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Federal Circuit Clarifies Test for Exception to Increasingly Rare Interference Proceedings

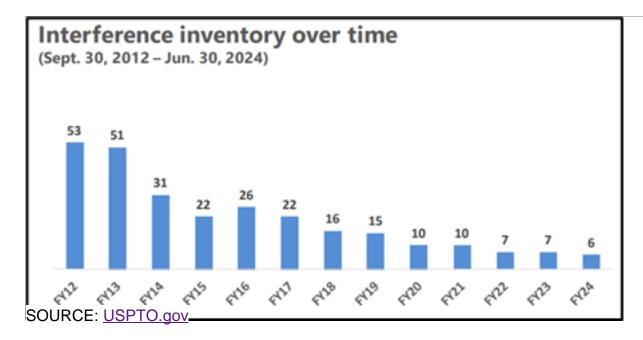
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<u>Speck v. Bates, No. 2023-1147 (Fed. Cir. May 23, 2024)</u> addressed two issues, (1) whether courts should apply a one-way test or a two-way test to determine if pre-critical claims materially differ from post-critical claims, such that an exception to the one-year time-bar on interference proceedings applies, and (2) whether Bates' pre-critical claim language materially differed from his post-critical claim language, which dictates whether his claims were time-barred.

I. Background

Interference Proceedings and the AIA

Interference proceedings resolve priority where two patent applications (or a patent application and an issued patent) are drawn to the same invention.[1] The USPTO may declare an interference where it believes that such an overlap in patentable subject matter exists. Pre-AIA 35 U.S.C. § 135(a). Because the AIA switched the US patent system from a first-to-invent to a first-to-file regime, priority disputes involving patent applications filed after the AIA (March 16, 2013) are instead resolved simply by referencing filing dates.[2] As more and more pre-AIA applications filter through the US patent system, interference proceedings are becoming increasingly rare:



The Federal Circuit's opinion here outlines the overall interference process: Once an interference is declared by the USPTO, the Board defines the subject matter in common between the patent filings (the "count"). The party owning the patent filing with the earliest filing date is called the "senior party," and the other party is called the "junior party." All claims that would be anticipated or rendered obvious by the count are considered to "correspond" to the count. Where a corresponding claim of the senior party would anticipate or render obvious a corresponding claim of the junior party (or *vice versa*)—there is an interference-in-fact. Where the Board identifies an interference-in-fact, the Board then must resolve which party was the first to invent the count. Finally, the Board cancels (in the case of issued patents) or refuses (in the case of patent applications) the claims of whichever party is determined to have invented later.

There is also a statute of repose which places a time limit on potential interference proceedings. The "critical period" terminates once one year passes after a patent has been issued, or after a patent application has been published. Claims filed after the critical period ("post-critical claims") are time-barred and the interference-in-fact is resolved. Pre-AIA 35 U.S.C. § 135(b).

However, there is a long-standing exception to the one-year time-bar—if the post-critical claims do not "materially differ" from claims filed by the applicant prior to the critical period ("pre-critical claims"), then the one-year time-bar does not apply.[3] According to the Federal Circuit, the policy behind this exception to the one-year time-bar is to allow for "belated interferences"—interferences that should have been declared by the USPTO during the critical period, but weren't.

II. Case Summary

Patent Filings and the Technology at Issue

The technology at issue here concerned drug-coated balloon catheters. Speck owned U.S. Patent No. 8,257,305 (the "305 patent"), which issued on September 4, 2012 and had a priority date of September 20, 2002. Within a year of issuance of Speck's '305 patent, Bates filed U.S. Patent Application No. 14/013,591 (the "591 application"). Via continuation, Bates' '591 application claimed a priority date of October 31, 2001—almost a year before the priority date of Speck's issued patent.

The claims in Bates' '591 application (and its parents) included limitations that required the balloon catheter to be free of a containment material. Over four years later, in 2018, Bates amended claims of the '591 application in response to an Examiner's rejection, such that they required the balloon catheter to be free of a containment material "atop the drug layer."

Previous Proceedings

The Board declared an interference identifying Bates (owner of the '591 application with priority to 2001) as the senior party, and identifying Speck (owner of the '305 patent with priority to 2002) as the junior party. Speck filed a motion to terminate the interference based on the claims of Bates' '591 application being time-barred under 35 U.S.C. § 135 (b) (pre-AIA). The critical date is one year after issuance of Speck's '305 patent, or September 4, 2013. Bates' 2018 claim amendments to his '591 application were therefore post-critical amendments.

The Board denied Speck's motion to terminate because it held that Bates' post-critical claim language did not materially differ from his pre-critical claim language. Without a material difference between the post-critical and pre-critical claim language, the Board applied the exception to the 1-year time-bar and found an interference-in-fact despite the critical date being years passed.

To determine whether Bates' post-critical claims materially differed from his pre-critical claims, the Board applied a "one-way test," i.e., the Board found material difference only if the pre-critical claims contained material limitations absent from the post-critical claims. Speck filed a motion for rehearing arguing that the Board should have instead applied a "two-way test," i.e., the Board should have found material difference if the pre-critical claims contained material limitations absent from the post-critical claims *or vice versa*. The Board insisted that the one-way test was correct and denied Speck's motion for rehearing.

The Board eventually awarded priority to senior party Bates and ordered the claims of Speck's '305 patent cancelled. Speck appealed to the Federal Circuit.

Issues

- 1. Should courts apply a one-way test or a two-way test to determine if pre-critical claims materially differ from post-critical claims?
- 2. Did Bates' pre-critical claim language (requiring the balloon catheter be free of a containment material) materially differ from his post-critical claim language (requiring that the balloon catheter be free of a containment material "atop the drug layer")?

Holdings and Reasoning

1. The Federal Circuit held that the two-way test formulation is the correct test to determine if precritical claims and post-critical claims materially differ.

The Federal Circuit first explained that, in all binding precedent identified by the parties[4], the court applied a test which was consistent with the "two-way test" framing. Second, the Federal Circuit explained that the policy of the exception to the 1-year time-bar—to allow for belated interferences that were overlooked by the USPTO—would be undermined under the one-way test. Under the one-way test, materially broader post-critical date claims would avoid being time-barred, even where the applicant's post-critical introduction of these material differences may be the source of the USPTO's

"belated" declaration of an interference. Finally, the Federal Circuit noted that a similar (but substantively different) two-way inquiry is involved in determining if there is an interference in fact, and that the Federal Circuit considers two-way analyses compelling for comparing two sets of claims.

2. Under the two-way test, the Federal Circuit held that Bates' pre-critical claim language (requiring the balloon catheter be free of a containment material) materially differed from his post-critical claim language (requiring that the balloon catheter be free of a containment material "atop the drug layer").

The Federal Circuit explained that Bates' claims pass the first pass of the two-way test because Bates' pre-critical claim language requiring balloon catheters be free of a containment material language was practically repeated in Bates' post-critical claims. However, Bates' claims fail the second pass of the two-way test because the post-critical claims contained the additional clause "...atop the drug layer" which permitted subject matter not excluded in the pre-critical claims. The post-critical claims would allow a containment material containing the drug layer, while the pre-critical claims would simply never allow a containment material. The Federal Circuit further reasoned that this difference between the post-critical claims and the pre-critical claims was material because both the "free of a containment material" and "atop the drug layer" language was added to overcome an office action rejection, and limitations added in response to an examiner's rejection are presumed to be material. *Adair v. Carter*, 668 F.3d 1334, 1337 (Fed. Cir. 2012).

Outcome

Because Bates' post-critical claims materially differ from his pre-critical claims the exception to the one-year time bar under pre-AIA 35 U.S.C. § 135(b) does not apply, and the claims of Bates' '591 application are time barred. Accordingly, the Federal Circuit found no interference in fact between the '305 patent and the '591 application.

The Board's decision applying the incorrect one-way test, finding that the claims in Bates' '591 application were not time-barred, and entering judgment on priority against Speck was reversed.

FOOTNOTES

- [1] Patent applications and issued patents will be referred to generally herein as "patent filings."
- [2] Compare Post-AIA 35 U.S.C. § 135, which defines derivation proceedings, with Pre-AIA 35 U.S.C. § 135, which defines interference proceedings. Interference proceedings are appropriate whenever a later inventor filed first, while derivation proceedings are appropriate only where the later inventor "derived" (more colloquially—stole) the earlier inventor's invention, and the later inventor filed first.
- [3] See, e.g., In re Berger, 279 F.3d 975, 982 (Fed. Cir. 2002); Corbett v. Chisholm, 568 F.2d 759, 765 (C.C.P.A. 1977); Adair v. Carter, 668 F.3d 1334, 1337 (Fed. Cir. 2012).
- [4] The Federal Circuit discussed *Stalego v. Heymes*, 263 F.2d 334 (C.C.P.A. 1959), *In re Sitz*, 331 F.2d 617 (C.C.P.A. 1964), *Corbett v. Chisholm*, 568 F.2d 759 (C.C.P.A. 1977), *In re Berger*, 279 F.3d 975 (Fed. Cir. 2002), *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).

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