

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE

PATENT TRIAL AND APPEAL BOARD

VITAL CONNECT, INC.

Petitioner

v.

BARDY DIAGNOSTICS, INC.

Patent Owner

U.S. Patent No. 11,051,743
Original Issue Date: Jul. 6, 2021
Title: ELECTROCARDIOGRAPHY PATCH

Case No. IPR2023-00381

**PETITIONER'S REQUEST FOR DIRECTOR REVIEW OF DECISION
DENYING INSTITUTION OF *INTER PARTES* REVIEW
OF U.S. PATENT NO. 11,051,743
PURSUANT TO THE INTERIM DIRECTOR REVIEW PROCESS**

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I. INTRODUCTION

Petitioner Vital Connect, Inc. (“**VitalConnect**”) respectfully submits this Request for Director Review of the Decision Denying Institution of *inter partes* review (“**IPR**”) of Patent No. 11,051,743 (“the ’743 patent”), issued July 11, 2023. Paper 7 (“Decision”). The Director should grant review because the Decision is based on legal error and reflects an abuse of discretion.

The Director should review the Board’s abuse of discretion in requiring *pro forma* language to avoid a discretionary denial under 35 U.S.C. § 325(d) here where Patent Owner merely showed three references relied on in the petition were listed among (or similar to) three of hundreds of prior art references cited in Information Disclosure Statements (IDSs) by applicant. It is undisputed that the challenged patent’s prosecution history before the Office lacks any record of substantive prior art discussions or reasons for patentability. The Board’s approach here puts it directly at odds with a substantive factual showing required by, for example, *Becton, Dickinson*, which expressly noted in exercising discretionary denial that “[t]his is not a case where the prior art was simply listed in an IDS during prosecution.” *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 at 23 (Dec. 15, 2017).

The present Decision highlights the Board’s misapplication of the § 325(d) discretionary denial standard because it solely relied on the fact that the Petition

purportedly presented art merely made of record. Paper 7 at 2. It is undisputed that the Petition explicitly detailed that the Examiner overlooked *all* prior art references because the Examiner never discussed *any* prior art references, much less a combination of references during prosecution. *Id.* Indeed, the Examiner did not even provide reasons for allowance. Petition at 12 (citing the File History at 15). In other words, ***there was no substantive prior art analysis at all.***

Patent Owner does not suggest otherwise and made no arguments that the substantive grounds in the Petition were cumulative over the patentability issues previously considered by the Office.¹ In fact, Patent Owner made no arguments as to how its claims distinguished over the prior art *at all*. To the contrary, based on the strength of the Petition, Patent Owner filed a statutory disclaimer of claims 1-10 of the subject patent. Ex. 2003.

Rather than presenting a substantive prior art dispute, Patent Owner relied solely on the superficial allegation that the prior art in the Petition was the same or similar to three (3) prior art references cited in an information disclosure statement (IDS) and listed among the over 500 references cited on the face of the '743 patent. Paper 6 at 10-12. Neither Patent Owner nor the Board contends that the references

¹ In fact, Patent Owner instead filed a statutory disclaimer of broader claims 1-10. Ex. 2003.

were substantively discussed or considered by the Examiner—because they were not.

The Board’s denial of institution, because the Petition purportedly failed to identify material error in the Office’s consideration of the allegedly same or similar prior art references, is contrary to law and an abuse of discretion because the Petition expressly confirmed that the Office provided no consideration of *any prior art* references. Petition at 11. Accordingly, Director Review is respectfully requested.

II. RELEVANT LAW

A. Standard Of Review

The revised interim Director Review process authorizes Director Review of the Board’s decision whether to institute trial, limited to decisions presenting (a) an abuse of discretion or (b) important issues of law or policy. “An abuse of discretion occurs where the decision is based on an erroneous interpretation of the law, on actual findings that are not supported by substantial evidence, or represents an unreasonable judgement in weighing relevant factors.” *Star Fruits S.N.C. v. United States*, 393 F.3d 1277, 1281 (Fed. Cir. 2005) (citing *Arnold P’Ship v. Dudas*, 362 F.3d 1338, 1340 (Fed. Cir. 2004)); *see also* 37 C.F.R. § 42.71(c). The party requesting rehearing “must specifically identify all matters [it] believes the

Board misapprehended or overlooked, and the place where each matter was previously addressed.” 37 C.F.R. § 42.71(d).

B. Discretionary Denial Under § 325(d) And Art/Arguments Previously Presented To The Office

Section 325(d) permits discretionary denial where “the same or substantially the same prior art or arguments were previously presented to the Office.”

The focus of § 325(d) is “a commitment to defer to previous Office *evaluations*² of the evidence of record.” *Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 9 (PTAB Feb. 13, 2020) (precedential) (*Advanced Bionics*). But, the Board’s decisions make clear that this is not blind deference and recognize the need to focus on the substance of what the Office previously considered. *Advanced Bionics* characterizes this as presenting “challenging factual questions, such as when a ground of unpatentability presents ‘substantially the same prior art or arguments.’” *Id.*

The characterization of this aspect of § 325(d) as presenting “challenging factual questions” assumes a normal prosecution footing with a record of the Office engaging in a prior art analysis. This typically creates an extensive factual record, including the Examiner providing reasoned rejections of the claims over prior art, the applicant responding, and the Examiner articulating how the claimed

² All emphasis added and citations omitted, unless stated otherwise.

invention differs from the prior art. Consistent with this, *Advanced Bionics* highlights a focus on the material substance of the Office’s analysis as set forth in the non-exclusive *Becton, Dickinson* factors, which all center around the substantive evaluation during prosecution. *See Becton, Dickinson*, Paper 8 at 17–18 ((a) similarities/differences related to “the prior art *involved during examination*;” (b) cumulativeness of “the prior art *evaluated during examination*;” (c) the extent to which the art “was *evaluated during examination*;” (d) overlap with “the *arguments made during examination*”; (e) how “the *examiner erred in its evaluation of the asserted prior art*.”); *see also, Advanced Bionics*, Paper 6 at 8 (“the Board’s decisions generally have required a showing that the Office erred in *evaluating the art or arguments*.”).

Indeed, the facts in both *Becton, Dickinson* and *Advanced Bionics* involved a comparison of the specific patentability arguments considered by the Office during prosecution and compared those to the arguments presented in the subject petitions. *Becton, Dickinson*, Paper 8 at 18-24 (analyzing prior art that was “substantively evaluated by the Examiner” during prosecution to find that “rearranging ***previously substantively considered prior art***, and advancing essentially the same positions raised by the Examiner during prosecution of the parent application” does not present “new evidence of unpatentability that was not evaluated previously by the Office.”); *Advanced Bionics*, Paper 6 at 11-19

(reviewing “whether Petitioner relies on [a new prior art reference] *in substantially the same manner* as the Examiner cited [a similar prior art reference] during prosecution such that [the new prior art reference] discloses substantially the same information as the similar prior art reference in relevant part.”). And *Becton, Dickinson* expressly made clear “[t]his is not a case where the prior art was simply listed in an IDS during prosecution.” *Becton, Dickinson*, Paper 8 at 23.

III. ARGUMENT

The Board abused its discretion and committed legal error when it denied the current Petition for relying on prior art that was merely listed (or similar to art listed) on the face of the '743 patent among over 500 other references. Decision, 2. This is particularly true here where the Office did not substantively reject the pending application over *any* prior art and there were no substantive reasons for allowance provided. Indeed, the Patent Owner does not identify any substantive analysis considered by the Office that the Petition Grounds were supposedly cumulative over. Rather, the Patent Owner disclaimed the patentability of some claims in response to the Petition. It is contrary to the law to accept the Board's position that merely listing a reference on the face of the patent—with nothing more—affirmatively requires the Petitioner to do more than point out the Office's lack of prior art analysis to overcome a § 325(d) discretionary denial. This merely introduces a non-substantive formality absent from the statute.

A. Discretionary Denial Under § 325(d) Requires More Than A Showing Of Prior Art Being Listed On An IDS

Patent Owner does not argue that grounds in the Petition were substantively similar to any arguments or basis for patentability addressed during prosecution of the '743 patent. This is because Patent Owner cannot do so, because it is also undisputed that there was no substantive patentability analysis performed during the prosecution of the '743 patent.

Rather than showing some substantive resemblance between the grounds in the Petition and the Office's analysis during prosecution, Patent Owner merely argued that the three references relied on in the grounds were similar to three of the five hundred plus references listed in IDSs and dumped by Patent Owner on the Office during prosecution.³ Paper 6, 10-12 (comparing the art applied in the grounds to specific art cited on the face of the patent, but not comparing either to the '743 patent claims).

The Board erred in reading *Advanced Bionics* as allegedly equating “previously presented art” to “art made of record by the Examiner” and nothing

³ Specifically, for these three references, Patent Owner argues that “*Oster* was presented to the Office via an IDS” and, admits that both *Yang* and *Mazar* were not before the Office during examination of the '743 Patent, but that Yang's parent and other patents issued to Mazar were listed on an IDS.

more. Decision, 14 (citing *Advanced Bionics*, 7-8). However, *Advanced Bionics* did not conclude that each one of hundreds of references commonly listed in IDSs immediately qualifies as “previously presented art” for purposes of discretionary denial under § 325(d). Instead, *Advanced Bionics* only exemplified that previously presented art can include art cited by both the Examiner *or* the applicant during prosecution. *Advanced Bionics*, 7-8. In other words, *Advanced Bionics* does not immediately disqualify thousands of prior art references that may be similar to any reference listed on an IDS—whether presented by an Examiner or applicant— independent of any showing of substantive analysis, or relevance of such art in the record.

To hold otherwise is completely at odds with *Advanced Bionics* and *Becton, Dickinson*, which emphasize that denial under § 325(d) requires a substantive factual analysis and showing that the grounds rehash issues already substantively addressed by the Office. Indeed, the Board has rejected superficial requests for § 325(d) denials like those put forth by Patent Owner. For example, in *Facebook, Inc. and Whatsapp Inc. v. Uniloc USA, Inc. and Uniloc Luxembourg, S.A.*, IPR2016-01756, Paper 36 at 6-7 (PTAB June 11, 2020):

Patent Owner argues that [the prior art] “should be rejected as cumulative” because the Examiner signed and dated an Information Disclosure Statement (“IDS”) that includes [the prior art].... However, Patent Owner neither identifies, on those pages, that with which [the

prior art] allegedly is “cumulative” nor how the fact that [the prior art] appears on an IDS impacts an analysis of patentability.... [W]e are not persuaded that we should exercise such discretion [for denial of institution under 35 U.S.C. § 325(d)]. Patent Owner does not point to any substantive discussion of [the prior art] by the Examiner or a consideration by the Examiner of the same or substantially the same analysis of [the prior art] presented in the Petition.

See also Maplebear Inc. v. Consumeron, LLC, No. IPR2022-01358, 2023 WL 2602371, at *4 (PTAB Mar. 3, 2023); *Fellowes, Inc. v. Treefrog Devs., Inc.*, No. IPR2020-01435, 2021 WL 707179, at *9 (PTAB Feb. 22, 2021) (“[T]he record is not sufficiently clear as to the extent the asserted prior art was meaningfully considered during examination. However, the obvious materiality of [the prior art]... and the absence of its use as a basis for rejection, suggests that it was not sufficiently considered during examination of the claims.”).

The Patent Owner cannot then meet their burden of showing that the same or substantially the same art previously was presented to the Office by merely showing that a reference was listed on an IDS. As before, *Becton, Dickinson* expressly distinguished factual scenarios where prior art is merely listed in an IDS during prosecution. *Becton, Dickinson*, Paper 8 at 23 (“***This is not a case where the prior art was simply listed in an IDS during prosecution.***”). And this situation is completely unlike *Becton, Dickinson* and *Advanced Bionics* where the

prior art relied on by the Petitioner was considered *and distinguished* during prosecution of the subject application. *Becton, Dickinson*, Paper 8 at 18-24; *Advanced*, Paper 6 at 11-19.

Thus, each of these cases provided prior art evaluations performed by the Office that warranted analysis under the *Becton, Dickinson* factors. In fact, the *Becton, Dickinson* factors call for an analysis of the record of what was “evaluated” during prosecution, including how the art in the petition overlaps with arguments made during the prosecution. *Becton, Dickinson*, Paper 8 at 17-18. But that sort of analysis is simply inapplicable here, where, as stated in the Petition, there was no prior art arguments by the Office to evaluate.

B. The Petition Demonstrated That The Prior Art and Grounds Presented Were Not Previously Considered By the Office

The Petition accurately stated that *no ground* presented by the Petition was previously considered by the Office and that the analysis in the Petition demonstrated that the challenged claims were unpatentable. Petition at 6. The Petition further summarized why the grounds of the Petition were strong and then later detailed those grounds at length. Petition at 17-82.⁴

⁴ The Petition also relied upon the Declaration of Dr. Joseph Akar, which was not previously before the Office. Ex. 1002. *Cont'l Auto. Sys., Inc. v. Horizon Glob.*

The Petition expressly explained the prosecution history, including the fact that the '743 patent faced no prior art rejections or substantive analysis related to patentability over the prior art. Petition, 11-12. The application for the '743 patent was allowed after a single Office Action, which single Office Action only raised a double patenting rejection over its parent, which was overcome by filing a Terminal Disclaimer. *Id.*

In other words, the Petition established that the Examiner overlooked the prior art, which was merely listed among hundreds of references identified in IDSs, and that the Examiner *never discussed the references at issue or any references*, much less the obviousness combination of the references presented in the Petition. *See, Becton, Dickinson* at 23 (finding that the prior art at issue were considered and that it was “*not a case where the prior art was simply listed in an IDS during prosecution.*”)

The Petition further highlights that the Examiner—rather than explaining any purported novelty of the '743 patent claims—only reasoned that a skilled artisan would recognize certain features as obvious in allowing the claims over its parent and requesting a Terminal Disclaimer. Petition, 11-12. The Petition also

Americas Inc., No. IPR2021-00322, 2021 WL 2183080, at *7 (PTAB May 28, 2021).

cited the Notice of Allowance, which failed to state how the claims distinguished over the prior art. *Id.*, 12 (citing Ex. 1007 at 15). To put it another way, the Petition sufficiently demonstrated that the error made by the Office was that there was no prior art analysis whatsoever. As such, there was simply no analysis or reasoning by the Office to compare and contrast against the current grounds in the Petition.

The Board misreads *Advanced Bionics* as requiring some formulaic statement even here where there is no analysis whatsoever to consider. This is erroneous because ultimately the statutory requirements of § 325(d) control, which have no such requirement. Moreover, *Advanced Bionics* emphasizes that the framework provided therein is non-exclusive and, ultimately, the issue to be determined is the factual analysis of the similarities between the prosecution issues and the grounds. The Board's assertion that something more was needed beyond the Petition's discussion of the prosecution history and the unrebutted fact that no prior art analysis was preformed misapplies *Advanced Bionics*, as this misapplication merely elevates form over substance.

Contrary to the Board's position that "there are no 'magic words' necessary to address material error" (Decision, 20), the facts here show "magic words" are exactly what the Board was looking for. As detailed at length above, the Petition expressly showed that there was no basis for patentability to analyze, and neither

the Patent Owner nor the Board identified any substantive patentability issues that were presented by the Office.⁵ Indeed, not only was Patent Owner unable to identify any substantive issues where the Petition’s grounds conflicted with the prosecution history, but it acknowledged the substantive strength of the grounds by disclaiming issued claims of the ‘743 patent in response to the Petition. As such, the Board could only have been calling for the Petition to somehow further prove the negative (*i.e.*, there was no evaluation by the Office to analyze), which is unreasonable. Otherwise, the Board was looking for the Petitioner to formulaically repeat its statement that there was nothing to rebut. This approach is completely at odds with purpose of the § 325(d) as articulated in *Advanced Bionics* and *Becton, Dickinson*.

Advanced Bionics does caution that “[i]f reasonable minds can disagree regarding the purported treatment of the art or arguments, it cannot be said that the Office erred in a manner material to patentability.” Decision, 19 (citing *Advanced Bionics* 6, 9). But this only emphasizes the error here. Reasonable minds must agree that a silent record does not evidence any prior treatment of the art or

⁵ The Board suggests it is “unclear why Petitioner did not allege an error and/or substantively address 325(d) in its Petition” (Decision, 19). But it is clear the Petition did allege—short of any “magic words” that the “Examiner erred”—that the Office overlooked *all* prior art by not discussing *any* prior art reference.

arguments. In other words, the material error by the Examiner in its evaluation of the asserted art is clear from the record, and particularly the lack thereof.

IV. CONCLUSION

Advanced Bionics confirms that the focus of § 325(d) is “a commitment to defer to previous Office *evaluations* of the evidence of record.” *Advanced Bionics*, Paper 6 at 9. In other words, in an effort to promote judicial efficiency, § 325(d) requires a challenging fact-intensive analysis to determine whether a ground of unpatentability presents substantially the same prior art or arguments. *Becton, Dickinson* substantiates this requirement of discretionary denial under § 325(d) by distinguishing cases where prior art was simply listed on an IDS. The Board’s Decision here does just the opposite.

But, even assuming that the Patent Owner met their burden in establishing that the same or substantially the same art or arguments were previously presented to the Office—which they did not—to require Petitioner to somehow further prove the negative in cases where there was no prior art analysis is impractical and a waste of judicial resources. For the foregoing reasons, Petitioner respectfully requests that the Director review and institute IPR of the ’743 patent.

Date: August 10, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies that a true and correct copy of Petitioner's Request for Director Review was served in its entirety on August 10, 2023, via electronic mail, on Patent Owner's counsel of record to:

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