

**United States Court of Appeals
for the Federal Circuit**

ULRICH SPECK, BRUNO SCHELLER,
Appellants

v.

**BRIAN L. BATES, ANTHONY O. RAGHEB, JOSEPH
M. STEWART, IV, WILLIAM J. BOURDEAU, BRIAN
D. CHOULES, JAMES D. PURDY, NEAL E.
FEARNOT,**
Appellees

2023-1147

Appeal from the United States Patent and Trademark
Office, Patent Trial and Appeal Board in No. 106,125.

Decided: May 23, 2024

BRITTANY BLUEITT AMADI, Wilmer Cutler Pickering
Hale and Dorr LLP, Washington, DC, argued for appel-
lants. Also represented by GARY M. FOX; MARK
CHRISTOPHER FLEMING, Boston, MA; BRYAN PATRICK
COLLINS, Pillsbury Winthrop Shaw Pittman LLP, McLean,
VA.

BLAKE ROBERT HARTZ, Woodard, Emhardt, Henry,
Reeves & Wanger, LLP, Indianapolis, IN, argued for appel-
lees.

Before DYK, BRYSON, and STOLL, *Circuit Judges*.

Dyk, *Circuit Judge*.

Ulrich Speck and Bruno Scheller (collectively, “Speck”) appeal from a Patent and Trademark Office (“PTO”) Patent Trial and Appeals Board (“Board”) final judgment in Interference No. 106,125, which entered judgment for Brian L. Bates, Anthony O. Ragheb, Joseph M. Stewart IV, William J. Bourdeau, Brian D. Choules, James D. Purdy, and Neal E. Fearnot (collectively, “Bates”) on the issue of priority.

The interference proceeding concerned U.S. Patent Application No. 14/013,591 (“’591 application”), owned by Bates (the senior party), and U.S. Patent No. 8,257,305 (“’305 patent”), owned by Speck (the junior party). In the interference proceeding, Speck filed two motions relevant to its appeal. Speck argued (1) that the claims of the ’591 application were time-barred under 35 U.S.C. § 135(b)(1) and (2) that the claims of the ’591 application are invalid for lack of written description. The Board denied those motions and awarded priority to Bates. We conclude that the Board erred in finding that the ’591 application was not time-barred under 35 U.S.C. § 135(b)(1), and do not reach the written description issue. We reverse, vacate, and remand.

BACKGROUND

I. INTERFERENCE PROCEEDINGS

“Patent priority establishes who is entitled to a patent on a particular invention claimed by different parties.” *SNIPR Techs. Ltd. v. Rockefeller Univ.*, 72 F.4th 1372, 1374 (Fed. Cir. 2023). Before the America Invents Act,¹ the U.S.

¹ Pub. L. No. 112-29, 125 Stat. 284 (2011).

patent system operated under a first-to-invent regime—“the first person to invent a claimed invention had priority and was entitled to a patent” “even when a later inventor beats the first inventor to filing a patent application.” *Id.* “Section 135 of the United States Code, Title 35, governs patent interference proceedings, which are designed to determine whether two patent applications (or a patent application and an issued patent) are drawn to the ‘same patentable invention’ and, if so, which of the competing parties was first to invent the duplicative subject matter.” *Eli Lilly & Co. v. Bd. of Regents of Univ. of Washington*, 334 F.3d 1264, 1267 (Fed. Cir. 2003). This case is governed by pre-AIA law.

In interference proceedings, the Board “defines the interfering subject matter between” the applications or patents at issue in the interference proceeding (i.e., the “count”). *In re Roemer*, 258 F.3d 1303, 1307 (Fed. Cir. 2001). The Board then determines which claims of the patents and applications correspond to the count. The Board determines that a claim corresponds to the count if the count, taken as prior art, anticipates or renders obvious the claim. 37 C.F.R. § 41.207(b)(2). An interference-in-fact exists when one party’s claims corresponding to the count anticipate or make obvious the other party’s claims, which correspond to the same count, and vice-versa (a so-called two-way test). *Noelle v. Lederman*, 355 F.3d 1343, 1351 (Fed. Cir. 2004) (citing *Eli Lilly*, 334 F.3d at 1268).

II. Section 135(b)(1)

35 U.S.C. § 135(b)(1) (2012) provides:

A claim which is the same as, or for the same or substantially the same subject matter as, a claim of an issued patent may not be made in any application unless such a claim is made prior to one year from the date on which the patent was granted.

Section 135(b)(1) has been described “as a statute of repose, placing a time limit on a patentee’s exposures to an interference proceeding.” *Regents of Univ. of California v. Univ. of Iowa Rsch. Found.*, 455 F.3d 1371, 1376 (Fed. Cir. 2006). “[S]ection 135(b)(1) limits the patentee’s vulnerability to a declaration of an interference only because it limits the window of time in which the cause of the interference can occur.” *Id.* Thus, claims in an application that are the “same as, or for the same or substantially the same subject matter” and filed later than one year after the patent was issued (i.e., after the “critical period”) will be time-barred. 35 U.S.C. § 135(b)(1).

However, there has been a long-standing exception to section 135(b)(1) when the applicant files its claim after the critical period but “had already been claiming substantially the same invention as the patentee” during the critical period. *Corbett v. Chisholm*, 568 F.2d 759, 765 (C.C.P.A. 1977) (citing *Chapman v. Beede*, 296 F. 956 (D.C. Cir. 1924)); see also *Adair v. Carter*, 668 F.3d 1334, 1337 (Fed. Cir. 2012). In such cases, those claims are not time-barred by section 135(b)(1). See, e.g., *In re Berger*, 279 F.3d 975, 982 (Fed. Cir. 2002); *Adair*, 668 F.3d at 1337.

The underlying issue in this case is whether the claims in the Bates ’591 application claim “substantially the same invention” as claims filed by Bates prior to the ’305 patent’s critical date, and thus are not subject to the time-bar of section 135(b)(1). This turns on whether amendments to the Bates ’591 application after the critical date changed the claims so that they are not substantially the same as the claims before the critical date.

III. Prosecution History and Interference Proceeding

The technology at issue here concerns a drug-coated balloon catheter. The ’305 patent, titled “Medical Device for Dispensing Medicaments,” claims priority to a German

patent application and has a priority date of September 20, 2002. The '305 patent was issued on September 4, 2012.

On August 29, 2013, six days before the one-year anniversary of the '305 patent's issuance (i.e., six days before its critical date), Bates filed the '591 application, which is a continuation in part of an application filed October 31, 2001. On August 30, 2013, still before the critical date, Bates filed a preliminary amendment that canceled all the original claims and replaced them with new claims. Bates asserted in the preliminary amendment that the newly added claims "include claims for the same or substantially the same subject matter as claims of" the '305 patent. J.A. 6095.

Significantly, Bates again amended the claims after Speck's critical date (one year after the '305 patent issued). On April 4, 2018, Bates amended the claims to require that the device be "free of a containment material atop the drug layer" in order to overcome a rejection. J.A. 6214 After initially rejecting the amended claims, the examiner allowed the claims. Representative claim 22 of the '591 application, which reflects the final claim language in the '591 application, recites:

22. A balloon catheter medical device that releases a drug for the selective therapy of specific diseased tissue or an organ part to which said drug will bind, comprising such a drug which is lipophilic and water-insoluble, adhered in a layer to a surface of the balloon of said catheter that comes into contact with the diseased tissue or organ part and that is free of a time-release layer and free of a containment material atop the drug layer, which adhered drug when pressed against said tissue or organ part at least for a short time, is released into said tissue or organ part.

J.A. 1148 (emphasis added to relevant part).

The Board declared an interference on August 10, 2020, identifying Bates as the senior party and Speck as the junior party.

Speck filed a motion to terminate the interference on the ground that the claims of the '591 application were time-barred under 35 U.S.C. § 135(b)(1) because Bates amended the claims in the '591 application more than one year after the '305 patent was published (i.e., after the critical date of September 4, 2013). The Board “consider[ed] whether all material limitations of the post-critical date claim necessarily occur in the prior claims[,] i.e., if all material limitations of the claim are present or ‘necessarily result from’ the limitations of the prior claims.” J.A. 16 (quoting *Berger*, 279 F.3d at 982). The Board denied Speck’s motion because it found that the later amended claims did not differ materially from the claims in other patents and patent applications Bates owned that were filed prior to the critical date because “Speck ha[d] not directed [the Board] to a material limitation of the Bates involved claims that is not present in the earlier Bates claims.” J.A. 25.

Speck filed a motion for rehearing, arguing that the Board applied the wrong legal test by “discussing only whether the limitations of Bates’ involved claims are present or necessarily result from the limitations of the pre-critical date claims” and it failed to address whether the amended claims were broader than the earlier claims. J.A. 62. The Board denied the motion for rehearing. The Board rejected Speck’s argument that it erred in applying a one-way test (i.e., looking only to see if the post-critical date claims are narrower than the pre-critical date claims) and reiterated that it correctly applied the test from *In re Berger*, which analyzed whether all of the material limitations in the post-critical date claim are necessarily found in the pre-critical date claims. J.A. 62–64; J.A. 68 (“[T]he question before us was whether Bates had shown that it had

claims on file sufficient to avoid the bar of § 135(b)(1) under the proper legal standard articulated in, e.g., *In re Berger*, as discussed in the Decision. We concluded that Bates did so.”).

The Board eventually awarded priority to Bates. The Board then ordered the claims in the '305 patent to be canceled. Speck appeals. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A).²

DISCUSSION

I

The Board determined that the exception to section 135(b)(1) applied to the '591 application amendments made after the critical date because the amended claims were substantially the same as the pre-critical date claims. The relevant issues on appeal here are whether there is pre-critical date support for the negative limitation “free of a containment material atop the drug layer” in the claims of the '591 application and whether the pre-critical date claims are materially different from the post-critical date claims in this respect. Bates argued that its U.S. Patent No. 7,803,149 ('149 patent), U.S. Patent Application No. 11/141,574 ('574 application), and U.S. Patent Application No. 12/359,884 ('884 application), which were all filed before the '305 patent's critical date, provided pre-critical date support for its post-critical date claims. *See generally Corbett*, 568 F.2d at 764–65 (the statute incorporates the

² As noted, Speck also filed a motion arguing that the claims of the '591 application are unpatentable for lack of written description. The Board denied the motion, which Speck also appeals in this case. Because we find that the claims of the '591 application are time-barred under section 135(b)(1), we do not need to address that part of Speck's appeal.

earlier equitable doctrine allowing the applicant to find support in any pre-existing patent claim); *see also Adair*, 668 F.3d at 1335–36. These pre-critical date claims recited limitations like “the balloon being free of a containment material and the balloon being free of a containment layer.” J.A. 18, Table 1; *see also* J.A. 19 (“not . . . covered by . . . a containment layer”); J.A. 22 (“free from any containment material for the paclitaxel”).

Speck argued that there is no pre-critical date support for the post-critical date claims because the post-critical date claims only exclude containment material atop the drug layer whereas the pre-critical date claims exclude all containment material. To put it another way, Speck argued that the post-critical date claims are materially different because they are broader than the pre-critical date claims by limiting the disallowed containment material (i.e., allowing containment material where the drug is incorporated within a containment layer).

The Board determined that Bates’ claims were not time-barred. The Board “consider[ed] whether all material limitations of the post-critical date claim necessarily occur in the prior claims[,] i.e., if all material limitations of the claim are present or ‘necessarily result from’, the limitations of the prior claims,” (i.e., that the amended claims are not narrower). J.A. 16 (quoting *Berger*, 279 F.3d at 982). Applying this test, the Board determined that the post-critical date claims (i.e., the amended claims of April 2018) were not materially different from the pre-critical date claims identified by Bates because there was no “material limitation of the Bates involved claims that is not present in the earlier Bates claims.” J.A. 25.

On appeal, Speck argues that the Board applied the wrong legal test to analyze whether the post-critical date claims and the pre-critical date claims are materially different. The Board only analyzed whether the post-critical

date claims were narrower than the pre-critical date claims. This is referred to by Speck as the “one-way test” because the inquiry requires only looking in one direction to see if all of the material limitations in the post-critical date claims are present in the pre-critical date claims.

Speck contends that section 135(b)(1)’s time-bar can only be avoided if two conditions are satisfied: “(1) the pre-critical-date claim . . . must not contain any material limitation that is absent from the post-critical-date claim, *and* (2) the post-critical-date claim must not contain any material limitation that is absent from the pre-critical-date claim.” Appellant Opening Br. 30. Speck refers to this analysis as the “two-way test” because it involves looking both ways to see if either set of claims contains a limitation not found in the other, rather than just looking to see if the post critical date claims have additional material limitations. Speck argues the two-way test was not satisfied because the post-critical date claims were broader than the pre-critical date claims.

The Board rejected Speck’s argument, applying only a one-way test, and declining to apply a two-way test. It looked only to see if the post-critical date claims were narrower, not whether they were broader.

II

The holdings of our predecessor court, the Court of Customs and Patent Appeals (“CCPA”), which is binding precedent on our court, supports the application of a two-way test. In *Stalego v. Heymes*, the CCPA articulated a test that is the same as the two-way test. 263 F.2d 334 (C.C.P.A. 1959). In that case, the CCPA in an interference proceeding addressed whether the post-critical date counts “were asserting claims ‘for the same or substantially the same subject matter’” as the claims in a pre-critical date application. *Id.* at 335. The CCPA explained that precedent held that “in effect, that claims are not for

substantially the same subject matter if one of them contains one or more material limitations which are not found in the other.” *Id.* (emphasis added). This articulation is the same as the two-way test, which requires comparing the two sets of claims to determine if either set contains material limitations not found in the other, rather than just looking to only see if the post-critical date claims contain material limitations not present in the pre-critical date claims. The CCPA evidently conducted a two-way analysis, as it noted that the pre-critical date claim contained three limitations not found in the post-critical date count, and the post-critical date count contained three limitations not present in the pre-critical date claim. *Id.* at 338. While the CCPA found that the two sets of claims covered substantially the same subject matter, its decision was based on its finding that these unshared limitations were not material. *Id.* at 337–38.

Likewise, in *In re Sitz*, the Patent Office Board of Appeals rejected claim 10 in appellant’s reissued application, finding it was time-barred under section 135(b)(1). 331 F.2d 617, 621–22 (C.C.P.A. 1964). On appeal, appellant “assert[ed] that his original claims 9 and 23 in his [prior] application . . . were for substantially the same subject matter as appealed claim 10 and were pending before the Patent Office during the ‘critical period.’” *Id.* at 622. The CCPA analyzed whether the pre-critical date claims “were for substantially the same subject matter as appealed claim 10.” *Id.* The CCPA affirmed the time-bar decision as it found that the pre-critical date claim embodied a combination of a fixed plugboard and a movable plugboard, but found that “nothing in the [post-critical date claims] would suggest the entire invention as embodied in the combination of a fixed plugboard and a movable plugboard,” i.e., the post-critical date claims were broader. *Id.* at 624. The CCPA determined that the scope of the pre-critical date claims “differ[ed] so widely in scope from the subject matter

claimed” in the post-critical date claims that they were “not substantially the same.” *Id.* at 624–25. This analysis is also consistent with the two-way test in that the CCPA found that the narrower pre-critical date claims did not provide support for the broader post-critical date claims.

The decision in *Corbett v. Chisholm*, 568 F.2d 759 (C.C.P.A. 1977), also supports the application of a two-way test. In that interference proceeding, the CCPA found three groups of pre-critical date claims did not recite limitations found in the post-critical date claims. *Id.* at 765–66. For the fourth group of pre-critical date claims, the CCPA determined that the pre-critical date claim required a diverter element. *Id.* at 766. The post-critical date claims, however, did not require a diverter but instead required a manifold device. *Id.* The CCPA determined that the pre-critical date claim could not be relied upon to avoid the time-bar because “the two claims are directed to patentably distinct inventions” because of this difference, i.e., the amended claims were broader because they eliminated the diverter requirement. *Id.* The CCPA effectively applied the two-way test.

Bates argues that this court’s opinion in *In re Berger* articulates and applies a one-way test while purporting to apply the holding of *Corbett*. 279 F.3d at 982. To be sure, *Berger* states that “[i]f all material limitations of the copied claim are present in, or necessarily result from, the limitations of the prior claims, then the copied claim is entitled to the earlier effective filing date of those prior claims for purposes of satisfying 35 U.S.C. § 135(b).” *Id.* However, that case only concerned whether the post-critical date claim contained additional limitations not present in the pre-critical date claims (i.e., were narrower), so the court had no need to focus on the two-way test. The issue in this case is whether pre-critical date claims contain additional material limitations not present in the post-critical date claims (i.e., whether the amended claims are broader).

The other cases Bates relies on do not support a one-way test. Bates cites to *Wetmore v. Miller*, 477 F.2d 960 (C.C.P.A. 1973), and *Thompson v. Hamilton*, 152 F.2d 994 (C.C.P.A. 1946), for support that pre-critical date claims that are narrower than post-critical date claims can still be substantially the same. But Bates misses the point. In *Wetmore* and in *Thompson*, the CCPA found the differences between the pre-critical date claims and the post-critical date claims were not material. In *Thompson*, the CCPA noted that pre-critical date claims contained a “bulged portion” not included in the post-critical date claims. 152 F.2d at 996. However, there is no finding that the “bulged portion” was a material difference. In fact, it seems immaterial given that the CCPA affirmed the Board’s conclusion that the “difference is more in the form of expression than in the inventive subject matter covered.” *Id.* at 997. Likewise, in *Wetmore*, the pre-critical date limitation not found in the post-critical date claim was not regarded as material. 477 F.2d at 964.

The limited exception to section 135(b)(1) is intended to permit certain “belated interferences”—interferences that should have been earlier declared by the PTO, but were not, and thus should not be barred by operation of section 135(b)(1). See *Regents of Univ. of California*, 455 F.3d at 1376. “When a material difference exists between the post- and pre-critical date claims, a belated interference is improper because it would be a ‘different interference []’ than that which ‘should have been earlier declared by the PTO.’” *Adair*, 668 F.3d at 1338–39 (quoting *Regents of Univ. of California*, 455 F.3d at 1376). Applying a one-way test would permit materially broader post-critical date claims to avoid section 135(b)(1), despite having a materially broader scope. Applying a one-way test in this situation would undermine the requirement of lack of material difference.

We also think applying a two-way test to analyze material differences makes sense given that a two-way test is used to determine if there is an interference in fact. *Noelle*, 355 F.3d at 1351. Even though the substance of these inquiries is different,³ we think the general principle of using a two-way analysis for comparing two sets of claims is compelling.

Because precedent and policy favor application of a two-way test, we hold that the two-way test should be applied to determine if pre-critical date claims and post-critical date claims are materially different.

III

The remaining issue with respect to Speck's time-bar appeal is whether under the two-way test the post-critical date claims and the pre-critical date claims here are materially different.

We review factual determinations by the Board for substantial evidence. *Berger*, 279 F.3d at 980. "The Board's interpretation and comparison of the claims here was a legal inquiry, reviewed without deference." *Pioneer Hi-Bred Int'l, Inc. v. Monsanto Tech. LLC*, 671 F.3d 1324, 1329 (Fed. Cir. 2012). Here the Board only determined that the claims were not materially different under the one-way test and did not address whether there were material differences under the two-way test. In the context of section 135, "the question as to the materiality of limitations is to be

³ *Adair*, 668 F.3d at 1338 ("The question of material differences between post- and pre-critical date claims for purposes of overcoming a § 135(b) bar 'is a distinctly different question from whether claims . . . are directed to the same or substantially the same subject matter' for purposes of provoking an interference." (quoting *Berger*, 279 F.3d at 982)).

considered on its merits, and limitations found to be immaterial may be disregarded.”⁴ *Rieser v. Williams*, 255 F.2d 419, 422 (C.C.P.A. 1958).

The ’884 application recites “free from any containment material.” Similarly, the claims of the ’149 patent recite “the balloon being free of a containment material and the balloon being free of a containment layer.” The claims in the ’574 application recite “not contained within or covered by either a time release layer or a containment layer.” On their faces, these limitations differ in scope from the ’591 application, which only excludes containment material atop the drug layer. *See* J.A. 3017, col. 19, ll. 38–39 (’149 patent, claim 1); J.A. 3819 (’884 application); J.A. 6266 (’574 application); *see also* J.A. 3785 (Bates’ expert acknowledging that “[t]he prior claim limitations could be considered narrower in the sense that they exclude all additional coatings.”). More specifically, the claims of the ’591 application permit including the drug within the containment layer, but the pre-critical date claims would not.

However, difference in scope alone does not necessarily mean claims are materially different. *See, e.g., Nitz v. Ehrenreich*, 537 F.2d 539, 545 (C.C.P.A. 1976) (finding that the “count is of greater breadth than that of the corresponding patent claim [wa]s in [that] case of no moment” because the difference in scope was not material as the limitation had existed in the prior art and was “not necessary for patentability of the claim”); *Wetmore*, 477 F.2d at 963–64. On the record before us, we conclude that as a matter of law under the two-way test the two sets of claims are materially different. The prosecution histories and other

⁴ This differs from the rule “applied in determining the right to make the count and priority of invention,” which is “that every limitation of an interference count must be considered material.” *Rieser*, 255 F.2d at 422.

proceedings before the PTO demonstrate the differences in these limitations are material to their respective inventions. “When an applicant adds limitations in response to an examiner’s rejection, and those limitations result in allowance, there exists a well[-]established presumption that those limitations are necessary to patentability and thus material.” *Adair*, 668 F.3d at 1339; *see also Parks v. Fine*, 773 F.2d 1577, 1579 (Fed. Cir. 1985), *modified*, 783 F.2d 1036 (Fed. Cir. 1986) (“The insertion of this limitation to overcome the examiner’s rejection is strong, if not conclusive, evidence of materiality.”); *Berger*, 279 F.3d at 983 (“Because the prior art applies in like manner to the claims as copied, the materiality of a limitation in a claim copied to provoke an interference translates to the copying inventor’s application for purposes of assessing compliance with 35 U.S.C. § 135(b).”). It follows that other representations in other PTO proceedings are highly relevant.

In a separate interference proceeding concerning the ’149 patent, Bates stated that “[a] basic and novel characteristic in Bates’ disclosure is the lack of a time-release layer, a containment material or a containment layer.” J.A. 6675. It would necessarily follow that the ’591 application, which permits some containment material, is materially different as it lacks this “basic and novel characteristic.” *Id.*

So too while prosecuting the ’574 application, Bates amended the claims to add the limitation “is not incorporated within a containment layer” to overcome an obviousness rejection. J.A. 6253; J.A. 6258–61. Compare this to the ’591 application’s prosecution history, in which Bates added the limitation “free of a containment material atop the drug layer” to overcome a rejection for obviousness. J.A. 6227. As noted above, the embodiment that is excluded by the amendment in the ’574 application (excluding a drug within a containment layer) is allowed by the amendment in the ’591 application (excluding only a

containment layer atop the drug layer). That each of these applications were amended to have these different limitations in order to overcome rejections is evidence that these limitations are material to their respective applications, and that their differences cannot be disregarded. These actions are strong evidence of the materiality of the amendment to add the “free of a containment material atop the drug layer” limitation to the ’591 application.

There is also no evidence in the record, let alone substantial evidence, to support a finding that this limitation is not material. The only evidence Bates cites to is its expert’s declaration stating that the two sets of claims are substantially similar, but these are just conclusory statements not entitled to any weight. *See, e.g.*, J.A. 3784–85 (“The prior claim limitations could be considered narrower in the sense that they exclude all additional coatings, but the emphasis of these limitations is the exclusion of containment materials or layers, and that is substantially the same in both the involved claims and the prior claims.”); *see also* J.A. 3781–82. “Conclusory expert testimony does not qualify as substantial evidence.” *TQ Delta, LLC v. CISCO Sys., Inc.*, 942 F.3d 1352, 1358 (Fed. Cir. 2019) (collecting cases).

On this record, we conclude that as a matter of law the pre-critical date claims are materially different from the post-critical date claims. The ’591 application is time-barred under section 135(b)(1).

CONCLUSION

For the reasons stated above, we conclude that the ’591 application is time-barred under section 135(b)(1). Accordingly, we find no interference in fact between the ’305 patent and the ’591 application. We reverse the Board’s decision and vacate its order canceling the claims of the ’305 patent and entering judgment on priority against

SPECK v. BATES

17

Speck, and remand for further proceedings consistent with this opinion.

REVERSED, VACATED, AND REMANDED

COSTS

Costs to Appellant.