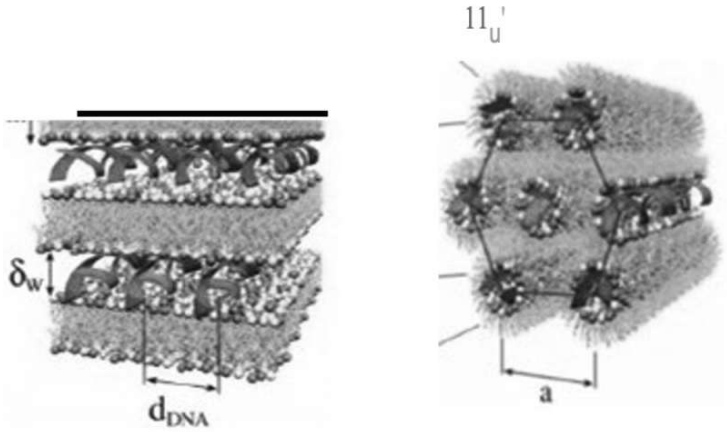
284 *Id.*
285 *Id.*
286 *Id.*
287 *Id.* at 1173.
288 *Id.* The amendments resulting in the claim language in the granted patents were included in the reasons for allowance. *Id.*
289 *Id.*
290 *Id.* at 1174 (citing Teva Pharms. USA, Inc. v. Sandoz, Inc., 574 U.S. 318, 331 (2015)).
291 *Id.* (citing Pickholtz v. Rainbow Techs., Inc., 284 F.3d 1365, 1372–73 (Fed. Cir. 2002)).
292 *Id.*

5. *Arbutus Biopharma Corp. v. ModernaTx, Inc.*, 65 F.4th 656 (Fed. Cir. 2023)

"This application claims priority to a [properly identified earlier-filed application], the disclosure of which is expressly incorporated herein in its entirety" is a phrase commonly found in patents and patent applications as an attempt to bolster disclosure without burdening the specification unnecessarily. Like many (most) stratagems, use of this phrase can give rise to unexpected (and unwanted) implications, as was noted in a Federal Circuit opinion affirming a decision by the Patent Trial and Appeal Board in *inter partes* review proceedings instituted at the behest of challenger ModernaTX that invalidated all claims of the challenged patent owned by Arbutus in *Arbutus Biopharma Corp. v. ModernaTx, Inc.*

The subject matter of the challenged patent, U.S. Patent No. 9,404,127, was stable nucleic acid lipid particles (SNALP) that occur in two morphologies:

Figure 2
Stable Nucleic Acid Lipid Particles



wherein the structure illustrated on the left is "lamellar" and the structure illustrated on the right is "non-lamellar"; the '127 patent claims are directed to the non-lamellar form. This "morphology limitation" is dependent upon how the SNALP is made, which is in turn dependent upon the lipids used in making the SNALP and the process used. With regard to the process SNALPs can be made by a Stepwise Dilution Method (SDM) or a Direct Dilution Method (DDM) and the formulations can have five different ratios for the composite lipids, with 1:62 and 1:57 being those relevant to the claims at issue and referring to a conjugated lipid and a cationic lipid, respectively.[293]

Independent claim 1 was reproduced in the opinion as being representative:

1. A composition comprising:
a plurality of nucleic acid-lipid particles, wherein each particle in the plurality of particles comprises:
(a) a nucleic acid;

[293] Arbutus Biopharma Corp. v. ModernaTx, Inc., 65 F.4th 656, 659–60 (Fed. Cir. 2023).

> (b) a cationic lipid;
> (c) a non-cationic lipid; and
> (d) a conjugated lipid that inhibits aggregation of particles, wherein at least about 95% of the particles in the plurality of particles have a non-lamellar morphology (with this limitation being the morphology limitation).[294]

The '127 patent issued from an application filed on March 9, 2015, that claimed priority to a provisional application filed on June 30, 2010.[295] The '127 patent incorporated by reference published U.S. Patent Application Publication Nos. 2007/0042031 (the '031 application, for disclosure of DDM) and 2004/0142025 (for SDM and apparatuses therefor), these publications being indisputably in the prior art at the '127 patent's earliest claimed priority date.[296]

The PTAB held all claims of the challenged '127 patent to be invalid as being anticipated by U.S. Patent No. 8,058,069, which was filed on April 15, 2009 and claimed priority to a provisional application filed one year earlier (with the Federal Circuit noting that the '127 patent did not claim priority to the '069 patent, even though these patents are commonly owned by Arbutus).[297] The basis for this decision was that the Board found that both patents:

> [A]re directed to the same purpose (providing SNALP, methods of making and delivering SNALP); disclose at least the 1:57 and 1:62 formulations; explain that SNALP can be formed by any method in the art including direct dilution, and direct the reader to rely on the '031 publication for details on using DDM.[298]

The '069 patent incorporated by reference several other patents that the Board held disclosed "several of the same disclosures and experiments" set forth in the '127 patent.[299]

The Board's decision focused on the claim 1(d) element (the morphology limitation) and whether it was inherently disclosed in the '069 patent.[300] The basis for Moderna's assertion of inherent anticipation was that the non-lamellar structure arose as a consequence of the composition of the SNALP and the method (DDM) used to produce it, which the Board found convincing (despite expert testimony based on experimental evidence to the contrary), and Arbutus's concession that the specification of a continuation of the '069 patent disclosed the morphology limitation.[301] Accordingly, the Board held all claims of the '127 patent to be invalid for anticipation.[302]

The Federal Circuit affirmed in an opinion by Judge Reyna, joined by Judges Schall and Chen. With regard to the question of incorporation by reference, the panel

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294 *Id.* at 660.
295 *Id.* at 659.
296 *Id.* at 660.
297 *Id.* at 660–61.
298 *Id.* at 661.
299 *Id.*
300 *Id.*
301 *Id.*
302 *Id.* at 662.

cited its precedent that "[w]hen a reference or material from various documents is incorporated, they are 'effectively part of the host document as if [they] were explicitly contained therein."[303] The panel, like the Board, rejected Arbutus's arguments that the DDM process comprised "many parameters that could be varied" based on Arbutus's expert's concession that the '435 patent (a continuation of the '069 patent) also disclosed the morphology limitation.[304] In the circumstances before the court, "the disclosure of the '069 patent and its incorporated references sufficiently demonstrate to a person skilled in the art how to make and use the claimed compositions, processed by DDM, that results in the Morphology Limitation."[305] The evidence before the Board satisfied the legal requirement for inherent anticipation that production of the claimed SNALPs was a "natural result flowing from" the disclosure in the prior art.[306] Here, the panel asserted that "the '127 and '069 patents disclose the same formulations with 'almost identical wording,'" ("[t]he specificity of the disclosure in the '069 patent is the same as in the '127 patent") including the 1:57 and 1:62 formulation ratios and that the other ratios disclosed and claimed in the '127 specification could be substituted without impacting the morphology limitation according to Arbutus's expert.[307] As set forth in the opinion, both the '127 and '069 patents reference the '031 application for disclosure of the DDM method for producing SNALPs having the claimed morphology limitation, with the challenged '127 patent incorporating by reference the '031 application disclosure, which supported the Board's conclusion that the '127 patent discloses this method the same way it was disclosed in the prior art '031 application.[308] The opinion concludes that because the PTAB found no error in the factual question of whether the prior art taught "the same formulations and the same DDM" disclosed and claimed in the '127 patent, the challenged claims were anticipated by the art and invalid.[309]

With regard to dependent claims directed to forms of the claimed SNALPs comprising mRNA (claim 3) or "fully encapsulated" nucleic acids (claim 8), the panel found these species were disclosed as formulations in the prior art,[310] wherein the court found SNALPs having specific three-dimensional structures (claim 9) to recite inherent properties of the SNALPs produced according to the cited art.[311] And regarding claims to percent ranges for the lipid components of the claimed SNALPs (claims 10–12), the court relied on its precedent that "[w]hen a patent claims a chemical composition in terms of ranges and a single prior art reference discloses a

303 *Id.* at 663 (citing Advanced Display Sys., Inc. v. Kent State Univ., 212 F.3d 1272, 1282 (Fed. Cir. 2000)).
304 *Id.* at 661.
305 *Id.*
306 *Id.* at 662 (citing SmithKline Beecham Corp. v. Apotex Corp., 403 F.3d 1331, 1343–44 (Fed. Cir. 2005)).
307 *Id.* at 663.
308 *Id.* at 663–64.
309 *Id.* at 664.
310 *Id.* at 665.
311 *Id.*

composition that falls within each of the ranges, the range is anticipated."[312] This disclosure arose in the cited prior art by incorporation by reference of U.S. Patent Application Publication No. 2006/0083780, U.S. Patent Application Publication No. 2004/0142025, and U.S. Patent No. 5,885,613.[313]

While not dispositive, this decision is relevant to the on-going disputes between owners of lipid nanoparticle IP and vaccine makers over COVID 19 and other mRNA-based vaccines against other diseases.

6. *Medtronic, Inc. v. Teleflex Life Scis., Ltd.*, 86 F.4th 902 (Fed. Cir. 2023)

In what was an otherwise a run-of-the-mill affirmance of a decision by the Patent Trial and Appeal Board (albeit somewhat noteworthy in affirming the Board's determination that the challenged claims were *not* invalid), the Federal Circuit heard but deigned not to consider the question of whether claims to methods for achieving a therapeutic outcome needed to be supported by a showing of actual reduction to practice (i.e., that the method had been shown to be operative for the claimed result) in *Medtronic, Inc. v. Teleflex Life Sciences Ltd*.

The case arose in two *inter partes* review decisions over reissue patent U.S. Patent No. RE46,116 directed to methods for "using a guide extension catheter with a guide catheter."[314] A portion of claim 25 of the '116 patent was reproduced in the opinion as being representative:

> 25. A method, comprising:
> advancing a distal end of a guide catheter having a lumen through a main blood vessel to an ostium of a coronary artery; . . .[315]

The original patent was filed in 2006 and the Board's assessment of the sufficiency of Medtronic's validity challenge was carried out under the provisions of the 1952 Patent Act.[316] Accordingly, the Board considered evidence of conception in 2005 and diligence from its conception date until filing of a patent application in May 2006 (constituting constructive reduction to practice).[317] Medtronic asserted U.S. Patent No. 7,604,612 against claims 52 and 53 of the '116 patent for anticipation (the Board held for Medtronic and this decision was not appealed); the combination of the '612 patent and U.S. Patent No. 7,736,355 for obviousness of claims 25–40, 42, 44–48, 52 and 53; and the '612 and '355 patents in combination with U.S. Patent Application Publication No. 2005/0015073 for obviousness of claim 45 (wherein in each case in which it was asserted Medtronic argued the '355 patent was prior art under 35 U.S.C. § 102(e)).[318]The opinion noted that Medtronic did not challenge the

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312 *Id.* at 666 (citing Titanium Metals Corp. of Am. v. Banner, 778 F.2d 775, 782 (Fed. Cir. 1985)).
313 *Id.* at 666.
314 Medtronic, Inc. v. Teleflex Life Scis., Ltd., 86 F.4th 902, 903 (Fed. Cir. 2023).
315 *Id.* at 904.
316 *Id.* at 903.
317 *Id.* at 904.
318 *Id.* at 904–05.

sufficiency of Teleflex's evidence for conception prior to the critical date of the '355 patent (September 21, 2005).[319] With regard to the '355 patent, the Board held that Teleflex had reduced to practice the invention claimed in the remaining challenged claims prior to the filing date of the '355 patent and had also satisfied the diligence requirements for its May 2006 filing date to qualify as a constructive reduction to practice.[320] This decision, the opinion notes, was consistent with the Board's earlier decision on whether the '355 patent qualified as prior art for claims to Teleflex's corresponding apparatus claims.[321]

The distinction, "unique to this case," that was raised in one of Medtronic's arguments in this appeal was the question of "whether or not *in vivo* testing was required for actual reduction to practice" because here the challenged claims recited the step of "advancing . . . a guide catheter . . . through a main blood vessel to an ostium of a coronary artery."[322] The Board held such evidence was not necessary and that evidence from alternative physical models could suffice.[323]

The Federal Circuit affirmed in an opinion by Judge Lourie, joined by Judges Prost and Chen. The sole issues raised in this opinion were "(1) whether or not *in vivo* testing was required for actual reduction to practice and (2) whether or not the patentee exercised reasonably continuous diligence until constructive reduction to practice," wherein the panel determined that Teleflex had established constructive reduction to practice and did not reach the issue of actual reduction to practice.[324] On this question, the Federal Circuit held that Medtronic had waived any challenge regarding the diligence issue by attempting to incorporate its arguments in that regard by reference to the Federal Circuit's judgment in a separate, related IPR.[325] The panel rejected this attempt, first, because in that related case the court had not vacated the Board's decision on sufficiency of asserted diligence, and second, that trying to "incorporate by reference *twenty* pages from another brief in another case, amounting to over 4,000 extra words" was "a clear violation of both the motions panel's order [denying Medtronic's motion for leave to expand its brief to 20,000 words] and our rules."[326] The panel characterized this attempt as a strategic decision by Medtronic not to include arguments directed at the diligence issue into its principal brief and, its attempt having failed held that Medtronic's challenge of the Board's finding of diligence had been waived.[327] Combined with Medtronic's decision not to contest

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319 *Id.* at 904.
320 *Id.*
321 *Id.*
322 *Id.*
323 *Id.* at 905.
324 *Id.* (noting that a showing of either species of reduction to practice was enough to affirm the Board's opinion).
325 *Id.* at 905–07.
326 *Id.* at 907.
327 *Id.*

conception of the claimed invention, the panel affirmed the Board's decision that the '355 patent was not prior art and that Medtronic's obviousness challenges failed.[328]

7. *Baxalta Inc. v. Genentech, Inc.*, 81 F.4th 1362 (Fed. Cir. 2023)

There has been, since the turn of the century, a steady, seemingly inexorable trend towards limiting patent rights and focusing the application of U.S. patent law towards an emphasis on preventing innovators from obtaining patent rights in any way or degree broader than the minimum to which they may be entitled. This focus puts putative interests the public may have in reducing present patent rights in favor of future ones, where granting such rights to present inventors (limited as they are in time) is more important than providing sufficient patent protection to permit exploitation and commercialization of the innovations disclosed in their patents. Examples of this trend can be seen in the loss of patent term adjustment awarded by statute due to Patent Office delay on the principle that the public has the right to freely use a patented invention including obvious variations thereof upon earliest patent expiry, the principle being found in Federal Circuit decisions from *AbbVie v. Mathilda & Terence Kennedy Institute of Rheumatology Trust*[329] and *Gilead Sciences v. Natco Pharma Ltd.*[330] and culminating in the Federal Circuit's recent *In re Cellect* decision.[331] In this climate, concerns quickly arose regarding how the recent Supreme Court decision in *Amgen v. Sanofi* would be interpreted by the Federal Circuit. The Federal Circuit did not disappoint, in its decision handed down in *Baxalta Inc. v. Genentech, Inc.*

The case arose in litigation over U.S. Patent No. 7,033,590 (having an earliest priority date of September 14, 2000, the significance of which will become readily apparent).[332] The claims of this patent were directed to monoclonal antibodies that could provide an alternative treatment for Hemophilia A, being immunologically specific for human blood clotting Factor IX and its activated form Factor IXa that would activate Factor X in the coagulation pathway in the absence of Factor VIII lacking as their definitive etiology in these hemophiliacs.[333] The coagulation pathway is set forth here for clarification:

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328 Medtronic asserted unsuccessfully these references as well as U.S. Patent Application Publication No. 2007/0260219 in a second IPR against the '116 patent, but Federal Circuit decisions in three related cases rendered moot Medtronic's appeal of the Board's decisions in this IPR, which was not further discussed in this opinion.

329 764 F.3d 1366 (Fed. Cir. 2014).

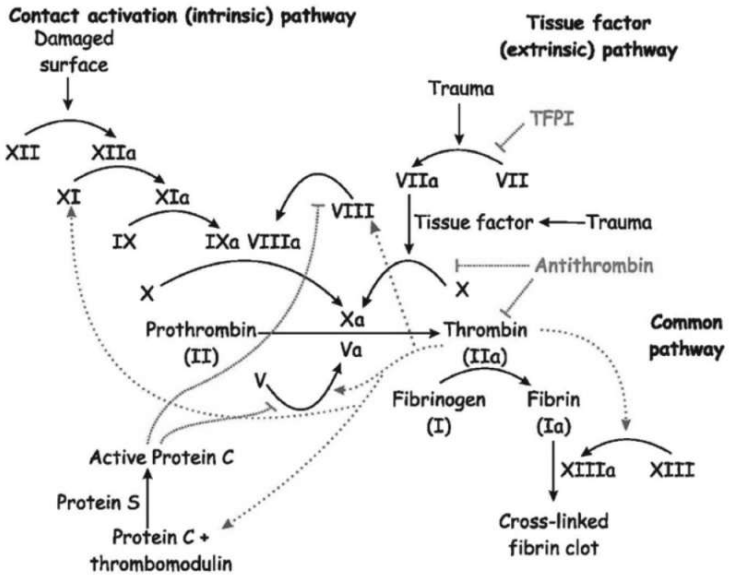
330 753 F.3d 1208 (Fed. Cir. 2014).

331 81 F.4th 1216 (Fed. Cir. 2023); *see infra* Part II.10.

332 Baxalta Inc. v. Genentech, Inc., 81 F.4th 1362, 1363 (Fed. Cir. 2023).

333 *Id.*

Figure 3
Coagulation Pathway



In the opinion, claim 1 of the '590 patent was set forth as being representative:

> 1. An isolated antibody or antibody fragment thereof that binds Factor IX or Factor IXa and increases the procoagulant activity of Factor IXa.[334]

By eliminating the need for Factor VIII these antibodies overcame the limitation of treatment by recombinant human Factor VIII (one of the triumphs of the application of recombinant DNA technology and transformation of cells to make useful amounts of the protein), in cases where patients developed antibodies against the Factor that disabled its ability to support coagulation and treat patients' diseases.[335]

As discussed in the opinion, the specification of the '590 patent disclosed use of hybridoma technology to produce such antibodies, which technology was considered sufficiently robust and predictable that it was the basis for the Federal Circuit's opinion in *Noelle v. Lederman*.[336] Indeed, until recently, the vulnerability of such claims was considered to be a failure to satisfy the written description requirement in light of the Federal Circuit's *en banc* decision in *Ariad v. Eli Lilly & Co*.[337]

Here, however, the matter was before the district court on remand from an earlier Federal Circuit decision, wherein Baxalta sued Genentech over the latter's

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334 *Id.*
335 *Id.*
336 *Id.*; *see also* Noelle v. Lederman, 355 F.3d 1343, 1352–53 (Fed. Cir. 2004) (considering the mere isolation of a novel antigen or epitope thereof sufficient to enable claims directed to antibodies to that antigen or epitope with no demonstration of actual production of any such antibodies).
337 *See generally* Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336 (Fed. Cir. 2010) (en banc).

Hemlibra® (emicizumb-kxwh) product and the Federal Circuit reversed based on the district court's incorrect claim construction (ironically, by Judge Dyk who was sitting by designation in the District of Delaware).[338] Judge Dyk, again sitting by designation, granted Genentech summary judgment that the asserted claims of the '590 patent were invalid for lack of enablement in view of the Supreme Court's intervening *Amgen v. Sanofi* decision.[339]

The Federal Circuit affirmed in an opinion by Chief Judge Moore, joined by Judges Clevenger and Chen. The court's basis for its decision, recited more than once, is that "[t]he facts of this case are materially indistinguishable from those in *Amgen*."[340] Sufficiently significant for the court to recite in the opinion were the facts that the hybridoma methods disclosed in the specification expressly disclosed eleven antibodies by amino acid sequence having the claimed binding properties and that such functional antibodies amounted to only 1.6% of the "thousands" of screened antibodies resulting from the Kohler and Milstein hybridoma protocol employed by the inventors.[341] The panel interpreted the Supreme Court's *Amgen* decision to require enablement of "the full scope of the invention as defined by its claims," allowing for "a reasonable amount of experimentation."[342] As in *Amgen*, the Federal Circuit appreciated the asserted claims of the '590 patent to likewise encompass millions of potential candidate monoclonal antibodies, the screening of which itself amounted to undue experimentation.[343] The court considered the circumstances here to be "materially indistinguishable" from those in *Amgen*, including here reliance on an experimental "roadmap" that required the skilled artisan to "(1) immunize mice with human Factor IX/IXa; (2) form hybridomas from the antibody-secreting spleen cells of those mice; (3) test those antibodies to determine whether they bind to Factor IX/IXa; and (4) test those antibodies that bind to Factor IX/IXa to determine whether any increase procoagulant activity."[344]

Moreover, the panel discerned that the specification provided no disclosure regarding "a quality common to every functional embodiment" that would permit the skilled worker to predict *which* of these potential millions of antibodies would have the claimed function.[345] These deficiencies included no disclosure of a comparison of the eleven disclosed antibodies that would provide such a structural key to identifying functional species.[346] Rather, the person of ordinary skill in the art would (as in *Amgen*) need to produce a surfeit of antibodies and then screen them for the desired

338 *Baxalta*, 81 F.4th at 1364.
339 *Id.*
340 *Id.* at 1366. This was not strictly speaking true; the Amgen claims recited producing antibodies based on their function of PCSK9 binding that prevented PCSK9 binding to LDL receptors, which is what elicited the blood cholesterol-reducing effect rather than, as here, antibodies directed to the target itself, a distinction without a difference to the court.
341 *Id.* at 1364.
342 *Id.* at 1364–65.
343 *Id.* at 1366.
344 *Id.*
345 *Id.*
346 *Id.* at 1366–67.

activity.[347] This amounted, in the panel's view, to no more than the type of "trial and error" disclosure found wanting for satisfying the enablement requirement in *Amgen*.[348]

More than ten years ago, Judge Lourie set forth rubrics that could satisfy that other aspect of § 112, the written description requirement, in the Federal Circuit's *en banc* opinion in *Ariad*:

> [A] description of a claimed genus disclosing either (1) "a representative number of species falling within the scope of the genus," . . . or (2) "structural features common to the members of the genus," either of which must enable *"one of skill in the art [to] 'visualize or recognize' the members of the genus*."[349]

The current emphasis on undue experimentation resonates with these requirements, which formed the reasoned basis for the Federal Circuit's decision in this case:

> Moreover, it is undisputed that the '590 patent contains no disclosures—such as "a quality common to every functional embodiment," *Amgen*, 598 U.S. at 614—that would allow a skilled artisan to predict which antibodies will perform the claimed functions. The patent does not disclose any common structural (or other) feature delineating which antibodies will bind to Factor IX/IXa and increase procoagulant activity from those that will not. Nor does the patent describe why the eleven disclosed antibodies perform the claimed functions, or why the other screened antibodies do not. The only guidance the patent provides is "to create a wide range of candidate antibodies and then screen each to see which happen to bind" to Factor IX/IXa and increase procoagulant activity. *Id. Amgen* makes clear that such an instruction, without more, is not enough to enable the broad functional genus claims at issue here. *Id.* at 614–15 ("[T]he . . . problem we see [is that] Amgen offers persons skilled in the art little more than advice to engage in 'trial and error.'").[350]

For anyone looking for a rationale that supports a broader disclosure of biological molecules than a recitation limited to the expressly disclosed species, it seems Judge Lourie's suggestions would be a good place to start.

8. *Medytox, Inc. v. Galderma S.A.*, 71 F.4th 990 (Fed. Cir. 2023)

It is not surprising that the Federal Circuit has taken the opportunity to apply the Supreme Court's recent precedent in *Amgen v. Sanofi* regarding the sufficiency of disclosure needed to satisfy the statutory enablement requirement under 35 U.S.C. § 112(a). After all, the decision is a rare affirmance of Federal Circuit decisions by the Supreme Court, and the legal rationale set forth is consistent with enablement jurisprudence developed by the Federal Circuit over recent years.[351] But the decision in *Medytox, Inc. v. Galderma S.A*. is itself significant because it adopts the analytical

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347 *Id.*

348 *Id.*

349 Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1350 (Fed. Cir. 2010) (en banc).

350 *Baxalta*, 81 F.4th at 1366–67.

351 *See generally* Wyeth & Cordis Corp. v. Abbott Lab'ys, 720 F3d 1380 (Fed. Cir. 2013); Enzo Life Scis., Inc. v. Roche Molecular Sys., Inc., 928 F.3d 1340 (Fed. Cir. 2019); Idenix Pharm. LLC v. Gilead Scis. Inc., 941 F.3d 1149 (Fed. Cir. 2019).

framework that the Patent and Trademark Office and district courts can be expected to follow going forward, for better or worse.

The case arose in a post-grant review (PGR) proceeding against U.S. Patent No. 10,143,728 before the Patent Trial and Appeal Board pursuant to 35 U.S.C. § 321 *et seq*. and brought by Galderma *et al*.[352] The challenged claims were directed towards "the use of an animal-protein-free botulinum toxin composition that exhibits a longer lasting effect in the patient compared to an animal protein-containing botulinum toxin composition," which encompasses a Medytox product designated MT10109L in the opinion. Substitute claim 19 was set forth in the opinion as representative:

> A method for treating glabellar lines ~~a condition~~ in a patient in need thereof, comprising:
> locally administering a first treatment of ~~therapeutically effective amount~~ of a botulinum toxin composition comprising a serotype A botulinum toxin in an amount present in about 20 units of MT10109L, a first stabilizer comprising a polysorbate, and at least one additional stabilizer, and that does not comprise an animal-derived product or recombinant human albumin;
> locally administering a second treatment of the botulinum toxin composition at a time interval after the first treatment;
> wherein said time interval is the length of effect of the serotype A botulinum toxin composition as determined by physician's live assessment at maximum frown;
> wherein said botulinum toxin composition has a greater length of effect compared to about 20 units of BOTOX®, when ~~whereby the botulinum toxin composition exhibits a longer lasting effect in the patient when compared to treatment of the same condition with a botulinum toxin composition that contains an animal-derived product or recombinant human albumin dosed at a comparable amount and~~ administered in the same manner for the treatment of glabellar lines and to the same locations(s) as that of the botulinum toxin composition; and
> wherein said greater length of effect is determined by physician's live assessment at maximum frown and requires a responder rate at 16 weeks after the first treatment of 50% or greater ~~that does not comprise an animal-derived product or recombinant human albumin, wherein the condition is selected from the group consisting of glabellar lines, marionette lines, brow furrows, lateral canthal lines, and any combination thereof.~~[353]

The compositions were disclosed in earlier applications incorporated by reference; this application newly provides in support of these method claims the results of two clinical trials that compared botulinum toxin stabilized with human serum albumin and animal-protein-free botulinum toxin composition.[354] One of these was results of a Phase III clinical trial making the relevant comparison between BOTOX® and the claimed MT10109L product (showing not surprisingly "significant improvement" with the Medytox product), and results of a Phase II clinical trial comparing the two products (showing consistent improved results with the Medytox product).[355]

The PTAB instituted a PGR against granted claims 1–10 of the '728 patent and Medytox filed a motion to amend by cancelling claims 1–10 and substituting claims

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[352] Medytox, Inc. v. Galderma S.A., 71 F.4th 990, 992–93 (Fed. Cir. 2023).

[353] *Id.* at 993 (emphasis in original) (presenting the claim with limitations removed from the substitute claim indicated by strikethrough and those added by underlining).

[354] *Id.* at 993–94.

[355] *Id.* at 994.

11–18.[356] Medytox also requested the Board to issue a preliminary guidance (as part of the PTO's Pilot Program regarding amendment practice in PGRs and other post-grant review proceedings) relating to the likelihood that the motion met statutory and regulatory requirements.[357] Galderma opposed the motion to amend on new matter grounds, and the PTAB issued a preliminary guidance that "Medytox had not shown a reasonable likelihood that it satisfied the statutory and regulatory requirements under 35 U.S.C. § 326(d) and 37 C.F.R. § 42.221(a)."[358] But the guidance also contained the caveat that the Board would not be bound by this guidance in its final written decision, which would depend on the full record before the Board at the end of the proceedings.[359] In response, Medytox moved to cancel original claim 6 and substitute the remaining claims with new claims 19–27, which Galderma also opposed.[360]

The Board issued its Final Written Decision (FWD) and canceled original claims 1–5 and 7–10.[361] On the merits of the remaining claims at issue, the Board construed the term "responder rate" with regard to Galderma's (a range of 50–100%) and Medytox's (a minimum threshold of 50%) constructions, ultimately deciding that the responder rate limitation had an upper limit of 100% (a construction that differed from the one in the preliminary guidance).[362] The Board also found that Medytox's substitute claims introduced new matter in the responder rate limitation and thus failed to meet the requirements for its revised motion to amend.[363] The Board accordingly found that the proposed substitute claims were invalid for failure to satisfy the written description requirement (a finding not addressed by the Federal Circuit on appeal in view of its other grounds for affirming the Board).[364] On the Board's decision that the substitute claims were also not enabled, the Board applied the factors set forth in *In re Wands* and, based in part on expert testimony, found that the full scope of the claims was not enabled because the specification would not have enabled the skilled worker to achieve a responder rate higher than 62% without undue experimentation.[365] All claims in the '728 patent were thus canceled or replaced with substitute claims precluded by their being invalid.[366] This appeal followed.

The Federal Circuit affirmed in an opinion by Judge Reyna, joined by Judges Dyk and Stark. The opinion first discussed claim construction, the panel holding that the Board properly construed the "responder rate" limitation to be a range.[367] The

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356 *Id.*
357 *Id.*
358 *Id.*
359 *Id.* at 994–95.
360 *Id.* at 995.
361 *Id.*
362 *Id.*
363 *Id.*
364 *Id.*
365 *Id.* at 995–96.
366 *Id.* at 996.
367 *Id.* at 996–98 (noting Galderma also argued that Medytox, for the first time on appeal, contended

court did not address Galderma's underlying forfeiture argument, asserting instead that the parties did not dispute that the "responder rate" limitation had an "inherent" upper limit of 100% and that "there appears to be no substantive difference in the claim construction proposed by the parties for the responder rate limitation," the Federal Circuit affirming the Board's construction on that basis.[368]

Turning to enablement, the Federal Circuit held that the Board had properly found the '728 specification did not satisfy the enablement requirement of § 112(a).[369] The panel rejected Medytox's argument that "the specification does not need to include a working example of 'every possible embodiment' to enable the full scope of the claims,"[370] and Medytox's reliance on expert testimony that there would require no undue experimentation because it was "routine to clinically confirm" whether a composition met the duration limitation (a "greater length of effect").[371] Galderma had argued that Medytox was required "to provide a clinical study for each formulation because clinical trials are not routine for 'determining whether pharmaceutical compositions fall within the scope of a patent claim."[372] The Federal Circuit agreed, cabining the extent of its agreement by asserting that "our caselaw may not require disclosure of every possible working example of responder rates" but noting that here the specification disclosed "at most three examples of responder rates above 50% at 16 weeks."[373] While citing earlier caselaw,[374] the panel based its decision on the Supreme Court rubric recently set forth in *Amgen v. Sanofi* that "[t]he more one claims, the more one must enable."[375] The opinion expressly states the basis for its analytical reasoning as also sounding in *Amgen*, that:

> Though a specification need not always "describe with particularity how to make and use every single embodiment within a claimed class," it must nevertheless "enable the full scope of the invention as defined by its claims," for example by "disclosing [a] general quality" of the class that may "reliably enable a person skilled in the art to make and use all of what is claimed."[376]

Applying these principles, the Federal Circuit affirmed the Board's non-enablement decision as being based on substantial evidence that "the arguments and evidence were insufficient to demonstrate enablement to a skilled artisan because said

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that its construction relied on intrinsic evidence in the specification rather than extrinsic, expert testimony understandably, in light of the substantial evidence standard of review of Board decisions based on factual determinations such as expert testimony).

368 *Id.* at 997.

369 *Id.* at 998–99.

370 *Id.* at 998 (citing (somewhat anachronistically) Bayer Healthcare LLC v. Baxalta Inc., 989 F.3d 964, 982 (Fed Cir. 2021)).

371 *Id.*

372 *Id.*

373 *Id.*

374 *Id.* (first citing Wyeth & Cordis Corp. v. Abbott Lab'ys, 720 F.3d 1380, 1385–86 (Fed. Cir. 2013); and then citing MagSil Corp. v. Hitachi Glob. Storage Techs., Inc., 687 F.3d 1377, 1381 (Fed. Cir. 2012)).

375 *Id.*

376 *Id.*

artisan 'would not have been able to achieve' responder rates higher than the limited examples provided in the specification."[377]

Procedurally, Medytox argued that the Board erred in changing its claim construction in the FWD from the construction in the preliminary guidance, violating the Administrative Procedures Act (APA) as being arbitrary and capricious under 5 U.S.C. § 706(2)(A).[378] Medytox's arguments focused on the Board's purported failure to consider intrinsic evidence and this had resulted in "'inconsistent conclusions on a nearly identical record' [that] render[ed] its decision arbitrary and capricious."[379] The Federal Circuit's assessment is in line with the arguments put forth by the Solicitor General on behalf of the Patent Office, that the preliminary guidance is preliminary and any contrary conclusions the Board may arrive at in its FWD are due to the further development of the record during the proceedings, something the Federal Circuit has held is an obligation falling on the Board.[380] Here, the panel held that the Board "provided a reasoned analysis for its ultimate claim construction" and consequently that the decision to change its construction of the claims with regard to the responder rate limitation was not arbitrary and capricious.[381]

Finally, Medytox argued that the Board's decision and the way it was arrived at denied them due process and was contrary to the APA.[382] The Federal Circuit considered the public notice in the Federal Register, that the Pilot Program would produce a preliminary guidance, and that the "initial" and non-binding nature thereof was evident.[383] Reviewing the procedural steps below, the court held that there were no irregularities or denial of due process. Some caution is provided by the court on the limits of the application of these processes, however:

> To be sure, the agency must inform the parties on procedures relevant to its practices, like the Pilot Program, and must respect the boundaries imposed by the APA. There must be structural integrity to the program in ensuring that the patent owners who have requested such guidance be given an opportunity to be heard and due process.[384]

But, on the record before the panel, the court held that these requirements were met.

However, because this is the first foray into applying the Supreme Court's latest imperative on how patent law will be interpreted, it is hard to say whether it bodes well. Perhaps it is the inevitable consequence of a generalist court steeped in considerations of the "totality of the circumstances" as the reviewing court for an inferior court charged by Congress with interpreting and harmonizing a specific area of the law. Perhaps it has something to do with that court spending more than a decade

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377 *Id.* at 999.
378 *Id.*
379 *Id.* (first citing BASF Corp. v. Enthone, Inc., 749 F. App'x 978, 985 (Fed. Cir. 2018); and then citing Robert Bosch, LLC v. Iancu, 778 F. App'x 871, 875 (Fed. Cir. 2019)).
380 *Id.* at 1000 (citing *In re* Magnum Oil Tools Int'l, Ltd., 829 F.3d 1364, 1377 (Fed. Cir. 2016)).
381 *Id.*
382 *Id.*
383 *Id.* at 1001.
384 *Id.* at 1002.

objecting to precedent from the inferior court that attempted to provide such harmony by developing a jurisprudence that could be applied reliably to diverse circumstances and technologies with a minimum of uncertainty. But as with so much of the Court's "guidance" (to both the courts, the Patent Office, and the patenting public), this one on enablement seems more attuned to the Potter Steward method of legal analysis, where "you know it when you see it." In addition to being anathema to the vision Congress and the early judges had in establishing the Federal Circuit, its difficulty in putting the rubrics (such as they may be) into practice has created disharmony in other areas of the law[385] that may now be the fate of enablement law. The one thread to be grasped in the Court's *Amgen* decision is the possibility of "[a] general quality" of the class that may "reliably enable a person skilled in the art to make and use all of what is claimed."[386] Whether this thread can be woven into a fabric through which enablement law can be applied consistently, of course, remains to be seen.

9. *Regents of the Univ. of Minn. v. Gilead Scis., Inc.*, 61 F.4th 1350 (Fed. Cir. 2023)

The anticipation regarding the Supreme Court's (re)consideration of the enablement requirement in *Amgen v. Sanofi* may have been the most closely watched patent case since *AMP v. Myriad Genetics*. But in a decision handed down recently, *Regents of the University of Minnesota v. Gilead Sciences, Inc.*, the Federal Circuit reminded us that the principles and considerations that form the basis for the Federal Circuit's recent enablement jurisprudence originated in that court's analysis of the other side of Section 112(a), the written description requirement.

The case arose in an *inter partes* review decision by the Patent Trial and Appeal Board involving Gilead's challenge of claims 1−9, 11−21, and 23−28 of U.S. Patent 8,815,830.[387] The issue was reached in the only way it can be in an IPR: Gilead challenged Minnesota's right to priority to applications earlier filed than Gilead's patent on its commercial product, sofosbuvir used to treat hepatitis C infections. The temporal relationships between the patents and applications at issue are set forth in this table in the opinion:

Table 1
'830 Patent Priority Claims

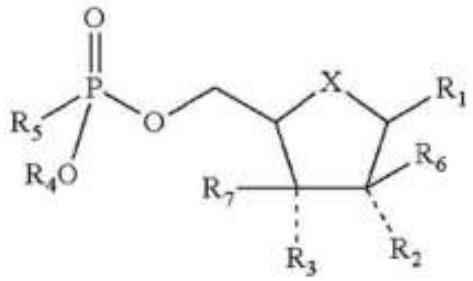
Description	Date
U.S. Provisional App. 60/634,677 ("P1")	Dec. 9, 2004
Int. App. PCT/US2005/044442 ("NP2")	Dec. 8, 2005
U.S. Patent App.11/721,325 ("NP3")	June 8, 2007
Sofia Publication	Jan. 21, 2010
U.S. Patent App. 13/753,252 ("NP4")	Jan. 29, 2013

[385] *See*, *e.g.*, Kevin E. Noonan, *An Analytic Approach to Patent Eligibility*, PATENTDOCS (Dec. 16, 2020), https://www.patentdocs.org/2020/12/an-analytic-approach-to-patent-eligibility.html.
[386] Amgen v. Sanofi, 598 U.S. 594, 611 (2023).
[387] Regents of the Univ. of Minn. v. Gilead Scis., Inc., 61 F.4th 1350, 1353 (Fed. Cir. 2023).

Claim 1 was considered representative of the claims challenged in the IPR and illustrate the legal principles that formed the basis for the court's opinion:

1. A compound of formula I:

Figure 4
Formula I



wherein:
R_1 is guanine, cytosine, thymine, 3-deazaadenine, or uracil, optionally substituted by 1, 2, or 3 U; wherein each U is independently halo, hydroxy, (C1-C6)alkyl, (C3-C6)cycloalkyl, (C1-C6)alkoxy, (C3-C6)cycloalkyloxy, (C1-C6)alkanoyl, (C1-C6)alkanoyloxy, trifluoromethyl, hydroxy(C1-C6)alkyl, $-(CH_2)_{1-4}P(=O)(OR_w)_2$, aryl, aryl(C1-C6)alkyl, or NR_xR_y;
R_2 is halo;
R_6 and R_7 are independently H or (C1-C6)alkyl;
R_3 is hydroxy;
R_4 is hydrogen, (C1-C6)alkyl, (C3-C6)cycloalkyl, aryl, aryl(C1-C6)alkyl, or 2-cyanoethyl;
R_5 is an amino acid;
X is oxy, thio, or methylene;
each R_w is independently hydrogen or (C1-C6)alkyl;
R_x and R_y are each independently hydrogen, (C1-C6)alkyl, (C3-C6)cycloalkyl, phenyl, benzyl, phenethyl, or (C1-C6)alkanoyl; or R_x and $R_y$together with the nitrogen to which they are attached are pyrrolidino, piperidino or morpholino;
wherein any (C1-C6)alkyl of R_1, R_4-R_7, R_w, R_x, and R_y is optionally substituted with one or more halo, hydroxy, (C1-C6)alkoxy, (C3-C6)cycloalkyl oxy, (C1-C6)alkanoyl, (C1-C6)alkanoyloxy, trifluoromethyl, azido, cyano, oxo(=O), (C1-C6)alkyl, (C3-C6)cycloalkyl, (C3-C6)cycloalkyl(C1-C6)alkyl, (C1-C6)alkyl-S-(C1-C6)alkyl-, aryl, heteroaryl, alkyl(C1-C6)alkyl, or heteroaryl(C1-C6)alkyl, or $NR_{aj}R_{ak}$; wherein each $R_{aj}$and R_{ak} is independently hydrogen, (C1-C6)alkyl, (C3-C6)cycloalkyl, phenyl, benzyl, or phenethyl;
and wherein any aryl or heteroaryl may optionally be substituted with one or more substituents selected from the group consisting of halo, hydroxy, (C1-C6)alkyl, (C3-C6)cycloalkyl, (C1-C6)alkoxy, (C3-C6)cycloalkyloxy, (C1-C6)alkanoyl, (C1-C6)alkanoyloxy, trifluoromethyl, trifluoromethoxy, nitro, cyano, and amino;
or a pharmaceutically acceptable salt thereof.[388]

It should be noted that this claim and the notational complexity thereof is not that different from many claims in chemical and biotechnological patents.

There was no dispute that the Sofia patent discloses every limitation of the claims challenged in the IPR, and thus the '830 patent claims would be invalid if the

[388] *Id.* at 1353–54.

patent was not entitled to priority to one of the three Minnesota patent applications (designated "P1," "NP2," and "NP3" in the opinion) that preceded it.[389]

As discussed in the opinion, the disclosure of the NP3 application was the same as the NP2 application, and the Board "focused its priority analysis on the disclosures of NP2 and P1, each of which was filed before Sofia was published."[390] The PTAB held that the challenged claims were invalid for anticipation by Gilead's Sofia publication because the disclosures of the NP2 and P1 prior applications did not provide an adequate written description of the claims in the '830 patent.[391] Thus, the '830 patent was not entitled to the priority date of any of these applications and the Sofia patent publication was anticipating prior art.[392] The basis of the Board's decision was that "these documents contained neither *ipsis verbis* support nor sufficient blaze marks to guide the skilled artisan to the claims of the '830 patent."[393] The Board issued a final written decision invalidating the challenged claims of the '830 patent and this appeal followed.

The Federal Circuit affirmed in an opinion by Judge Lourie, joined by Judges Dyk and Stoll.[394] The opinion addressed Minnesota's three grounds for appeal in order: first, that the Board erred in finding no adequate written description for the '830 claims in the priority documents; second, that the decision was contrary to the Administrative Procedures Act; and third, that Minnesota as a sovereign State was immune from the Board's jurisdiction.[395]

With regard to the written description question *per se*, the opinion sets forth a brief but informative synopsis of the standard properly applied by the Board. As part of the patent "*quid pro quo*," the panel noted that the "judicial gloss" imposed by the courts is that a disclosure must show that the applicant made what was claimed.[396] In the context of claims to a chemical genus, the court apprehends "particular issues" to be raised because such claims must be supported by disclosure of "either a representative number of members of the genus or structural features common to the members of the genus, in either case with enough precision that a relevant artisan can visualize or recognize the members of the genus."[397] Minnesota's argument sounded in the second basis for an adequate written description, setting forth "blaze marks"

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389 *Id.* at 1355.
390 *Id.*
391 *Id.*
392 *Id.*
393 *Id.*
394 *Id.* at 1360. It should be remembered that Judge Lourie almost single-handedly developed the modern application of the court's written description jurisprudence, particularly for biotechnology claims, in cases including *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 972 F.2d 1200 (Fed. Cir. 1991), *Fiers v. Revel*, 984 F.2d 1164 (Fed. Cir. 1993), *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956 (Fed. Cir. 2002), *University of Rochester v. G.D. Searle Co.*, 358 F.3d 916 (Fed. Cir. 2004), and most particularly *Regents of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997), and *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co*, 598 F.3d 1336 (Fed. Cir. 2010).
395 *Id.*
396 *Id.*
397 *Id.* at 1356 (citing Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1350–52 (Fed. Cir. 2010)).

sufficient to disclose the genus.[398] Under the substantial evidence standard applied to factual questions decided by the Board,[399] the Federal Circuit agreed that the Board did not err in finding against Minnesota.[400] Minnesota contended that a collection of dependent claims, each being directed to species for one of the several substituents (P1 Claim 47 for R_7 substituents, P1 Claim 45 for R_6 substituents, P1 Claim 33 for R_5 substituents, P1 Claim 21 for R_3 substituents, P1 Claim 13 for R2 substituents, and P1 Claim 2 for R_1 substituents, and P1 Claim 1 for R_4 substituents and X) provided *ipsis verbis* disclosure of the subgenus claimed in the '830 patent.[401] Calling this recitation a "maze-like path" needing to be followed, with "each step providing multiple alternative paths," this is "not a written description of what might have been described if each of the optional steps had been set forth as the only option."[402] The inadequacy in the argument (and the written description) is its indeterminacy and lack of direction because "all those optional choices do not define the intended result that is claim 1 of the '830 patent."[403] The panel states that the situation before them was analogous to the claims invalidated on written description grounds in *Fujikawa v. Wattanasin*, which provided what the court characterized in that case to be an assertion of "laundry list disclosure of every possible moiety for every possible position" as providing an adequate written description, which the court rejected because "such a disclosure would not 'reasonably lead' those skilled in the art to any particular species."[404] In this case, the panel asserted that the disclosure relied upon by Minnesota recited "a compendium of common organic chemical functional groups, yielding a laundry list disclosure of different moieties for every possible side chain or functional group" and, "[i]ndeed, the listings of possibilities are so long, and so interwoven, that it is quite unclear how many compounds actually fall within the described genera and subgenera."[405] On this basis, the Federal Circuit held that the P1 priority document does not provide sufficient *ipsis verbis* support for the challenged '830 patent claims to entitle these claims to its priority date.[406]

Turning to the question of whether the prior applications provided the requisite "blaze marks" to satisfy the written description requirement, the Federal Circuit again agreed with the PTAB that they did not.[407] In doing so (after stretching the "tree in the forest" analogy about as far as it could be taken), the opinion rejects Minnesota's attempted reliance on rubrics from *Ariad*, stating that *Ariad* stood for the principle that what is required is:

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398 *Id.*
399 *Id.* (noting that, for written description issues, the primary factual considerations "must be assessed on a case-by-case basis" under *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1562 (Fed. Cir. 1991)).
400 *Id.* at 1357.
401 *Id.* at 1357–58.
402 *Id.* at 1357.
403 *Id.*
404 *Id.* (citing Fujikawa v. Wattanasin, 93 F.3d 1559, 1571 (Fed. Cir. 1996)).
405 *Id.*
406 *Id.*
407 *Id.* at 1357–58.

> [A] description of a claimed genus disclosing either (1) "a representative number of species falling within the scope of the genus," which the parties do not dispute is lacking here, or (2) "structural features common to the members of the genus," either of which must enable *"one of skill in the art [to] 'visualize or recognize' the members of the genus.*"[408]

In the applications considered here (P1 and NP2) "the structures here are so extensive and varied that the structures of P1 claim 47, which, through its multiple dependencies, encompasses a significantly larger genus than that claimed in the '830 patent, are not sufficiently common to that of claim 1 of the '830 patent to provide written description support."[409] Under these circumstances there are no "blaze marks" in the P1 nor NP2 applications to the subgenus claimed in the '830 patent for the skilled worker to appreciate.[410] Having failed to satisfy either alternative basis for an adequate written description, the Federal Circuit held that the PTAB properly invalidated the challenged claims as being anticipated by the Sofia publication.

Minnesota's remaining grounds for appeal were dealt with by the court more expeditiously. With regard to the APA challenge, the opinion rejects there being an APA basis for objection to the Board "disregard" for Minnesota's experts, because the court states "[i]t is within the discretion of the Board to weigh the evidence of record," and regardless the record showed that the Board had cited Minnesota's experts "more than a dozen times" in its Final Written Decision (FWD).[411] Nor does the APA require the Board to perform a "creditability determination" for expert witness testimony according to the panel.[412] The court also rejected Minnesota's claim that the Board's decision was contrary to an earlier decision involving Gilead, reciting five ways in which the earlier case was different from this one.[413] Additionally, the panel rejected Minnesota's objections on certain procedural grounds, stating that they had been given an adequate opportunity to respond during the IPR.

Finally, the opinion summarily rejected Minnesota's sovereign immunity claims, based on its earlier decision in *Regents of the University of Minnesota v. LSI Corp.*, on collateral estoppel and *stare decisis* grounds.[414]

As with enablement, the Federal Circuit (albeit supported by over thirty years of precedent) has established a standard requiring heightened disclosure supporting claims to chemical and biological inventions. The inherent complexity in these arts provides a logical basis for the distinctions drawn in this case and in earlier written description cases, and the court's concern over a patentee receiving claims of broader scope than what is expressly disclosed is a consistent theme in these cases and the more recent enablement cases before the Federal Circuit. This parsimony is likely to

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408 *Id.* at 1358 (emphasis in original).
409 *Id.*
410 *Id.*
411 *Id.* at 1359 (citing Tiger Lily Ventures Ltd. v. Barclays Cap. Inc., 35 F.4th 1352, 1365−66 (Fed. Cir. 2022)).
412 *Id.*
413 *Id.*
414 *Id.* (citing Regents of the University of Minnesota v. LSI Corp., 926 F.3d 1327 (Fed. Cir. 2019)).

resonate with the Supreme Court and thus encase in stone the disclosure requirements for written description developed for a generation by the Federal Circuit.[415]

10. *In Re Cellect*, 81 F.4th 1216 (Fed. Cir. 2023).

The Federal Circuit this year decided a question left open during a recent spate of opinions involving the judicially created doctrine of obviousness-type double patenting (OTDP): the effect patent term adjustment (PTA) can, or should, have on creating circumstances where OTDP will operate to find a patent invalid in the absence of a timely filed terminal disclaimer.

The issue arose in a series of *ex parte* reexaminations over five patents owned by Cellect (U.S. Patent Nos. 6,424,369, 6,452,626, 6,982,742, and 7,002,621) that involve solid state image sensors which are configured to be of a minimum size and used within communication devices specifically including video telephones according to the '621 patent (only 4 of these patents were invalidated, the fifth not having any PTA that raised the issue).[416] The chronological situation is set forth in an exhibit in the Federal Circuit's opinion.

There was no dispute that the claims in these applications were patentably indistinct. The Board issued four decisions on appeal affirming the reexamination division's invalidation of the '369, '626, '621, and '742 patents, all on the grounds that the provisions of 35 U.S.C. § 154(b)(2)(B), stating:

> "No patent the term of which has been disclaimed beyond a specified date may be adjusted under this section beyond the expiration date specified in the disclaimer."[417]

The Board mandated that a terminal disclaimer be filed under circumstances where obviousness-type double patenting arose due to extension of patent term as PTA, i.e., that OTDP must be determined *after* application of PTA.[418] Because all of these patents had expired (but Cellect retained the right to sue for prior infringement under 35 U.S.C. § 286), the Board's decision invalidated these patents with no available remedy for Cellect.[419] In its consolidated decision, the Board emphasized the potential inequities to the public due to the possibility of harassment by different parties owning patents to obvious variants of one another (in the absence of a terminal disclaimer preventing this potentiality) as representing an unjust extension of patent term to the public's detriment.[420] Finally, the Board rejected arguments that the Federal Circuit's jurisprudence did not rely on whether or not there was

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[415] Such an objection has not, sadly, prevented the Patent Office from making arguments encompassing prior art laundry list disclosures in asserting lack of patentability.

[416] *In re* Cellect, LLC, 81 F.4th 1216, 1219 (Fed. Cir. 2023); U.S. Patent No. 7,002,621 (filed August 21, 2001).

[417] *Id.* (quoting 35 U.S.C. § 154(b)).

[418] *Cellect*, 81 F.4th at 1222 (citing 35 U.S.C. § 154(b)(2)(B)). It will be recalled that the Federal Circuit reached a different conclusion with regard to patent term extension (PTE) under 35 U.S.C. § 156. In *Novartis AG v. Ezra Ventures LLC*, the court expressly refused to permit "a judge-made doctrine to cut off a statutorily-authorized time extension." 909 F.3d 1367, 1375 (2018).

[419] *See Cellect*, 81 F.4th at 1222.

[420] *Id.*; *see also In re* Fallaux, 564 F.3d 1313 (Fed. Cir. 2009).

gamesmanship or the potential thereof under *Gilead Sciences, Inc. v. Natco Pharma Ltd*., but that under *In re Longi*, the public was entitled to the assumption that it is free to practice what is claimed in a patent and obvious modifications and variants thereof once the patent has expired.[421]

In its appeal Cellect presented five arguments. The first was based on the Board's putative legal error in interpreting the statute to justify treating term adjustment under PTA differently from term extension under patent term extension (PTE).[422] Second, Cellect argued that application of OTDP in this case was inequitable, due to the lack of remedy as well as there being no unjust extension because Cellect had engaged in no gamesmanship.[423] Third, Cellect argued as a fallback position that OTDP should be used here to cancel the term extended by PTA rather than invalidating the patents in their entirety.[424] The final two arguments were that the reexamination had been improperly instituted, because there was no substantial new question of patentability and that any ancillary obviousness rejections raised in the reexamination were ultimately based on the OTDP of these patents (which argument the Board argued Cellect had waived).[425]

Cellect's first argument was based on statutory interpretation. Cellect argued that both PTA and PTE are statutory grounds for extending a patent term and there was no legal nor logical basis for treating them differently, i.e., the court should interpret the PTA statute here as the court had interpreted the PTE statute in *Ezra*.[426] Further, Cellect argued that the statutory language for PTA is that the term "shall" be extended.[427] Cellect argued that the provisions the Board relied upon were intended for situations where a terminal disclaimer *had been* filed, not one where PTA creates OTDP.[428] The consequence of the Board's interpretation created a situation requiring "preemptive" terminal disclaimer filings, which Cellect argued Congress had not intended.[429] Cellect also cited several district court cases, including *Amgen, Inc. v. Sandoz Inc*. and *Mitsubishi Tanabe Pharma Corp. v. Sandoz Inc*., that had interpreted

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421 *Cellect*, 81 F.4th at 1222 (first citing Gilead Sciences, Inc. v. Natco Pharma Ltd., 753 F.3d 1208 (Fed. Cir. 2014); and then citing *In re* Longi, 759 F.2d 887 (Fed. Cir. 1985)).

422 Cellect, LLC's Principal Brief at 18, *In re* Cellect, 81 F.4th 1216 (Fed. Cir. 2023) (No. 2022-1293), 2022 WL 1617872.

423 *Id.* at 19.

424 *Id.* at 20.

425 *Id.* at 19–20.

426 *Id.* at 22.

427 *Id.* at 23. Although, there certainly have been other instances (e.g., regarding provisions of the BPCIA, see Sandoz Inc. v. Amgen Inc., 582 U.S. 1 (2017)), where "shall" has not been given commanding effect.

428 *See id.* at 27; *compare id.* at 28 (Cellect arguing the Board interpreted the language regarding a "patent the term of which [may need to be] disclaimed [if adjustment is granted]" with 35 U.S.C. § 154(b)).

429 Cellect, LLC's Principal Brief at 28, *In re* Cellect, 81 F.4th 1216 (Fed. Cir. 2023) (No. 2022-1293), 2022 WL 1617872.

the court's *Ezra* decision to support giving statutory deference to respecting PTA over a "judge-made doctrine."[430]

Regarding the equities, Cellect argued that the purpose of OTDP was to prevent "unjust timewise extension of patent term" and to prevent "harassing litigation filed by multiple patent owners" for patents on "not-patentably-distinct" inventions.[431] Cellect's argument emphasized the *unjust* extension aspect, which Cellect tied to the gamesmanship (or potential therefor) the Court recognized in *Gilead*.[432] And in this case Cellect contended that "[t]he Board used an equitable doctrine to achieve an inequitable result."[433] In an effort to avoid this outcome, Cellect argued that applying the Board's interpretation to retroactively disclaim the PTA-extended term but *not* invalidate the patents would not only cure the inequitable effects of the Board's decision but also as precedent notify future applicants who could have the opportunity to decline PTA to avoid invalidation on OTDP grounds.[434]

The Solicitor's argument emphasized the inequities to the public occasioned by *any* extension of patentably-indistinct inventions (in view of the government's interpretation of the statute).[435] The brief cited in opposition the court's decision in *AbbVie Inc. v. Mathilda & Terence Kennedy Institute of Rheumatology Trust*,[436] arguing that OTDP applies whenever there is an extension of patent term for patents claiming a patentably indistinct invention.[437] The Solicitor also noted that, under circumstances where OTDP would invalidate a patent, having PTE will not save it and that the differences in the statutes permit PTA to produce OTDP where PTE cannot (because § 156 does not contain the "disclaimer" in § 154(b)(2)(B)).[438] Regarding Cellect's arguments for forswearing PTA but preserving the patent, the PTO cited *Boehringer Ingelheim Int'l. GmbH v. Barr Laboratories Inc*. when arguing that a patentee that had benefited from notice to the public of the later expiration date had already obtained an "unjustified advantage."[439] Finally, the Solicitor argued that the term extension issue here is not dispositive because OTDP also prevents potential harassment by multiple assignees.[440]

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430 *Id.* at 33–38 (first citing Amgen, Inc. v. Sandoz Inc., 2021 WL 5355506, No. 18-11026 (D.N.J. 2021); and then citing Mitsubishi Tanabe Pharma Corp. v. Sandoz Inc., 533 F. Supp. 3d 170 (D.N.J. 2021)).

431 *Id.* at 19.

432 *Id.* at 33.

433 *Id*. at 7.

434 *See generally id.* at 20 (finding that the court should, at most, invalidate the patent term adjustments and not the patent itself).

435 Brief for Appellee, Dir. of the U.S. Pat. and Trademark Off. at 9, *In re* Cellect, 81 F.4th 1216 (Fed. Cir. 2023) (No. 22-1293).

436 764 F.3d 1366, 1373 (Fed. Cir. 2014).

437 *Id.* at 1.

438 *Id.* at 11–12.

439 *Id.* at 38 (citing Boehringer Ingelhim Int'l Gmbh v. Barr Lab'ys, Inc., 592 F.3d 1340, 1346 (Fed. Cir. 2010)).

440 *Id.* at 21.

A number of amici filed briefs were filed in favor and against the Board's decision. Briefs in opposition to the Board's application of OTDP in these circumstances were filed by the Intellectual Property Owners Association (IPO), the Pharmaceutical Research and Manufacturers of America (PhRMA), and the Biotechnology Innovation Organization (BIO). The IPO's brief emphasized that the only reason OTDP arose in this case was the application of PTA, and that the statute mandates extension (and accordingly the Board's decision was contrary to congressional intent).[441] PhRMA's brief focused on the purpose of OTDP, which was to avoid unjust enrichment, and it argued that the PTO's "speculative" harassment rationale was inconsistent with Federal Circuit precedent.[442] BIO's brief discussed the Board's statutory interpretation errors and that the inequitable outcome in this case is inconsistent with the equitable underpinnings of OTDP.[443]

Briefs in favor of the Board's decision were filed by Alvogen, the Association for Accessible Medicines (AAM), and Samsung. Alvogen's brief argued that there was no reason OTDP should not apply to PTA because the doctrine was intended to establish term limits on patents to patentably-indistinct inventions and that, in their view, gamesmanship was not required by the statute and is an "unstable benchmark."[444] AAM's brief was entirely outcome-oriented, based on the amici's perspective that patents increase drug costs and the Board's decision was a good one because it reduced patent term (no matter that the patents at issue were not related to drug products).[445] Finally, Samsung's brief argued that the decision was consistent with the policy bases for the OTDP doctrine and that, accordingly, there was no inequitable result.[446] The Federal Circuit affirmed the Board's judgment in these re-examinations in an opinion by Judge Lourie joined by Judges Dyk and Reyna. Although the patentee asserted five arguments in its briefing, the court discussed only three of these arguments (albeit in some instances apparently condensing the five arguments to three).[447]

The first argument (which was dispositive for the court in its affirmance) was Cellect's position that PTA under 35 U.S.C. § 154 and PTE under 35 U.S.C. § 156 should be treated equivalently as Congressional mandates that should not be abridged

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441 *See* Brief for Intell. Prop. Owners Ass'n as Amicus Curiae in Support of Appellant, *In re* Cellect, 81 F.4th 1216 (Fed. Cir. 2023) (No. 22-1293).

442 *See* Brief of Pharm. Rsch and Mfrs. of Am. (PhRMA), as Amicus Curiae in Support of Appellant, *In re* Cellect, 81 F.4th 1216 (Fed. Cir. 2023) (No. 22-1293).

443 *See* Brief of Amicus Curiae Biotechnology Innovation Org. in Support of Appellant, *In re* Cellect, 81 F.4th 1216 (Fed. Cir. 2023) (No. 22-1293).

444 *See* Brief of Amicus Curiae Alvogen PB Research & Dev. LLC in Support of the Director and Affirmance, *In re* Cellect, 81 F.4th 1216 (Fed. Cir. 2023) (No. 22-1293).

445 *See* Brief for The Ass'n for Accessible Meds. as Amicus Curiae in Support of the Director and Affirmance, *In re* Cellect, 81 F.4th 1216 (Fed. Cir. 2023) (No. 22-1293).

446 *See* Corrected Brief of Amici Curiae Samsung Electronics Co., LTD and Samsung Electronics America, Inc. in Support of the Director and Affirmance, *In re* Cellect, 81 F.4th 1216 (Fed. Cir. 2023) (No. 22-1293). It should be noted that Samsung is a competitor and is involved in litigation with Cellect on other patents.

447 *In re* Cellect, 81 F.4th 1216, 1222 (Fed. Cir. 2023).

by judicially created doctrines, like obviousness-type double patenting.[448] The court's opinion to the contrary was based on three principles. The first was that, it is inequitable to the public that a second, later-expiring, patent should be obtained ("an unjustified timewise extension of patent term") on an obvious variant of a patented invention, based on *AbbVie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Tr.*[449] The panel's opinion found support in the statute (as had the Board), wherein application of PTA was limited under circumstances where there was or should have been a terminal disclaimer filed: "*Disclaimed term.— No patent the term of which has been disclaimed beyond a specified date may be adjusted under this section beyond the expiration date specified in the disclaimer."*[450] There is no such limitation in 35 U.S.C. § 156 and, even though both statutes recite that an extension of the term *shall* be granted, the distinction between the two types of extension was enough to convince the court that the Board had come to the correct conclusion.[451]

This conclusion was based in part by the court's precedent, particularly *AbbVie*, and by the panel's agreement with the distinction in statutory construction between 35 U.S.C. § 154 and § 156 as advocated by the Solicitor representing the USPTO.[452] The overriding policy consideration was the court's focus on the need to "ensure that the applicant does not receive an unjust timewise extension of patent term" (as it has for over a decade.)[453] The fact that the limitations of terminal disclaimers is in the PTA statute but not the PTE statute indicated to the court that Congress intended the effect of ODP to differ between these two approaches to statutory term restoration.[454] They "are dealt with in different statutes and deal with differing circumstances," and while "the expiration date used for an ODP analysis where a patent has received PTE is the expiration date before the PTE has been added" pursuant to *Novartis AG v. Ezra Ventures LLC*[455] and *Merck & Co. v. Hi-Tech Pharmacal Co*.,[456] the "expiration date used for an ODP analysis where a patent has received PTA is the expiration date after the PTA has been added" as the holding in this case.[457] Cellect's argument that both PTA and PTE should be treated equally because they "provide statutorily authorized

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448 *Id.* at 1224.

449 *Id.* at 1227–28; *see also* AbbVie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Tr., 764 F.3d 1366, 1373 (Fed. Cir. 2014).

450 *Cellect*, 81 F.4th at 1223 (emphasis in original) (quoting 35 U.S.C. § 154(b)(2)(B)).

451 *Id.* at 1226.

452 *Id.*

453 *Id.* at 1225; *see also In re* Janssen Biotech, Inc, 880 F.3d 1315 (Fed. Cir. 2018); G.D. Searle LLC v. Lupin Pharmaceuticals, Inc., 790 F.3d 1349 (Fed. Cir. 2015); AbbVie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Tr., 764 F.3d 1366, 1373 (Fed. Cir. 2014); Gilead Sciences, Inc. v. Natco Pharma Ltd., 753 F.3d 1208 (Fed. Cir. 2014); Eli Lilly & Co. v. Teva Parenteral Medicines, Inc., 689 F.3d 1368 (Fed. Cir. 2012); Sun Pharmaceutical Industries, Ltd. v. Eli Lilly & Co., 611 F.3d 1381 (Fed. Cir. 2010).

454 *In re* Cellect, 81 F.4th at 1225.

455 909 F.3d 1367 (Fed. Cir. 2018).

456 482 F.3d 1317 (Fed. Cir. 2007).

457 *In re* Cellect, 81 F.4th at 1226; Novartis AG v. Ezra Ventures LLC, 909 F.3d 1367 (Fed. Cir. 2018); Merck & Co. v. hi-Tech Pharmacal Co., 482 F. 1317 (Fed. Cir. 2007).

time extensions" is "an unjustified attempt to force disparate statutes into one" according to the opinion.[458]

The panel perceived differences in the statutes that justify the distinctions raised in this opinion, noting that "each has its own independent framework established through an independent statutory schema" despite the similarities that "both PTA and PTE are statutorily authorized extensions, and each serves to recover lost term," because they have "quite distinct purposes."[459] Importantly, the panel construed the statute in this manner because, for them, "[t]here is nothing in the PTA statute to suggest that application of ODP to the PTA-extended patent term would be contrary to the congressional design."[460] On the contrary, the court understood Cellect's position to "effectively extend the overall patent term awarded to a single invention [as] contrary to Congress's purpose" (which is to limit an extended term for a patentably distinct invention).[461] In the panel's view, the overriding consideration is "to ensure that the applicant is not receiving an unjust extension of time."[462]

Finally, in this regard, the court understood that if terminal disclaimers are the solution to the problem of unjust extensions of time precluded by ODP, permitting PTA to apply where a terminal disclaimer has *not* been filed (to avoid application of 35 U.S.C. § 154(b)(2)(B)) would "frustrate the clear intent of Congress [by permitting] applicants to benefit from their failure, or an examiner's failure, to comply with established practice concerning ODP" (i.e., using terminal disclaimers to avoid invalidation).[463]

The opinion refused to find the equities asserted in Cellect's second argument, arising from the particular circumstances in this case, to be a basis to come to a different conclusion than the Board had. The Federal Circuit recognized the preeminent policy purpose for applying ODP to the PTA circumstances in this case. If, as the Board asserted and the Federal Circuit agreed, Cellect's patents received an "unjust timewise extension" of their patent term, the absence of gamesmanship does not remedy these circumstances nor excuse Cellect from the consequences arising therefrom.[464] Moreover, the Federal Circuit agreed with the Board that a risk continued to exist regarding the other consideration in ODP: the possibility of separate ownership of patents that are not patentably distinct (no matter Cellect's promises that it would not alienate them, nor how remote or theoretical these risks might be).[465]

Finally, the Federal Circuit rejected Cellect's third argument that the re-examinations were improvidently granted because there was no substantial new

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458 *In re* Cellect, 81 F.4th at 1226.
459 *Id.* at 1227.
460 *Id.*
461 *Id.*
462 *Id.* at 1228.
463 *Id.* at 1229.
464 *Id.* (noting "it does not matter how the unjustified extensions are obtained").
465 *Id.*

question of patentability raised in them, based on the same examiner being responsible for permitting these patents to grant and not issuing a rejection in any of them based on ODP.[466] The panel found that institution of these re-examinations was supported by substantial evidence because, *inter alia*, there was nothing in the prosecution history of any of these patents that "affirmatively indicates that the examiner considered whether or not an ODP rejection should be made."[467] The court also rejected the alternative proposed by Cellect of only considering the adjustment term, and not the entire patent term, for invalidation as an attempt to have the PTO or the court grant a "retroactive" terminal disclaimer, giving Cellect "the opportunity to benefit from terminal disclaimers that it never filed."[468]

Cellect petitioned for rehearing and in June, the Court affirmed the Board's judgment under Rule 36 in Reexamination No. 90/014,452 and *Cellect, LLC v. Samsung Electronics Co*. in *inter partes* review proceedings IPR2020-00475, IPR2020-00476, IPR2020-00477, and IPR2020-00512.

We have come a long way from the conventional use of terminal disclaimers to protect the public from shenanigans of intentional delay, by doling out patentably indistinct variations on an invention to extend protection beyond the statutory 17-year term prior, to revision of the patent stature in response to U.S. accession of the GATT/ TRIPS agreement. However, the philosophy applied by the Court in this decision is consistent with that earlier judicial attempt to prevent "unjust" extensions of patent rights. Of course, there are stratagems existing and to be developed to adapt to the regime established by the Federal Circuit's decision, which only reinforces the value of the clever draftsman in protecting important technologies under creative applications of the law, as the Federal Circuit construed it in this case, some of which are set forth below.

Having spoken plainly (and seeing that the likelihood the Supreme Court will weigh in is substantially zero), the question remaining is: what prosecution stratagems can be devised to permit maximizing patent term by (at a minimum) having a patent receive its statutory PTA without running afoul of concerns over public expectations? Some have argued that filing "preemptive" terminal disclaimers would at least prevent patents from being invalidated on ODP grounds, after the exclusivity of such patents has been relied upon to protect investment in drugs and other inventions requiring exclusivity terms that provide a sufficiently robust return on investment. The drawback of these strategies is that, by definition, they relinquish PTA even before entitlement to such PTA has been challenged and, thus, such terminally disclaimed patents may not provide the requisite exclusivity to support investment in the claimed technology.

There are, however, several alternative approaches. The most direct is to take advantage of the safe harbor provisions of 35 U.S.C. § 121 for claims subject to a

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466 *Id.* at 1230.
467 *Id.* at 1231.
468 *Id.*

restriction requirement. Particularly for inventions having claims encompassing several statutory categories under 35 U.S.C. § 101 (compositions, methods of making, methods of using, etc.), having a restriction requirement issued can provide a basis to avoid having to file a terminal disclaimer, because the various claim groupings have been judged by the patent examiner to be patentably distinct. While not immune from later challenge, the presumption is that the Office's determination was correct and thus will be subject to the clear and convincing standard for invalidating patents for ODP. This tactic carries the responsibility to make certain that claims in the various groups are kept within their patentably distinct "silos" to maintain the safe harbor, a concept termed "consonance" in this regard. And it can also be prudent to avoid taking the opportunity to request rejoinder under M.P.E.P. § 821.04 of certain otherwise patentably distinct groups of claims (such as method claims being rejoined to allowed composition claims), which has the effect of having these patentably distinct claims issued in the same granted patent, and thus, having the same expiration date (which could in some instances be less than could be obtained under the PTA statute).

Substantively, assertion of ODP can be addressed as with any other obviousness rejection, by challenging the motivation-to-combine the disclosure of related applications with other prior art references, or whether species encompassed by ODP-rejected claims have features (like unexpected results) not shared with earlier claimed embodiments. Other objective indicia (like commercial success) may be available for species claims to the eventual commercial embodiment. Such strategies will require more careful consideration of what claims are pursued and in what order, which in turn will benefit from close coordination between business development actors and patent prosecutors that, while always recognized as being beneficial, has not always been pursued with sufficient diligence. In this regard, it is important to remember that "the patent disclosure [of an earlier related patent asserted in an ODP rejection] is not 'prior art' and cannot be looked to for what it teaches,"[469] which renders such patents much more limited than other prior art.[470] Moreover, a species claim is not necessarily obvious over an earlier genus claim and can be found to be patentably distinct using the analytical rubrics contemplated herein,[471] an illustrative example is *In re Vogel*, where the Court of Customs and Patent Appeals held that claims to a method of preparing a beef product in a later application was patentably distinct from claims to a similar but not identical method for preparing a pork product, but claims to a similar method for making a meat product were not patentably distinct.[472] This is also true for distinguishing claims to compositions and methods for using them.[473]

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469 *In re* Baird, 348 F.2d 974, 979 (C.C.P.A. 1965).

470 Other prior art can be considered for obviousness purposes for all that it teaches and is not limited to whether the reference is enabling. *See* Amgen Inc. v. Hoechst Marion Roussel Inc., 314 F.3d 1313, 1357 (Fed. Cir. 2003) ("Under § 103, however, a reference need not be enabled; it qualifies as a prior art, regardless, *for whatever is disclosed therein*." (emphasis added)).

471 *See In re* Sarett, 327 F.2d 1005, 1012 (C.C.P.A. 1964).

472 *See In re* Vogel 422 F.2d 438, 441–42 (C.C.P.A. 1970).

473 *See In re* Boylan, 392 F.2d 1017, 1022–23 (C.C.P.A. 1968).

Implementing these various ways of avoiding ODP rejections and the need for PTA-destroying terminal disclaimers takes intentional planning when drafting claims and assessments that, heretofore, have not had compelling reasons to be performed, for time-saving and drafting-efficiency reasons. In view of the Federal Circuit's decisions precluding any consideration of what is fair to the patentee (as opposed to the public), making the effort to avoid the need for filing a terminal disclaimer seems worth doing to the broadest extent possible.

III. Conclusion

The biotechnology patent landscape in 2023 has been a crucible of legal, scientific, and ethical challenges, reflecting the accelerating pace of innovation and the legal system's attempts to keep pace. The top ten biotechnology patent decisions of the year navigated a complex maze of issues including utility, enablement, written description, anticipation, obviousness, standing, and more. These cases underscored the ongoing tension between protecting innovations and ensuring public access to advancements in medical, agricultural, and industrial biotechnologies.

The legal odyssey through cases like *United Therapeutics Corp. v. Liquidia Technologies Inc.*, which reaffirmed the division of responsibilities between patent law and FDA regulation,[474] to *Allgenesis Biotherapeutics Inc. v. Cloudbreak Therapeutics Inc.*, highlighting standing requirements for appeals in inter partes review proceedings,[475] showcases a legal landscape in flux. The past year brought to the forefront the pressing need for clarity on the patentability of diagnostic methods and the nuances of DNA molecule patenting, amidst congressional debates on amending the Patent Act.

Looking forward, there is a palpable sense of anticipation for a harmonious resolution that balances the scales of innovation protection with public interest. The biotechnology sector is on the verge of breakthroughs that promise to redefine our understanding and interaction with the biological world. As we navigate these legal and ethical quandaries, the hope is for a future where patent law not only adapts to but also anticipates the needs of a rapidly evolving biotechnology landscape.

While the courts weave through the genomic sequences of legal precedent and the alchemical mix of biotech patents, one can only hope they find the philosopher's stone of jurisprudence. May their decisions serve as the enzymes that catalyze innovation, not as antibodies that attack it. After all, in the court of biotechnology patent law, it's not just about splitting the DNA double helix of legal and ethical dilemmas, but also about ensuring that innovation and access to it remain in a state of symbiotic coevolution.

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[474] United Therapeutics Corp. v. Liquidia Techs., Inc., 74 F.4th 1360, 1369 (Fed. Cir. 2023).

[475] Allgenesis Biotherapeutics, Inc. v. Cloudbreak Therapeutics, Inc., 85 F.4th 1377, 1381–82 (Fed. Cir. 2023).