

Nos. 23-1512, -1513, -1514

IN THE
United States Court of Appeals
FOR THE FEDERAL CIRCUIT

ALIVECOR, INC.,

Appellant,

v.

APPLE INC.

Appellee.

Appeals from the United States Patent and Trademark Office,
Patent Trial and Appeal Board
Nos. IPR2021-00970, IPR2021-00971, and IPR2021-00972

CORRECTED BRIEF OF *AMICUS CURIAE*
MEDICAL DEVICE MANUFACTURERS ASSOCIATION
IN SUPPORT OF APPELLANT AND REVERSAL

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August 17, 2023

CERTIFICATE OF INTEREST

Pursuant to Fed. Cir. R. 47.4 and Fed. R. App. P. 26.1, counsel for *Amicus Curiae* Medical Device Manufacturers Association certifies the following:

1. Provide the full names of all entities represented by undersigned counsel in this case:

Medical Device Manufacturers Association.

2. Provide the full names of all real parties in interest for the entities.

Do not list the real parties if they are the same as the entities

None/Not Applicable.

3. Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities.

None.

4. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities:

*

5. Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

*

6. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees).

None.

Respectfully submitted,

Date: August 17, 2023

By: /s/ David Balto

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STATEMENT OF INTEREST OF *AMICUS CURIAE*

The Medical Device Manufacturers Association (“MDMA”) is a national trade association based in Washington, D.C., providing educational and advocacy assistance to innovative and entrepreneurial medical technology companies.¹ Since 1992, MDMA has been the voice for smaller companies, playing a proactive role in helping to shape policies that impact the medical device innovator. MDMA’s mission is to promote public health and improve patient care through the advocacy of innovative, research-driven medical device technology.

SUMMARY OF THE ARGUMENT

Amicus MDMA submits this brief in support of appellant AliveCor, Inc. (“AliveCor”) with regard to the third question raised by AliveCor: “Whether the Board’s decisions should be vacated where Apple withheld evidence of secondary indicia of non-obviousness despite its obligation under Board rules to produce evidence inconsistent with its position that the AliveCor patents are obvious.”

¹ In accordance with Federal Rule of Appellate Procedure 29(c)(4) and (5), MDMA states that Appellant consents to the filing of this brief and that Appellee takes no position, and MDMA states that no party’s counsel in this matter authored this brief in whole or in part; no party or party’s counsel contributed money intended to fund preparing or submitting this brief; and no person, other than the *amicus curiae* or its counsel, contributed money that was intended to fund preparing or submitting this brief.

MDMA writes to provide context on the third question that may not be apparent from AliveCor's brief.

The issue of agencies considering different and incomplete evidence to reach conflicting results on the same issues is one of national concern, including for medical device manufacturers and others that assert and defend against patents. Consistent and informed agency decision-making is vital to commerce.

Strategic reliance on protective orders to withhold evidence undermines consistent and informed agency decision-making. A party's reliance on a protective order to withhold such evidence raises particular concerns because opposing parties risk being accused of violating a protective order by merely requesting such discovery in another forum.

For these reasons, compliance with and enforcement of 37 C.F.R. § 42.51(b)(1)(iii) and the duty of candor and good faith are particularly important. 37 C.F.R. § 42.51(b)(1)(iii) requires that a party produce "relevant information that is inconsistent with a position advanced by the party during the proceeding concurrent with the filing of the documents or things that contains the inconsistency." The fact that the "information may be business confidential ... does not shield it from routine discovery." *Aker Biomarine AS v. Neptune*, IPR2014-00003, Paper 93 (PTAB Oct. 6, 2014), at 6.

Accordingly, *Amicus* MDMA respectfully submits that this Court should vacate the PTAB's decisions and remand for consideration of the evidence relied on by the ITC to reach a different conclusion. This Court should emphasize the importance of 37 C.F.R. § 42.51(b)(1)(iii) and the duty of candor and good faith in IPR proceedings. The Court should strongly caution parties to comply with their obligations to produce evidence they understand another may argue is conflicting.

ARGUMENT

I. CONSISTENT AND INFORMED AGENCY DECISION-MAKING IS VITAL TO COMMERCE

Consistent decision-making is vital to reliance interests in commerce. Indeed, consistency avoids the arbitrary and capricious decision-making forbidden by statute. *See* 5 U.S.C. § 706(2)(A). “The [Administrative Procedure Act] is structured to ensure predictability and protect reliance interests....” *William Beaumont Hospital - Royal Oak v. Price*, 455 F. Supp. 3d 432,447 (E.D. Mich. 2020). “[A]gencies are subject to the requirement that they not act arbitrarily or capriciously, see 5 U.S.C. s 706(2)(A) (1976), and have an obligation to render consistent opinions....” *Chisholm v. Defense Logistics Agency*, 656 F.2d 42, 47 (3d Cir. 1981). Consistency is important to “certainty of affairs,” *id.* at 46; *see also Kimble v. Marvel Entm't, LLC*, 576 U.S. 446, 455 (2015) (consistent

decision-making is a “foundation stone of the rule of law” because it provides predictability and respects reliance interests).

Informed decision-making is equally important to commerce. “The function of the court is to assure that the agency has given reasoned consideration to all the material facts and issues.” *Greater Boston Television Corp. v. FCC*, 444 F.2d 841, 851 (D.C. Cir. 1970). Insisting that an agency consider all material facts promotes consistency because it ensures the “agency’s policies effectuate general standards, applied without unreasonable discrimination.” *Id.* “The importance of reasoned decision-making in an agency action cannot be over-emphasized. When an agency ... is vested with discretion to impose restrictions on an entity’s freedom to conduct its business, the agency must exercise that discretion in a well-reasoned, consistent, and evenhanded manner.” *Greyhound Corp. v. ICC*, 668 F.2d 1354, 1359 (D.C. Cir. 1981).

When a party strategically withholds relevant evidence from an agency, the resulting decision may be just as uninformed, arbitrary and capricious as a decision resulting from agency refusing to consider submitted evidence. The resulting decision disrupts the predictability and consistency of agency action. In its appeal, AliveCor alleges that Apple withheld from the USPTO the evidence the USITC relied on to reach an inconsistent result. Such actions undermine the predictability and informed decision-making of such agencies. *See Kingman Reef*

Atoll Dev., L.L.C. v. United States, 116 Fed. Cl. 708, 766 (2014) (“different agencies within the federal government [taking] inconsistent positions” is not “good practice”); see *In re Baxter Int’l, Inc.*, 678 F.3d 1357, 1365 (Fed. Cir. 2012) (“the PTO ideally should not arrive at a different conclusion” from a court); *Novartis AG v. Noven Pharms. Inc.*, 853 F.3d 1289, 1294 (Fed. Cir. 2017) (“It is unsurprising that different records [at the USPTO] may lead to different findings and conclusions.”).

That Apple allegedly relied on a protective order to withhold documents is of no moment. As discussed below, protective orders are intended to protect the publication of confidential business information, not withhold relevant evidence from decision-makers. Reliance on protective orders to selectively provide evidence to various agencies undermines consistency and ignores the widely recognized “connection between reliable and predictable IP rights and more innovation, job creation, and overall economic growth.” See Remarks by Director Iancu at the U.S. Chamber of Commerce Event “How Innovation and Creativity Drive American Competitiveness” (Jan. 19, 2021).²

² Available at <https://www.uspto.gov/about-us/news-updates/remarks-director-iancu-us-chamber-commerce-event-how-innovation-and/>.

II. WITHHOLDING EVIDENCE UNDERMINES CONSISTENT & INFORMED AGENCY DECISION-MAKING

Protective orders are designed to protect parties' confidential and sensitive business information from public disclosure. To avoid the improper use of such confidential information, protective orders typically require that designated information be used for that particular litigation only.

Unfortunately, some parties use such provisions to resist disclosing relevant information in separate litigations. Such withholding of information does not further the purpose of protecting sensitive information from public disclosure. Instead, such tactics undermine the orderly administration of justice. *See, e.g., Halo Elecs., Inc. v. XFMRS, Inc.*, 2012 WL 2238022, at *1, *3 (N.D. Cal. June 15, 2012) (prohibiting use of discovery in another case could “deprive plaintiff of an opportunity to meaningfully impeach” witness).

Strategic withholding of evidence under a protective order is particularly problematic if the withholding party argues that merely reflecting on or requesting such evidence in another case violates the protective order. AliveCor asserts that Apple made that very argument in this case. As a result, the Board did not have a complete record to examine obviousness. Dkt. 17 at 59. The Board thus issued an uninformed decision that is just as arbitrary and capricious as a decision where the Board refuses to consider such evidence.

MDMA members have repeatedly encountered the issue of an opposing party withholding relevant discovery, including parties withholding ITC information during proceedings at the USPTO. This problem is likely to be vastly unreported because of threats that even requesting discovery subject to a protective order would violate that order. Indeed, courts have sanctioned attorneys for using information subject to a protective order in another proceeding. *See, e.g., Errant Gene Therapeutics, LLC v. Sloan-Kettering Institute for Cancer Research*, 2017 WL 2418742 at *3 (S.D.N.Y. June 5, 2017) (“SKI argues that use of protected information alone, even without disclosure, is a violation of the Protective Order. The Court agrees. Courts in this District have found violations of similar protective orders where a party used protected information in another action.”) (internal citations omitted).³ The USPTO may also discipline an attorney for such conduct. *See In the Matter of Janka*, Proceeding No. D2011-57 (USPTO Dir. Nov. 21, 2011) (disciplining attorney for

³ *See For Your Eyes Only: IP Atty’s Who Misuse Confidential Documents Face Sanctions, Discipline*, available at <https://ipethicslaw.com/for-your-eyes-only-ip-attys-who-misuse-confidential-documents-face-sanctions-discipline/>

submitting documents subject to court protective order); *In the Matter of Bollman*, Proceeding No. D2010-40 (USPTO Dir. Oct. 19, 2011) (same).⁴

The issue of protective orders limiting discovery may be particularly significant when it comes to evidence of secondary considerations. Such evidence, in particular, is important to avoid inconsistent opinions. Yet such evidence may be produced only in a district court proceeding due to comparably broader discovery rules in district court. At least one district court has relied on evidence of secondary considerations to issue a preliminary injunction despite a PTAB final written decision of invalidity. *See, e.g., Liqwd, Inc. v. L'Oreal USA, Inc.*, 2019 WL 1873281, at *3, *4 (D. Del. Apr. 26, 2019). This Court later vacated the PTAB decision of invalidity based on secondary considerations. *See Liqwd, Inc. v. L'Oreal USA, Inc.*, 941 F.3d 1133, 1139 (Fed. Cir. 2019). This Court has similarly affirmed a preliminary injunction despite the PTAB's final written decision of indefiniteness. *See Tinnus Enterprises, LLC v. Telebrands Corp.*, 846 F.3d 1190, 1202 & n.7 (Fed. Cir. 2017); *see also Tinnus Enterprises, LLC v. Telebrands Corp.*, 733 Fed. App'x 1011, 1021 (Fed. Cir. May 30, 2018)

⁴ *See* PTAB And District Court Litigators Risk USPTO Ethical Discipline For Protective Order Violations, *available at* <https://ipethicslaw.com/ptab-and-district-court-litigators-risk-uspto-ethical-discipline-for-protective-order-violations/>

(later reversing PTAB decision). Incomplete discovery at the PTAB creates a substantial risk of inconsistent decisions between the PTAB, other agencies, and the courts.

III. THE COURT SHOULD MAKE CLEAR THAT THE DUTY OF CANDOR AND GOOD FAITH AND 37 C.F.R. § 42.51(B)(1)(III) MANDATES THAT PARTIES MUST VOLUNTARILY DISCLOSE TO THE PTAB ALL ARGUABLY CONFLICTING EVIDENCE.

To address the problems discussed above, the Court should emphasize the importance of 37 C.F.R. § 42.51(b)(1)(iii) and the duty of candor and good faith in IPR proceedings. The Court should make clear that the duty of candor applies to petitioners, and that this duty mandates disclosure of any and all conflicting evidence.

Title 37 C.F.R. § 42.51(b)(1)(iii) provides that “a party must serve relevant information that is inconsistent with a position advanced by the party during the proceeding concurrent with the filing of the documents or things that contains the inconsistency.” As AliveCor explains, the fact that the “information may be business confidential ... does not shield it from routine discovery.” *Aker Biomarine AS v. Neptune*, IPR2014-00003, Paper 93 at 6 (PTAB Oct. 6, 2014). Further, as AliveCor explains, this obligation is “self-executing and self-enforcing.” *See BlackBerry Corp. v. Wi-Lan USA Inc.*, IPR2013-00126, Paper 15 at 2 (PTAB Aug. 19, 2013).

That relevant information is subject to a protective order in another litigation is no reason to withhold the evidence from the USPTO. *See Olympic Refining Co. v. Carter*, 332 F.2d 260, 265 (9th Cir. 1964) (no “rule or statute called to our attention, authorizes a district court to protect” confidential information from “disclosure as is relevant to the subject matter involved in a pending action”); *Carter–Wallace, Inc. v. Hartz Mountain Indus.*, 92 F.R.D. 67, 69 (S.D.N.Y. 1981) (finding no case law “support[ing] the absurd tenet that a party can avoid discovery in one case merely because it disclosed the same material to an adversary bound by a protective order in another case”). Indeed, the USPTO should be required to consider information considered by another agency on overlapping issues for consistency and predictability.

Parties also have a “duty of candor and good faith to the” Board. *L’Oreal USA, Inc. v. Liqwd, Inc.*, PGR2017-00012, Paper 37 at 13 (PTAB Sept. 27, 2017). Thus, “hiding relevant information within the scope of 37 C.F.R. § 42.51(b)(1)(iii) is improper.” *Id.* As Alivecor explains, the Board has recently imposed sanctions on a party for withholding evidence inconsistent with its arguments. *Spectrum Solutions LLC v. Longhorn Vaccines & Diagnostics, LLC*, IPR2021-00847, Paper 113 at 48-49 (PTAB May 3, 2023).

Emphasizing the importance of 37 C.F.R. § 42.51(b)(1)(iii) and the duty of candor and good faith would help ensure that agencies have the evidence

necessary to ensure informed agency decision-making that is predictable rather than arbitrary and capricious. Doing so here would make clear that parties cannot escape the consequences of violating these rules even if the malfeasance is not discovered until later, including on appeal.

Declining to address this issue encourages the type of malfeasance apparent here. AliveCor alleges that Apple threatened that even referencing or requesting discovery from the ITC would violate the relevant protective order. A party should not have to request such evidence in the first place—the withholding party should have voluntarily produced the evidence under 37 C.F.R. §§ 42.51(b)(1)(iii) and the duty of candor and good faith. Litigants should be on notice that the failure to produce the relevant evidence may undermine a subsequent favorable decision. Such an approach would help prevent gamesmanship from withholding evidence. Courts have not hesitated to adopt policies to ensure that “neither party is withholding evidence unfavorable to its position” before an agency. *See County of San Miguel v. Kempthorne*, 587 F. Supp. 2d 64, 71 (D.D.C. 2008).

Courts have also long invoked equitable principles to decline to enforce Patent Office decisions resulting from withholding relevant information. *See, e.g., Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240, 243 (1933) (affirming appeals court’s decision declining to enforce PTO-issued patent where patentee knew of “a possible prior use” by a third party before filing a patent

application but did not inform the PTO); *see also Shepley v. Cowan*, 91 U.S. 330, 340 (1875) (“If [Land Department officers] err in the construction of the law applicable to any case, or if fraud is practiced upon them, or they themselves are chargeable with fraudulent practices, their rulings may be reviewed and annulled by the courts when a controversy arises between private parties founded upon their decisions.”).

Here, the appropriate and equitable course of action would be, at a minimum, vacatur of the PTAB’s decisions and remand for consideration of the evidence relied on by the ITC to reach a different conclusion. *See Columbus Bd. of Educ. v. Penick*, 443 U.S. 449, 465 (1979) (“[T]he remedy imposed by a court of equity should be commensurate with the violation”).

CONCLUSION

For the reasons discussed above, this Court should vacate the PTAB’s decisions and remand for consideration of the evidence relied on by the ITC to reach a different conclusion.

Respectfully submitted,

Date: August 17, 2023

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B). This brief contains 2,410 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). This Brief has been prepared in a proportionally spaced typeface using Microsoft Word 2010 in Times New Roman 14-point font.

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