An Examination of the Impact of *Chevron*'s Death on Certain Intellectual Property Laws

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INTRODUCTION

A. The Supreme Court's Overruling of *Chevron*

Since the Supreme Court's 1984 *Chevron* decision, in the absence of the clear intent of Congress on a statutory construction, courts were required to defer to "permissible" agency constructions of the statutes those agencies administer.[1] In its June 28, 2024, decision in *Loper*, the Supreme Court overruled *Chevron*.[2] Until *Loper* was decided, even in a situation where a court disagreed with an agency's statutory interpretation, the court was nonetheless required to apply the agency's interpretation, so long as *Chevron* deference applied. Now that *Chevron* has been overruled, courts are no longer bound to agency statutory interpretations with which they disagree. Instead, courts are free to interpret statutes by applying their ordinary toolkit of interpretative canons. In *Loper*, the Supreme Court clarified that its overruling of *Chevron* "do[es] not call into question prior cases that relied on the *Chevron* framework" and further stated that "[t]he holdings of those cases that specific agency actions are lawful . . . are still subject to statutory *stare decisis* despite our change in interpretive methodology."[3]

Naturally, legal practitioners and their clients will wonder how the reverberations of this seismic legal development might reach them. The impact of *Loper* on the interpretation of statutes that the U.S. Patent and Trademark Office (PTO), the U.S. International Trade Commission (ITC), and the U.S. Food and Drug Administration (FDA) are charged with administering is of particular interest to the intellectual property community.

To that end, this article first summarizes the extent to which the PTO, ITC, and FDA were afforded *Chevron* deference on substantive issues of intellectual property law before *Loper*.

Second, this article highlights a few cases in which those agencies were afforded *Chevron* deference on patent law issues but where judges in those cases expressed their disagreement with the agencies' statutory interpretations.

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PRE-*LOPER*

A. PTO

1. The Scope of Chevron *Deference Given to the PTO*

In *Merck v. Kessler*, a panel of the U.S. Court of Appeals for the Federal Circuit declined to give *Chevron* deference to the PTO's "interpretive 'Final Determination' regarding the interrelationship" between the URAA [Uruguay Round Agreements Act] and the Hatch-Waxman Act on the issue of patent term extension.[4] The panel explained that "Congress ha[d] not vested the [PTO] Commissioner with any general substantive rulemaking power. . . ."[5] Thus, *Chevron* deference did not apply. The panel added that "the broadest of the PTO's rulemaking powers – 35 U.S.C. § 6(a) – authorizes the Commissioner to promulgate regulations directed only to 'the conduct of proceedings' in the PTO."[6]

The limited *Chevron* deference historically afforded to the PTO is illustrated in the Federal Circuit's en banc opinions in *Aqua Products*.[7] In *Aqua Products*, despite a fractured en banc court that produced five different opinions, a plurality emerged that stated: "Where Congress has chosen to delegate rulemaking authority by regulation, including in the grant of delegated authority before us today, the exercise of that delegated authority must be through the promulgation of regulations in order to be entitled to *Chevron* deference."[8] Though the PTO had the authority to promulgate rules governing inter partes review proceedings, the plurality determined that the PTO's regulation had not gone

through the "notice-and-comment" rulemaking process and was, thus, not entitled to *Chevron* deference.[9] In doing so, the plurality cited a law review article that observed "that the PTO's powers remain significantly limited, particularly with respect to its ability to bind courts to an agency interpretation of substantive provisions of the Patent Act."[10]

2. Instances in Which the PTO Was Afforded Chevron Deference

a. Cooper Techs.

In *Cooper Techs.*, the Federal Circuit reviewed the PTO's interpretation of the American Inventors Protection Act of 1999 (AIPA).[11] In relevant part, section 4608 of the AIPA makes inter partes reexamination procedure available for "any patent that issues from an *original application* filed in the United States on or after" November 29, 1999 – the date that the AIPA was enacted.[12] The PTO interpreted the phrase "original application" as encompassing "utility, plant, and design applications, including first filed applications, continuations, divisionals, continuations-in-part, continued prosecution applications and the national stage phase of international applications."[13] The Federal Circuit "conclude[d] that the Patent Office had the authority under 35 U.S.C. § 2 to interpret section 4608, because *that interpretation both governs the conduct of proceedings* in the Patent Office, *not matters of substantive patent law*, and is a prospective clarification of ambiguous statutory language."[14] The PTO's interpretive authority under 35 U.S.C. § 2, the panel noted, is generally subject to the requirement set forth in 5 U.S.C. § 553 that "notice of proposed rule making shall be published in the Federal Register. . . ."[15] But as the Federal Circuit noted, "interpretative rules" are exempt from the "notice" requirement, and, therefore, the court concluded that the PTO's "interpretation of 'original application' was therefore not subject to the formal notice-and-comment requirements of section 553."[16] The Federal Circuit then concluded that the PTO's interpretation of the AIPA was entitled to *Chevron* deference "[b]ecause the [PTO] is specifically charged with administering statutory provisions relating to 'the *conduct of proceedings in the Office*. . . ."[17]

b. Eastman Kodak

The Federal Circuit also gave the PTO's Trademark Trial and Appeal Board (Board) *Chevron* deference in a few instances.[18] In an opposition Kodak filed against B & H's trademark application, the Board granted B & H's motion for summary judgment that the applied-for marks were not merely descriptive.[19] "On the issue of mere descriptiveness, the Board stated that it 'believe[s] that it is possible for a numerical designation, which functions only in part to designate a model or grade, to be inherently distinctive and registrable without a showing of secondary meaning.'"[20] Kodak appealed. The Federal Circuit panel identified the "principal issue" before it as "whether the Board's implied creation of a presumption in favor of the applicant for a numerical mark intended for use as more than a model designator is a reasonable interpretation of the Board's authority under the Lanham Act."[21] The panel "h[e]ld that it is."[22]

c. Hacot-Colombier

In *In re Hacot-Colombier*, the Board affirmed an examiner's refusal of Hacot-Colombier's trademark application.[23] Hacot-Colombier filed its application under Section 44(d) of the Trademark Act[24] seeking to rely on the priority date of its French application. The examiner rejected the application, however, finding that the mark in the U.S. application was not a "substantially similar representation" of the mark in the French application.[25] In doing so, the examiner applied a standard set forth in the PTO's regulation[26] in which it interpreted section 44 of the Trademark Act as requiring "the drawing of the trademark [to] be a substantially exact representation of the mark" in the foreign application.[27] Hacot-Colombier appealed, but the Board affirmed the examiner's rejection, and Hacot-Colombier appealed the case to the Federal Circuit. Citing *Chevron* and the Federal Circuit's *Eastman Kodak* case in which it gave *Chevron* deference to the Board's "interpretation of an ambiguous provision of the trademark statute," the panel stated that it "defer[red] to the agency's reasonable statutory interpretation."[28]

d. Kohler

As another example, in *Kohler*, the Seventh Circuit found that it owed *Chevron* deference to the Board's interpretation of Section 45 of the Lanham Act, which is codified at 15 U.S.C. § 1127.[29] There, the Board had "necessarily concluded that § 45 of the [Lanham] Act provides trademark protection

for product configurations."[30] The panel noted that Section 45 of the Lanham Act does not list "product configuration" as an example of a trademark.[31] In assessing whether *Chevron* deference applied, the panel stated that "Congress explicitly granted the Commissioner the duty of administering the Act, including rule making[,]" citing 35 U.S.C. § 6 (1988).[32] Ultimately, the panel applied *Chevron* deference, finding that the Board's interpretation of Section 45 as covering product configurations was a "permissible construction."[33]

3. Cases Where Judges Disagreed with PTO Statutory Interpretations That Were Afforded Chevron Deference

a. Ethicon

In *Ethicon*, the Federal Circuit was confronted with the PTO's interpretation of provisions in the America Invents Act (AIA) regarding who has the authority to determine whether an *inter partes* review should be instituted.[34] Specifically, the AIA gave "the Director" the power to institute such proceedings.[35] The PTO promulgated a regulation allowing "[t]he Board [to] institute[] the [inter partes review proceeding] on behalf of the Director."[36] Writing for the majority, Judge Dyk, joined by Judge Taranto, held that the PTO's rule "is entitled to *Chevron* deference."[37] That was so, the majority wrote, because "[t]he reference to 'the Director' in the statute is ambiguous as to whether it requires her personal participation and the regulation is a permissible interpretation of the statute."[38]

Judge Newman dissented. She noted that the practice of having a single PTAB panel both decide to institute an inter partes review and not only conduct the trial but also make the validity decision "has been criticized by practitioners" concerned about the actual or perceived bias against the patent owner.[39] "It cannot be ignored that this transfer to the Board of the Director's statutory assignment[,]" Judge Newman wrote, "violates the text, structure, and purpose of the America Invents Act."[40]

B. ITC

1. The Scope of Chevron Deference Given to the ITC

Similar to the PTO, the ITC's statutory interpretations on issues relating to substantive issues of patent and trademark law were afforded *Chevron* deference in only limited instances.

2. Instances in Which the ITC Was Afforded Chevron Deference

a. Enercon

In *Enercon*, the Federal Circuit considered the ITC's interpretation of Section 1337(a)(1)(B) of Title 19 of the U.S. Code, which deems unlawful "[t]he importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that infringe a valid and enforceable United States patent."[41]

Specifically, the ITC concluded that the term "sale" in that statute includes contracts for sale within the meaning of Uniform Commercial Code (U.C.C.) § 2-106(1).[42] "The ITC then found that Enercon and NWP had entered into a contract for sale of the E–40 wind turbines, thereby bringing those devices within its jurisdiction under section 337."[43] After its threshold determination that it had jurisdiction on that basis, the ITC entered an exclusion order against Enercon. On appeal, Enercon argued that ITC should have interpreted "sale" more narrowly, as requiring a "delivery" of the goods to the purchaser.[44] Since there was no delivery, Enercon argued, the ITC lacked jurisdiction and its exclusion order should be vacated.[45]

The Federal Circuit disagreed: "The ITC's determination that the phrase 'sale for importation' includes the situation in which a contract for goods has been formed in accordance with section 2–204(1) of the U.C.C. is a reasonable interpretation of 19 U.S.C. § 1337 that we must uphold under the standards set forth by the Supreme Court in *Chevron*."[46]

b. InterDigital

In *InterDigital*, the "domestic industry" requirement of Section 1337(a)(2) and (3) was at issue. Nokia argued that satisfying that statute required InterDigital to establish that there is a U.S. industry "relating to the articles protected by the patent" and further argued that proof of licensing activities, without more, is insufficient to meet that requirement.[47] The administrative law judge disagreed, arguing that the domestic industry requirement can be met based on substantial investment in

the patent's exploitation, including vis-à-vis patent licensing.[48] Writing for the majority, Judge Bryson, joined by Judge Mayer, favored the administrative law judge's interpretation and noted that, "[i]f there were any ambiguity as to whether the statute could be applied to a domestic industry consisting purely of licensing activities, the Commission's consistent interpretation of the statute to reach such an industry would be entitled to deference under the principles" of *Chevron*.[49]

3. Cases Where Judges Disagreed with ITC Interpretations of Statutes That Were Afforded Chevron Deference

a. Suprema

In *Suprema*, the meaning of the phrase "articles that . . . infringe" in Section 337 of the Tariff Act of 1930 (codified at 19 U.S.C. § 1337) was at issue. The ITC interpreted that provision to include the importation of goods that the seller induces the importer to later use to directly infringe after importation.[50] A majority panel of the Federal Circuit disagreed with the ITC and held that there are no "articles that infringe" at the time of importation if direct infringement does not occur until after importation.[51] The Federal Circuit vacated that panel decision and, sitting en banc, "conclude[d] that . . . Section 337 does not answer the question[,]" and held that "the [ITC's] interpretation [wa]s reasonable . . . ."[52] Thus, the majority found that the ITC's interpretation was entitled to *Chevron* deference.[53] Judge O'Malley, joined by Chief Judge Prost and Judges Lourie and Dyk, dissented.[54] The dissent began:

> The majority today authorizes the International Trade Commission ("Commission") to bar the importation of articles of commerce that may or may not be later used by third parties to infringe a method patent, based only on the putative intent of the importer. And, it does so in circumstances in which it is undisputed that the patented method cannot be practiced unless the imported article is used in combination with software neither embedded in the imported article nor sold by the importer. Because 19 U.S.C. § 1337 unambiguously fails to provide the Commission with the authority the majority endows on it, I respectfully dissent.[55]

Therefore, according to the dissent, the ITC's interpretation of Section 337 was not entitled to *Chevron* deference.

C. FDA

1. The Scope of Chevron Deference Given to the FDA

Congress "clearly" delegated authority to the FDA generally to make rules carrying the force of law with respect to "both the FDCA as a whole and the Hatch-Waxman Amendments in particular."[56] For example, the U.S. Court of Appeals for the District of Columbia Circuit "consistently accorded *Chevron* deference to the FDA's letter rulings, including its responses to citizen petitions."[57]

2. Instances in Which the FDA Was Afforded Chevron Deference

a. ViroPharma

In the *ViroPharma* case mentioned in the above paragraph, through its letter ruling denying ViroPharma's citizen petition, the FDA interpreted certain provisions in the Federal Food, Drug, and Cosmetic Act (FFDCA) relating to exclusivity rights.[58] Faced with the FFDCA's use of the phrase "condition of use . . . approved before,"[59] which the FDA deemed ambiguous, the FDA "announced that it would interpret [that provision] 'to permit 3-year Hatch-Waxman exclusivity for Old Antibiotics only for *a significant new use* for an Old Antibiotic . . ., not for refinements in labeling related to previously approved uses for Old Antibiotics.'"[60] The FDA then determined that ViroPharma's drug, Vancocin®, was not eligible for Hatch-Waxman exclusivity because the 2011 approval of ViroPharma's supplemental New Drug Application (sNDA) did not constitute approval of a significant new use for the drug.[61] In response, ViroPharma sued, inter alios, the Food and Drug Administration (FDA), alleging that its approval of three Abbreviated New Drug Applications (ANDAs) violated ViroPharma's statutory right to a three-year period of exclusivity for Vancocin®.[62] The court found that the FDA's interpretation was entitled to *Chevron* deference and rejected ViroPharma's claim on the merits.

3. Cases Where Judges Disagreed with FDA Interpretations of Statutes That Were Afforded Chevron Deference

a. Dr. Reddy's Laboratories

Though courts often found that the FDA's statutory interpretations were entitled to *Chevron* deference, in some cases, courts have signaled that alternative interpretations were also "permissible." One such case was *Dr. Reddy's Laboratories v. Thompson*.[63] Dr. Reddy's Laboratories Ltd. (Reddy) submitted an ANDA to the FDA, seeking to market a generic omeprazole product. The FDA ultimately denied Reddy exclusivity based on its interpretation of the Hatch-Waxman Act.[64] Specifically, Reddy's ANDA included a Paragraph IV certification listing a patent that had already expired by the time the FDA rendered its exclusivity decisions. An FDA regulation requiring that such certifications be kept accurate until the date of final approval formed the basis for the FDA's denial of exclusivity to Reddy.[65] Reddy argued that the FDA erroneously interpreted the term "containing" to mean "continuing to contain."[66] Reddy argued that the FDA's interpretation is contrary to the incentives the Hatch-Waxman Act is intended to create:

> Reddy explains that even if a patent expires before final approval, an ANDA applicant who has submitted a paragraph IV certification on the patent has already incurred the risk and cost of patent litigation. Reddy notes that the incentive operated appropriately in this case because it 'vigorously litigated the validity of the [] patent' before it expired, but court delays prevented trial before the expiration date. Therefore, the phrase at issue must mean an application 'containing' a paragraph IV certification at some time during the approval process, not the time of final approval, else the incentive to ANDA applicants like Reddy is removed.[67]

The court found Reddy's interpretation to be "certainly permissible" but applied the FDA's interpretation, which it likewise found to be permissible, under *Chevron*.[68]

POST-*LOPER*

A. Suprema

In the immediate aftermath of *Loper*, many commentators shined a light on the Federal Circuit's *Suprema* decision, flagging the Commission's interpretation of Section 337 as ripe for the Federal Circuit to revisit after the death of *Chevron*. On September 10, 2024, the Federal Circuit addressed that issue in *Sonos, Inc. v. ITC*.[69]

In that case, Sonos filed a complaint at the ITC alleging that Google was violating Section 337 of the Tariff Act of 1930[70] by importing audio players and controllers that infringed five Sonos patents.[71] The Commission held "that certain originally-accused products infringed each of the asserted patents" but "that certain non-infringing alternatives . . . did not infringe any of the [asserted claims]."[72] On appeal, Google argued inter alia that "the Commission's authority under section 337 'is limited to cases in which the accused articles infringe at the time of importation, and that district courts are the proper forum for allegations of inducing post-importation infringement.'"[73] Judge Stark, joined by Judges Dyk and Reyna, dismissed that argument, explaining that the panel was bound by *Suprema*'s holding to the contrary.[74]

A few days before *Loper* was decided, Google petitioned the Federal Circuit to rehear en banc the *Sonos* case "and reconsider *Suprema* in light of the Supreme Court's guidance in *Loper Bright* . . . ."[75] Google argued that the Commission's interpretation of Section 337, which the majority in *Suprema* afforded *Chevron* deference, is not the best interpretation of the statute.[76] On September 10, 2024, in a per curiam order joined by Chief Judge Moore and Judges Lourie, Dyk, Prost, Reyna, Taranto, Chen, Hughes, Stoll, and Stark, the Federal Circuit denied Google's petition for an en banc rehearing.[77] Thus, *Suprema* remains binding precedent.

B. Bristol-Myers

A recent decision in a case Novartis brought against the FDA is illustrative of an additional category of pre-*Loper* cases – those in which it was unclear whether the court had applied *Chevron* deference to an agency's statutory interpretation or

not.[78] In the case it filed against the FDA, Novartis shined the light on the *Bristol-Myers* case.[79] The *Bristol-Myers* case involved the requirement in the FFDCA, as amended by the Hatch-Waxman Act, that an ANDA applicant must:

> show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug . . . except for changes required because of differences approved under a petition filed under [§ 355(j)(2)(C)] or because the new drug and the listed drug are produced or distributed by different manufacturers.
>
> The FDA's regulation implementing that statutory provision stated:
>
> Labeling (including the container label and package insert) proposed for the new drug product must be the same as the labeling approved for the reference listed drug, except for . . . omission of an indication or other aspect of labeling ... accorded exclusivity under [§ 355(j)(4)(D)].[80]

The court identified the "crux of the dispute" as "whether 21 U.S.C. § 355(j)(2)(A)(v) permits the [FDA] to approve an ANDA for a new generic drug even though the label of the generic product will not include one or more indications that appear on the label of the pioneer drug upon which the ANDA is based."[81] It answered that question in the affirmative.[82] The court cited *Chevron* but did not make clear in its short opinion whether it had, in fact, analyzed whether *Chevron* applied.[83]

Fast-forwarding to its post-*Loper* lawsuit against the FDA, Novartis argued that the D.C. Circuit's longstanding interpretation of 21 U.S.C. § 355(j)(2)(A) as permitting an ANDA to be approved for less than all of the indications for which the listed drug has been approved was not the best reading of the statute.[84] Novartis argued that *Bristol-Myers* "was decided under the outdated *Chevron* rubric, which has now been overturned."[85] The court rejected Novartis's argument, stating that "[i]n *Bristol-Myers Squibb*, the D.C. Circuit relied on its own interpretation of § 355(j)(2)(A)(v), rather than deferring to FDA's reading under *Chevron* step two."[86]

CONCLUSION

Decisions in which the PTO, ITC, and FDA were afforded *Chevron* deference with respect to substantive issues of intellectual property law should be monitored carefully. Those pre-*Loper* decisions in which judges expressed reservations or even outright disagreement with agency interpretations of statutes that were afforded *Chevron* deference may be of particular interest. If and when those interpretations are relitigated, courts may have opportunities to apply what they view as the best statutory interpretations – which may differ from the agencies' statutory interpretations. As the Supreme Court clarified in *Loper*, agencies' pre-*Loper* statutory interpretations are entitled to stare decisis. But how that shakes out will need to be evaluated on a case-by-case basis.

Notes

1. Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984).
2. Loper Bright Enterprises et al. v. Raimondo, Secretary of Commerce, et al., No. 22-451, 144 S. Ct. 2244 (2023).
3. Loper Bright Enterprises, 144 S. Ct. at 2273 (citation omitted).
4. Merck & Co., Inc. v. Kessler, 80 F.3d 1543, 1550 (Fed. Cir. 1996).
5. Id.
6. Id. at 1549.
7. Aqua Products, Inc. v. Matal, 872 F.3d 1290 (Fed. Cir. 2017).
8. Id. at 1331.
9. Id.
10. See John M. Golden, Working Without Chevron: The PTO as Prime Mover, 65 DUKE L.J. 1657, 1691 (2016).
11. Cooper Techs. Co. v. Dudas, 536 F.3d 1330 (Fed. Cir. 2008).
12. Id. at 1331.
13. Id.
14. Id. at 1336 (emphasis added).
15. Id.
16. Id. at 1336-37 (citation omitted).
17. Id. at 1337 (emphasis added) (citing 35 U.S.C. § 2(a)(2)(A)).
18. Eastman Kodak Co. v. Bell & Howell Doc. Mgmt. Products Co., 994 F.2d 1569 (Fed. Cir. 1993).
19. Id. at 1570.
20. Id. at 1571 (citing the Board's decision).
21. Id.
22. Id.

23. In re Hacot-Colombier, 105 F.3d 616, 617 (Fed. Cir. 1997).
24. 15 U.S.C. § 1126(d) (1994).
25. In re Hacot-Colombier, supra.
26. 37 C.F.R. § 2.51(a)(3) (1996).
27. In re Hacot-Colombier, supra, at 618.
28. Id.
29. Kohler Co. v. Moen Inc., 12 F.3d 632 (7th Cir. 1993).
30. Id. at 635.
31. Id.
32. Id. at 636.
33. Id.
34. Ethicon Endo-Surgery, Inc. v. Covidien LP, 812 F.3d 1023, 1028 (Fed. Cir. 2016).
35. See, e.g., 35 U.S.C. § 314(a).
36. See 37 C.F.R. § 42.4(a).
37. Ethicon Endo-Surgery, Inc., 812 F.3d at 1033 (citing Chevron).
38. Id. (citations omitted).
39. Id. at 1038. (citation omitted).
40. Id.
41. Enercon GmbH v. ITC, 151 F.3d 1376, 1381 (Fed. Cir. 1998).
42. Id.
43. Id.
44. Id.
45. Id.
46. Id. at 1383.
47. InterDigital Cmmcn's, LLC v. ITC, 690 F.3d 1318 (Fed. Cir. 2012).
48. Id. at 1329.
49. Id. at 1330 (citations omitted).
50. Suprema, Inc. v. ITC, 796 F.3d 1338, 1340 (Fed. Cir. 2015).
51. Suprema, Inc. v. ITC, 742 F.3d 1350 (Fed. Cir. 2013) (Judge O'Malley writing for the majority, joined by Chief Judge Prost).
52. Suprema, 796. F.3d at 1340-41 (Judges Moore and Stoll did not participate).
53. Id. at 1340.
54. Id. at 1354.
55. Id.
56. Dr. Reddy's Lab'ys, Inc. v. Thompson, 302 F.Supp.2d 340, 349 (D.N.J. Oct. 14, 2003).
57. ViroPharma, Inc. v. Hamburg, 898 F.Supp.2d 1, 18 (D.C. 2012) (citations omitted).
58. ViroPharma, 898 F.Supp.2d 1 (D.C. 2012).
59. 21 U.S.C. § 355(v)(3)(b)).
60. ViroPharma, supra, at 13 (citation omitted).
61. Id. at 13.
62. Id. at 5.
63. Dr. Reddy's Lab'ys, Inc. v., Thompson, 302 F. Supp. 2d 340, 355 (D.N.J. 2003).
64. That statutory exclusivity period would be shared with another ANDA applicant, Andrx Pharmaceuticals, Inc.
65. 21 C.F.R. § 314.94(a)(12)(viii)(C)(1).
66. Dr. Reddy's Lab'ys, 302 F.Supp.2d at 352.
67. Id. at 355 (citation omitted).
68. Id.
69. Sonos, Inc. v. ITC, No. 2022-1421, D.I. 115 (Fed. Cir. Sept. 10, 2024).
70. 19 U.S.C. § 1337.
71. Sonos, Inc. v. ITC, No. 2022-1421, D.I. 90 at 2-3 (Fed. Cir. Apr. 8, 2024).
72. Id. at 3.
73. Id. at 25 (citing Google's brief).
74. Id.
75. Sonos, Inc. v. ITC, No. 2022-1421, D.I. 98 (Fed. Cir. June 24, 2024).
76. Id. at 10.
77. Sonos, Inc. v. ITC, No. 2022-1421, D.I. 115 (Fed. Cir. Sept. 10, 2024).
78. Novartis Pharms. Corp. v. Xavier Becerra et al., No. 24-cv-02234 (DLF), 2024 WL 4492072 (D.C. Oct. 15, 2024).
79. Bristol-Myers Squibb Co. v. Shalala, 91 F.3d 1493 (D.C. Cir. 1996).
80. Id. at 1496 (citing 21 C.F.R. 314.94(a)(8)(iv)).
81. Id. at 1499.
82. Id. at 1499-1500.
83. Id.
84. Novartis Pharms. Corp. v. Xavier Becerra, No. 1:24-cv-022345-DLF, D.I. 42 at 28 (D.C. Sept. 16, 2024).
85. Id.
86. Novartis Pharms., 2024 WL 4492072, at *7 (D.C. Oct. 15, 2024).