NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

ALERE, INC.,
Appellant

v.

REMBRANDT DIAGNOSTICS, LP,
Appellee

2018-1812

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2016-01502.

Decided: October 29, 2019

JASON M. WILCOX, Kirkland & Ellis LLP, Washington, DC, argued for appellant. Also represented by JOHN C. O'QUINN; AMANDA J. HOLLIS, Chicago, IL.

JOSEPH F. JENNINGS, Knobbe, Martens, Olson & Bear, LLP, Irvine, CA, argued for appellee. Also represented by JARED C. BUNKER.

Before NEWMAN, DYK, and REYNA, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* REYNA.

Opinion dissenting in part filed by *Circuit Judge* DYK.

REYNA, *Circuit Judge*.

Alere, Inc., appeals from a final written decision of the Patent Trial and Appeal Board in an *inter partes* review proceeding, upholding certain challenged claims as not unpatentable. We conclude that the Board correctly construed the disputed "wherein" clause in claim 1 and affirm that limited portion of the Board's final written decision. Because the Board improperly declined to institute review on certain claims and grounds included in Alere's petition and its final written decision did not address those claims and grounds, we vacate the remaining aspects of the final written decision and remand for further proceedings.

BACKGROUND

I. The Challenged Patent

Rembrandt Diagnostics, LP, owns U.S. Patent No. 6,548,019 ("the '019 patent"). The patent, entitled "Method for Single Step Collection and Assaying of Biological Fluids" relates to a device and method for collecting biological fluid samples. The '019 patent explains that prior art immunoassay devices used wicking material to bring test sample fluid into contact with the sample loading zone of assay test strips. According to the '019 patent, the method of using wicking material was undesirable because it was slow in producing results, the wicking could occur unevenly, and it increased manufacturing costs because of the need to overlap the wicking material with the test strips.

The '019 patent overcomes these problems by removing the wicking material and introducing the sample loading zone of the test strip directly into the fluid sample while also providing a means for preventing oversaturation of the test strip. The '019 patent discloses one such means that uses "flow control channels" consisting of liquid impervious

walls and backing that encapsulate the assay test strip, except where one liquid pervious side has an opening through which the sample loading zone of the assay test strip protrudes. Figure 3 from the '019 patent shows this configuration:

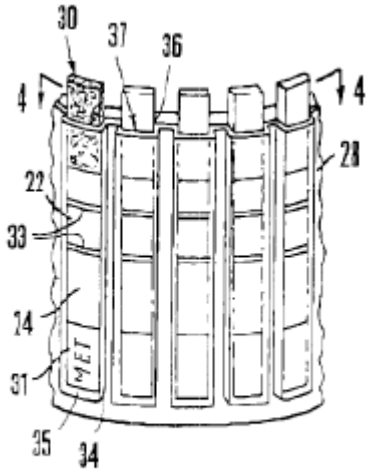
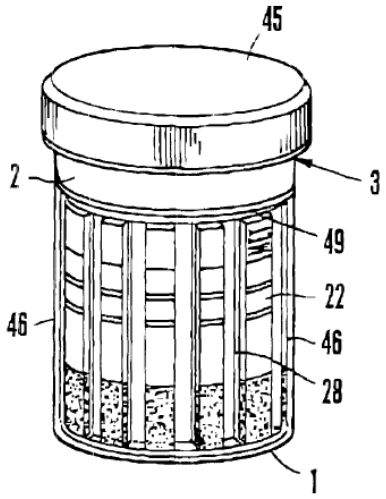


Fig. 3

'019 patent Fig. 3. In Figure 3, 36 labels the opening, 34 labels the flow control channel, and 30 labels the sample loading zone of the assay test strip (22). *Id.* at col. 6 ll. 10–15. In the patented device, several flow control channels are placed around the perimeter of a collection cup with the opening (36) oriented toward the bottom. As fluid is introduced into the cup, the fluid contacts the sample loading zone of the test strip and "begins migrating up through the assay test strip." *Id.* at col. 6 ll. 55–57. The trapped air and ambient air pressure within the flow control channel prevent oversaturation of the test strip. *Id.* at col. 1 ll. 39–47.

Figure 6 shows the assay sample fluid collection device with the assembly of Figure 3 in place in a collection cup.



Id. Fig. 6. Figure 6 confirms that the openings of the flow control channels shown in Figure 3 are oriented toward the bottom of the cup when disposed in the collection cup.

Claim 1 is illustrative of the challenged claims and includes the disputed claim terms:

> 1. *A device for collecting and assaying a sample of biological fluid*, the device comprising:
>
> (a) a flow control channel defined by at least one liquid pervious side joined to liquid impervious sides, wherein the internal dimensions of the flow control channel are sufficient to permit placement therein of an assay test strip;
>
> (b) an assay test strip within the flow control channel, wherein the assay test strip has a sample loading zone therein, and wherein further the assay test strip is disposed within the flow control channel so the sample fluid contacts the sample loading zone at a liquid pervious side of the flow control channel; and
>
> (c) a sample fluid container having a base, an open mouth, and walls connecting the base to the mouth;

> ***wherein*** *the flow control channel is disposed inside the sample fluid container with the liquid pervious side oriented toward the base of the sample fluid container so that the assay sample fluid, when added to the container, is delivered to the sample loading zone of the assay test strip by entry through a liquid pervious side of the flow control channel without migration through an intermediate structure*, and wherein entry of the fluid into the flow control channel creates an ambient pressure within the flow control channel equivalent to the ambient pressure outside of the flow control channel, thereby eliminating a pressure gradient along which excess sample fluid could flow into the flow control channel.

'019 patent col. 8 l. 42–col. 9 l. 2 (emphases added). Like claim 1, all claims in the '019 patent are directed to a "device."

II. The IPR Proceedings

Alere, Inc., filed a petition for *inter partes* review challenging claims 1–6 and 9–15 of the '019 patent on thirteen grounds. The Board instituted review as to only claims 1–5, 9, and 11–15 on certain grounds but declined to institute review as to those same claims on other grounds raised in the petition. After institution, Rembrandt disclaimed claims 1, 9, and 11–15, leaving dependent claims 2–5 in the proceeding.

In its final written decision and relevant to this appeal, the Board construed the "wherein" clause in part (c) of claim 1 "to require a structure that is capable of allowing liquid to enter the container when the flow control channel is disposed therein and capable of directing this liquid to the sample loading zone of the assay test strip without the liquid having to migrate through an intermediate structure." J.A. 17. The Board determined that Alere had

shown claim 2 to be unpatentable but had not shown claims 3–5 to be unpatentable.

Alere appeals. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

DISCUSSION

The Administrative Procedure Act ("APA") at 5 U.S.C. § 706(2) guides our review of Board decisions. *Dickinson v. Zurko*, 527 U.S. 150, 152, 165 (1999). Under the APA, we review the Board's legal determinations de novo and its factual findings for substantial evidence. *ACCO Brands Corp. v. Fellowes, Inc.*, 813 F.3d 1361, 1365 (Fed. Cir. 2016). As such, we review the Board's ultimate determinations on claim construction de novo and any subsidiary factual findings for substantial evidence. *HTC Corp. v. Cellular Commc'ns Equip., LLC*, 877 F.3d 1361, 1367 (Fed. Cir. 2017).

Alere challenges the Board's patentability determinations as to claims 3–5 and the Board's decision not to institute review as to certain claims and grounds in its petition. We first address Alere's arguments related to the claim construction relied on by the Board in reaching its patentability determinations.

I. Claim Construction

Alere argues that the Board erred in construing the "wherein" clause to require that the claimed device be capable of allowing the addition of fluid after the flow control channel is in place in the collection cup. Appellant Br. 34. Rembrandt responds that the Board's construction is consistent with plain language of the claim and disclosures in the specification. Appellee Br. 20–21. We agree with the Board's construction.

We start with the plain language of the claim.[1] *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005). The disputed "wherein" clause is found in claim 1 and states:

> wherein the flow control channel *is disposed* inside the sample fluid container with the liquid pervious side oriented toward the base of the sample fluid container so that *the assay sample fluid, when added to the container, is delivered to the sample loading zone of the assay test strip by entry through a liquid pervious side of the flow control channel* without migration through an intermediate structure . . . .

'019 patent col. 8 ll. 57–64 (emphases added). This clause includes functional language that informs us of the structural requirements of the claim. *K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1363 (Fed. Cir. 1999). The most natural reading of this claim language shows a functional limitation that simply requires that in the claimed device, when the flow control channel is in place (*i.e.*, "disposed inside the . . . container"), fluid can be "added to the container" and "delivered to" the loading zone of the assay test strip without migration through another structure. In other words, when (1) the flow control channel is in place and (2) fluid is added to the container, then the fluid is delivered to the loading zone.

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[1] The '019 patent expired in November 2018, after the Board issued its final written decision. We do not need to decide the question about whether the broadest reasonable interpretation standard or the *Phillips* standard applies for resolution of this appeal because the Board's construction is "correct on the point at issue" under either standard. *Pers. Web Techs., LLC v. Apple, Inc.*, 848 F.3d 987, 990 (Fed. Cir. 2017).

This understanding of the plain language of the claim is entirely consistent with the specification. *See Phillips*, 415 F.3d at 1312–14. The capability of adding fluid to the container after the flow control channel is disposed inside is apparent from the figures and corresponding portions of the written description. Figure 3 of the '019 patent shows the flow control channels arranged in a panel. According to the '019 patent describing Figure 3, "[a]s assay sample fluid collects in cup 2, it contacts sample loading zone 30 and begins migrating upwards through assay test strip 22." '019 patent col. 6 ll. 55–57. Figure 6 shows the channels arranged in the panel disposed in the described cup, capable of allowing fluid to enter. No figure shows a device incapable of having fluid added after a flow control channel is placed inside.

The Board's construction is also consistent with the title and the abstract of the '019 patent, which describe the invention as a "single-step" collecting and assaying device, meaning that one need only add sample fluid to the container when the flow control channel is disposed inside to collect and assay the sample. *See id.* Title, Abstract. The written description further describes the "invention" as "a combination assaying device and collection chamber which is capable of easily collecting and testing a biological fluid . . . ." *Id.* at col. 1 ll.62–64. Although these references do not limit the claims to a single unitary structure, they are consistent with the Board's claim construction with respect to the capability of adding fluid after the flow control channel is placed in the container. *See* J.A. 13, 15–16.

Nothing in the claim language excludes a container that contains fluid before the flow control channel is disposed inside or imports a temporal limitation on when fluid must be introduced into the container. As the Board pointed out, the claim recites a device, not a method—an important distinction. *See IPXL Holdings, L.L.C. v. Amazon.com, Inc.*, 430 F.3d 1377, 1384 (Fed. Cir. 2005). Thus, the claim language does not create a process limitation.

Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1468 (Fed. Cir. 1990) (stating that "apparatus claims cover what a device is, not what a device does"). That the written description includes examples of embodiments where the flow control channel is placed into fluid already in the container does not mean that the device disclosed is incapable of allowing the addition of fluid after the flow control channel is "disposed inside." Further, there are no embodiments that disclose devices without that capability. Accordingly, nothing in the specification is inconsistent with the requirement of being able to add fluid to the container once the flow control channel is placed inside.

The Board correctly construed the wherein clause as creating a functional limitation for structural relationships of the device. Accordingly, we agree with the Board's construction of the "wherein" clause found in claim 1(c) as "requir[ing] a structure that is capable of allowing liquid to enter the container when the flow control channel is disposed therein and capable of directing this liquid to the sample loading zone of the assay test strip without the liquid having to migrate through an intermediate structure."

II. Remand

The parties agree that Alere is entitled to remand under *SAS Institute, Inc. v. Iancu*, —— U.S. ——, 138 S.Ct. 1348, 200 L.Ed.2d 695 (2018) in order for the Board to consider the non-instituted claims and grounds in the petition. The parties dispute whether we should first reach the merits of the unpatentability challenges for the instituted claims and grounds. We have previously declined parties' invitations to address the merits of instituted claims and grounds before remanding partially instituted proceedings, recognizing that, "[a]ppellate courts have historically disfavored piecemeal litigation and permitted appeals from complete and final judgments only." *BioDelivery Scis. Int'l, Inc. v. Aquestive Therapeutics, Inc.*, 898 F.3d 1205, 1210 (Fed. Cir. 2018) (quoting *W.L. Gore & Assocs., Inc. v. Int'l*

Med. Prosthetics Research Assocs., Inc., 975 F.2d 858, 861 (Fed. Cir. 1992)). Other panels of this court, however, have taken a different approach, addressing the merits of the instituted claims and grounds and then remanding for the Board to consider the non-instituted claims and grounds. *E.g.*, *Medtronic, Inc. v. Barry*, 891 F.3d 1368, 1371 n.1 (Fed. Cir. 2018).

We conclude that the better course of action in this case is to remand without addressing the merits of the patentability challenges. Here, there are both non-instituted claims and non-instituted grounds. As Alere points out, the Board did not institute review on the same claims at issue in this appeal for four other challenges included in the petition. The likelihood of having to review the Board's patentability determinations for some of the same claims for different grounds after the Board considers all claims and grounds included in the petition weighs in favor of awaiting a "complete and final" decision without further addressing the merits.

CONCLUSION

We discern no error in the Board's construction of the "wherein" clause found in claim 1(c) of the '019 patent and we affirm that limited aspect of the Board's final written decision. Under *SAS,* however, the Board erred by instituting review on less than all claims and grounds included in Alere's petition. We therefore vacate the remainder of Board's final written decision and remand for the Board to review all claims and grounds included in the petition and issue a complete final written decision.

AFFIRMED-IN-PART, VACATED-IN-PART, AND REMANDED

COSTS

Each party shall bear its own costs.

NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

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2018-1812

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2016-01502.

DYK, *Circuit Judge*, dissenting in part.

The Board in this *inter partes* review proceeding held that the petitioner had failed to establish that dependent claims 3–5 of the '019 patent are obvious, based on its construction of the claim language of independent claim 1. The majority affirms the Board's claim construction. I respectfully disagree that the Board correctly construed the relevant claim language in claim 1.

Claim 1 recites:

A device . . . comprising:

(a) a flow control channel . . .;

> (b) an assay strip within the flow control channel . . .; and
>
> (c) a sample fluid container . . .; wherein the flow control channel is disposed inside the sample fluid container . . . so that the assay sample fluid, when added to the container, is delivered to the sample loading zone of the assay test strip by entry through a liquid pervious side of the flow control channel without migration through an intermediate structure . . . .

'019 patent 8:41–9:2. This language is ambiguous as to whether the test strip may be inserted after the fluid is added to the container. However, the specification discloses two embodiments: (1) disposing the control channel into the container before adding the sample fluid, '019 patent 6:40–45, or (2) immersing the control channel into sample fluid that is already in the container, *id.* 5:60–63. It is clear from the specification that the claim covers both embodiments. The majority agrees that claim 1 includes both embodiments. *See* Majority Op. 9.

The Board's construction adds a limitation to the second embodiment that is not recited in the claim language or specification. The Board construed the "when added to the container" language in claim 1 "to require a structure that is capable of allowing liquid to enter the container when the flow control channel is disposed therein." J.A. 17. The Board explained that this construction requires that the device allow "additional sample fluid [to] enter[] the container" if the flow control channel is placed into fluid that is already in the container. J.A. 21 (emphasis added). Similarly, the majority clarifies: "[t]hat the written description includes examples of embodiments where the flow control channel is placed into fluid already in the container does not mean that the device disclosed is incapable of allowing the addition of fluid after the flow control channel is 'disposed inside.'" Majority Op. 9.

Yet there is nothing in the claim language or specification that describes adding fluid to the container, placing the flow channel into the fluid, and then adding more fluid. In short, the specification does not disclose adding more fluid to a container that already has sample fluid. Indeed, there is no logical reason to add more sample fluid to a container that already has fluid. Even if, as the majority states, "nothing in the specification is inconsistent with the requirement of being able to add fluid to the container once the flow control channel is placed inside," Majority Op. 9, this does nothing to support a requirement that the device have that capability.

I respectfully dissent from the majority's affirmance of the Board's claim construction, though I agree with the majority that this case should be remanded under *SAS Institute, Inc. v. Iancu,* 138 S.Ct. 1348 (2018) for further consideration.