United States Court of Appeals for the Federal Circuit

ABS GLOBAL, INC., GENUS PLC,
Appellants

v.

CYTONOME/ST, LLC,
Appellee

2022-1761

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2021-00088.

Decided: October 19, 2023

STEVEN J. HOROWITZ, Sidley Austin LLP, Chicago, IL, argued for appellants. Also represented by STEPHANIE P. KOH.

Z.W. JULIUS CHEN, Akin Gump Strauss Hauer & Feld LLP, Washington, DC, argued for appellee. Also represented by PRATIK A. SHAH; DANIEL LYNN MOFFETT, San Antonio, TX.

Before REYNA, TARANTO, and STARK, *Circuit Judges.*

TARANTO, *Circuit Judge.*

Cytonome/ST, LLC owns U.S. Patent No. 10,583,439, which describes and claims a microfluidic device for use in processing particles of interest contained in a sample fluid. ABS Global, Inc. and Genus plc (collectively, ABS) petitioned the Patent and Trademark Office (PTO) for an inter partes review, under 35 U.S.C. §§ 311–19, of the patentability of claims 1, 2, 6, 8, and 9 of the '439 patent. The PTO's Patent Trial and Appeal Board, acting for the PTO's Director, granted the petition. After conducting the review, the Board determined that ABS had not shown any of the challenged claims to be unpatentable. *ABS Global, Inc. v. Cytonome/ST, LLC*, No. IPR2021-00088, 2022 WL 1406461 (P.T.A.B. Apr. 28, 2022) (*Final Written Decision*).

ABS appeals. We agree with ABS's principal contention—that the Board erred in its claim construction of a limitation common to all challenged claims. Having rejected the Board's construction, we reverse the Board's final written decision with respect to claims 1 and 8, vacate the decision with respect to claims 2, 6, and 9, and remand the matter to the Board.

I

A

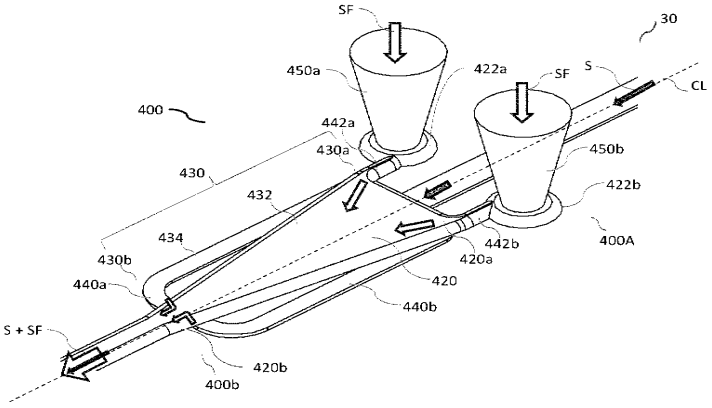
The '439 patent, issued in 2020 (on an application filed in 2014 after a 2013 provisional application) and titled "Hydrodynamic Focusing Apparatus and Methods," describes and claims a microfluidic device for "particle" processing. '439 patent, col. 1, lines 14–35. Microfluidic devices employ small channels for the movement of fluids—in particular, fluids that contain cells, molecules, or other particles of interest to the device user, who may wish, *e.g.*, to sort, count, analyze, or test them. *See* U.S. Patent No. 6,506,609, cols. 1–2 (Wada) (filed 2000, issued 2003) (J.A. 2221); Declaration of David Issadore ¶ 46 (J.A. 1983); *see also Bio-Rad Laboratories, Inc. v. 10X Genomics Inc.*, 967 F.3d 1353,

1360 (Fed. Cir. 2020). The '439 patent concerns the focusing of the flow of a sample fluid by use of other fluids ("hydrodynamic focusing") in such a device. '439 patent, col. 1, lines 14–19.

Under certain conditions, if one fluid is introduced into a microchannel and then a second fluid is introduced into the same microchannel, the two fluids travel in "laminar flow," *i.e.*, in parallel layers (which may, for example, be horizontally or vertically aligned), without mixing. *See* J.A. 1983; Albert Folch, Introduction to BioMEMS 101 (2012) (J.A. 2384). "Sheath flow" is a type of laminar flow in which a layer of "sample fluid" that contains particles is abutted on more than one side by a layer of particle-free sheath fluid. '439 patent, col. 1, lines 23–25 ("surrounded by another layer of focusing fluid on more than one side"). By introducing focusing fluid (*e.g.*, sheath fluid) to "focus" (*i.e.*, squeeze and confine) the sample fluid, a device user can accurately position particles (*e.g.*, "in a single row file") for inspection or other use at a point in the flow path. *Id.*, col. 1, lines 25–46; *see* Wada, col. 1.

Figure 3A of the '439 patent shows one focusing device (with S=sample fluid, SF=sheath fluid, and CL=channel):

FIG. 3A



The record before us discloses some general properties of hydrodynamic focusing. The sheath fluid's speed, relative to that of the sample fluid, affects whether and how the sample fluid is focused. Chih-Chang Chang et al., *Three-dimensional Hydrodynamic Focusing in Two-layer Polydimethylsiloxane (PDMS) Microchannels*, 17 Journal of Micromechanics and Microengineering 1479, 1483 (2007) (Chang) (J.A. 2782). At some speeds, some sheath and sample fluids will mix. *See* U.S. Patent No. 6,159,739, cols. 1–2 (Weigl) (filed 1997, issued 2000) (J.A. 2176). Generally, though, the greater the sheath fluid's speed relative to that of the sample fluid, the more the sample fluid is compressed to reduce (along one or more axes) the cross-section of its flow profile. Chang at 1483 (J.A. 2782). If the relative-speed ratio is especially high, the sample fluid can split, producing a lane of sheath fluid between two lanes of sample fluid. *Id.* (showing an experiment result in which "the focused stream . . . has a gap in the middle").

Independent claim 1 of the '439 patent claims a microfluidic device configured to focus sample fluid:

> 1. A microfluidic assembly for use with a particle processing instrument, the microfluidic assembly comprising:
>
> a substrate; and
>
> a flow channel formed in the substrate, the flow channel having:
>
> an inlet configured to receive *a sample stream*;
>
> a *fluid focusing region configured to focus the sample stream*, the fluid focusing region having a lateral fluid focusing feature, a first vertical fluid focusing feature, and a second vertical fluid focusing feature, the lateral, the first vertical, and the second vertical fluid focusing features provided at

> different longitudinal locations along the flow channel, wherein a bottom surface of the flow channel lies in a first plane upstream of the first and second vertical fluid focusing features and the bottom surface of the flow channel shifts vertically upward to lie in a second plane downstream of the first and second vertical focusing features; and
>
> an inspection region at least partially downstream of the fluid focusing region.

'439 patent, col. 18, lines 43–63 (emphases added).

Claims 2, 6, 8, and 9 depend on claim 1. The narrowing limitation of claim 2, which is of particular relevance to the key dispute before us, requires that the "lateral fluid focusing feature" of claim 1 be "configured to *introduce* focusing fluid into the flow channel symmetrically with respect to *a centerline* of the sample stream." *Id.*, col. 18, lines 64–67 (emphases added). Also of relevance to the dispute before us is a definition stated in the patent's specification: "[F]or the purposes of the present disclosure, the term 'a' or 'an' entity refers to one or more of that entity. As such, the terms 'a' or 'an', 'one or more' and 'at least one' can be used interchangeably herein." *Id.*, col. 18, lines 27–30.

B

In October 2020, ABS petitioned for an inter partes review of claims 1, 2, 6, 8, and 9 of the '439 patent, arguing unpatentability for anticipation and/or obviousness based on three references: Claire Simonnet & Alex Groisman, *High-Throughput and High-Resolution Flow Cytometry in Molded Microfluidic Devices*, 78 Analytical Chemistry 5653 (2006) (Simonnet); Dong Sung Kim et al., *An Efficient 3-Dimensional Hydrodynamic Focusing Microfluidic Device By Means of Locally Increased Aspect Ratio*, 86 Microelectronic Engineering 1343 (2009) (Kim); A. Kummrow et al., *Microfluidic Structures for Flow Cytometric Analysis of*

Hydrodynamically Focussed Blood Cells Fabricated by Ultraprecision Micromachining, 9 Lab on a Chip 972 (2009) (Kummrow). *See Final Written Decision*, at *4. ABS submitted other prior art, including Folch, Wada, Chang, and Weigl, for background understanding, but resolution of the claim-construction issue we decide does not turn on those references or anything but legal principles and evidence intrinsic to the '439 patent.

ABS challenged claims 1, 2, 6, and 8 as unpatentable under 35 U.S.C. § 102 for anticipation by Simonnet. *Id.*[1] ABS also asserted that all challenged claims are unpatentable under 35 U.S.C. § 103 for obviousness. *Id.* Specifically, regarding obviousness, ABS relied for claims 1, 2, 6, and 8 on Simonnet alone, for claim 8 on Simonnet in combination with Kim, and for claim 9 on Simonnet in combination with Kummrow. *Id.*

In its final written decision, the Board held that ABS had not proved any of the challenged claims to be unpatentable. *Id.* at *25. In rejecting ABS's challenges, the Board's sole stated basis was that Simonnet failed to disclose one claim limitation—specifically, "the sample stream" component of the "fluid focusing region" element. *Id.* at *20, *24–25. The Board determined that, as a matter of claim construction, "the sample stream" language in claim 1 had a singular-only meaning, not allowing a plurality of streams or a split stream. *Id.* at *9–12.

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[1] It is undisputed that the applicable versions of §§ 102 and 103 are the ones that pre-date the amendments to those sections made by the Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011). *Final Written Decision*, at *4 n.2. Regardless, no AIA-made change has been suggested to be material to this appeal. We therefore omit the date in citing the statute.

With regard to ABS's anticipation challenges, the Board found that Simonnet did not disclose a "fluid focusing region configured to focus the sample stream." *Id.* at *15–16. That finding rested on a claim construction and a finding about what Simonnet disclosed. The claim construction was that the quoted claim limitation requires that there be only a single sample stream from entry of the sample at least to inspection. *Id.* at *9–12. The finding about Simonnet was that it did not disclose such a single stream. Specifically, the Board found that figures 3(a) and 3(b) in Simonnet, which are micrographs of cross-sections of sample fluid in two experiments, both show a *split* sample stream with a gap in the middle, which the Board held was not the single stream required by the Board's claim construction. *Id.* at *15–16. This rationale precluded anticipation by Simonnet of independent claim 1 and, necessarily, of dependent claims 2, 6, and 8. *Id.* at *20.

The Board also rejected ABS's obviousness challenges, and the reasoning depended on the claim construction that claim 1 required that there be only a single stream, precluding a split one. *Id.* at *21–25. Under the adopted claim construction, a modification of Simonnet would be required for obviousness, but the Board determined that ABS had not "provided adequate reasoning as to why a person of ordinary skill would have sought to modify the teachings of Simonnet, *e.g.*, to vary the flow rate ratios and eliminate the gap in the sample streams." *Id.* at *22. That rationale required rejection of ABS's challenge to claims 1, 2, 6, and 8 for obviousness over Simonnet alone. *Id.* at *24. And because neither Kim nor Kummrow remedied the deficiency in the ground of obviousness for claim 1 over Simonnet, the Board concluded that ABS also could not establish that claim 8 or claim 9 was unpatentable for obviousness. *Id.* at *24–25.

C

The Board issued its final written decision on April 28, 2022, and ABS timely appealed. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

II

ABS has presented several arguments on appeal. The principal argument is that the Board erred in its claim construction limiting claim 1's disputed language to a flow channel's focusing region configured for only a single sample stream, not more than one. ABS also argues, among other things, that Simonnet meets the single-stream requirement even under the Board's construction. We reverse the Board's claim construction, without addressing other arguments independent of the correctness of the Board's construction. We then explain the effect of that reversal on the challenges to the five claims at issue.

A

We decide the proper claim construction in this case de novo, as intrinsic evidence is decisive of the proper construction. *See*, *e.g.*, *Polaris Innovations Ltd. v. Brent*, 48 F.4th 1365, 1372 (Fed. Cir. 2022); *Best Medical International, Inc. v. Elekta Inc.*, 46 F.4th 1346, 1355 (Fed. Cir. 2022). The Board determined that the '439 patent's claim language requires that the flow channel's focusing region of claim 1 (and hence all claims challenged here) be configured for only a single, contiguous sample stream, not more than one. *Final Written Decision*, at *9–12. In light of the claim language and specification, we reject this construction.

The specific claim language at issue is "a fluid focusing region configured to focus the sample stream." The use of the definite article, "the," means that the phrase "the sample stream" refers back to earlier language as an antecedent. The antecedent language is "a sample stream" in the preceding limitation, and it is the singular-only or plural-

allowing meaning of that limitation which is determinative. The reference-back "the" language takes its meaning from the meaning of the antecedent, so if "a sample stream" has a plural-allowing meaning, so does the reference-back "the sample stream" phrase. *See*, *e.g.*, *Salazar v. AT&T Mobility LLC*, 64 F.4th 1311, 1315 (Fed. Cir. 2023); *Lite-Netics, LLC v. Nu Tsai Capital LLC*, 60 F.4th 1335, 1346 (Fed. Cir. 2023); *Baldwin Graphic Systems, Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1342–43 (Fed. Cir. 2008).

Two familiar aspects of claim-construction analysis strongly support the plural-allowing meaning here. First, "at least in an open-ended 'comprising' claim," like claim 1 of the '439 patent, "use of 'a' or 'an' before a noun naming an object" requires that the phrase be construed to mean "'one or more' unless the context sufficiently indicates otherwise." *Lite-Netics*, 60 F.4th at 1345; *see Salazar*, 64 F.4th at 1315; *Convolve, Inc. v. Compaq Computer Corp.*, 812 F.3d 1313, 1321 (Fed. Cir. 2016); *Baldwin*, 512 F.3d at 1342–43. The court has called this the "general rule," adding that an exception "only arises where the language of the claims themselves, the specification, or the prosecution history necessitate a departure from the rule." *Baldwin*, 512 F.3d at 1343. Second, the specification here states: "[F]or the purposes of the present disclosure, the term 'a' or 'an' entity refers to one or more of that entity. As such, the terms 'a' or 'an', 'one or more' and 'at least one' can be used interchangeably herein." '439 patent, col. 18, lines 27–30. That definition reinforces, rather than negates, the applicability here of the "one or more" general rule concerning "a" or "an." It also brings into play the lexicography principle—that, with narrow exceptions, "[w]here the specification instructs as to the meaning of a claim term, 'the inventor's lexicography governs.'" *Grace Instrument Industries, LLC v. Chandler Instruments Co.*, 57 F.4th 1001, 1010 (Fed. Cir. 2023) (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005) (en banc)); *see Thorner v. Sony Computer Entertainment America LLC*, 669 F.3d

1362, 1365 (Fed. Cir. 2012); *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1380 (Fed. Cir. 2009).

There is no sufficient basis for rejecting the plural-allowing meaning of "a sample stream" here. The prosecution history has not been shown, or even meaningfully argued, to do so. Nor does anything in the specification supply a "clear and manifest disavowal" of that meaning, *Martek*, 579 F.3d at 1380, or "totally negate[]" it, *id.* at 1383 (Lourie, J., dissenting in part). In particular, the singular-only meaning is not demanded by the specification's embodiments, described as nothing more than examples. *See*, *e.g.*, '439 patent, col. 3, lines 52–57; *id.*, col. 18, lines 16–22. Nor has Cytonome shown an operational impossibility or something comparable that requires rejecting the plural-allowing meaning.

The Board relied centrally, for its singular-only construction, on the conclusion that a plural-allowing scope of "a sample stream" would be inconsistent with claim 2's requirement that the focusing fluid be "*introduced* into the flow channel symmetrically with respect to *a centerline of the sample stream*." *Id.*, col. 18, lines 64–67 (emphases added); *Final Written Decision*, at *10–11. We disagree. Claim 2's language does not support rejection of the doubly presumed plural-allowing meaning of "a sample stream."

The Board at one point stated: "[T]he claim refers to the centerline of the sample stream, and not simply the center of the device." *Final Written Decision*, at *10. To the extent that the Board, in referring to "*the* centerline," suggested that there can be only one centerline, that suggestion relies on a departure from the language of claim 2, which refers to "*a* centerline." That language is itself presumptively plural-allowing for the reasons already discussed regarding "a sample stream." It presumptively covers one or more centerlines of one or more sample streams.

ABS urges that claim 2 therefore covers at least (a) separate centerlines of separate streams and (b) a single centerline of a pair of streams (or branches of a split stream). We need not endorse or reject that position (or either portion of it) to conclude that claim 2 does not require narrowing the disputed claim 1 limitation to a singular-only meaning.

The Board's core reasoning was that "a centerline of the sample stream" must lie *in* the sample fluid—which, the Board said, would not be true of a centerline (understood as a singular) of a pair of streams or a split stream with a gap in the middle filled by focusing fluid, where the centerline ran through the focusing fluid. *Id.* at *10–11. But that reasoning does not address the drawing of separate centerlines for separate streams (or of the branches of a split stream). And even as to the drawing of a single centerline for a pair of streams (or branches of a split stream), the language on its face is broad enough to cover such a centerline, like a centerline of a highway that runs through a plant-filled median or a centerline of a river that runs through islands in the river. Here, the symmetry property expressly required by claim 2 is symmetry in "introduc[ing]" the focusing fluid—not necessarily symmetry of focusing fluid everywhere along the length of a sample stream. '439 patent, col. 18, lines 65–67. A "centerline of the sample stream" is merely a reference point for how focusing fluid should be introduced. It has not been shown that satisfaction of the claim 2 requirement precludes a sample-stream centerline from running through focusing fluid.

The Board also reasoned that a "centerline of the sample stream" must lie in the sample fluid in order to avoid redundancy with the terms "a centerline of the flow channel" and "a centerline of the microfluidic channel" in claims 5 and 20, respectively. *Final Written Decision*, at *10–11. But there is no such redundancy to be avoided. "A centerline of the flow channel" and "a centerline of the microfluid

channel" refer to a centerline through the solid physical boundaries of the channel, even when no sample fluid is flowing in the apparatus. *See* '439 patent, col. 19, lines 23–25 (requiring that "the first pair and the second pair of fluid focusing channels are *symmetrically arranged* with respect to a centerline of the flow channel" (emphasis added)); *id.*, col. 21, lines 5–7 (requiring that "the first and second focusing fluid channels are *located* to a first side of a centerline of the microfluidic channel" (emphasis added)). "A centerline of the sample stream" refers to a centerline of the *fluid* flow of the sample through that channel, when there is such a fluid flow. *See id.*, col. 18, lines 65–67 (requiring that "the lateral fluid focusing feature is *configured to introduce focusing fluid* into the flow channel symmetrically with respect to a centerline of the sample stream" (emphasis added)). Although the three phrases share a term, "centerline," the additional terms ("of the sample stream," "of the flow channel," and "of the microfluid channel") make clear that the phrases as a whole refer to different things (even if they may overlap)—precluding the conclusion of redundancy on which the Board relied.

For the foregoing reasons, we reverse the Board's claim construction and hold that "the sample stream" is not limited to a singular-only sample stream.

B

In many cases involving reversal of a Board claim construction, the appropriate course of action is to vacate the Board's decision and remand the matter. *See*, *e.g.*, *Kaken Pharmaceutical Co., Ltd. v. Iancu*, 952 F.3d 1346, 1355 (Fed. Cir. 2020); *Arista Networks, Inc. v. Cisco Systems, Inc.*, 908 F.3d 792, 798 (Fed. Cir. 2018). In some cases, however, depending on what contentions were made to the Board and what evidence the record contains, "where only one answer is supported by substantial evidence and there is . . . [no] apparent reason to grant a second record-making opportunity, reversal is warranted." *Owens Corning v.*

Fast Felt Corp., 873 F.3d 896, 901–02 (Fed. Cir. 2017). Thus, it is appropriate to reverse the Board's determination when the evidence supports only the conclusion that the challenged claims are unpatentable, where no properly raised issues still need to be decided by the Board in order to adjudicate a particular patentability challenge. *See id.*

We address claim 1 first, then the dependent claims.

1

Under the correct claim construction, we conclude that the evidence requires the finding that independent claim 1 is anticipated by Simonnet. A claim is anticipated if "each and every element as set forth in the claim is found, either expressly or inherently, in a single prior art reference." *Arbutus Biopharma Corp. v. ModernaTx, Inc.*, 65 F.4th 656, 662 (Fed. Cir. 2023). Anticipation is a question of fact reviewed for substantial evidence. *Id.*

The Board rejected ABS's anticipation challenge solely on the ground that the Simonnet device produces only a split sample stream, which is not a "singular" stream and thus "does not satisfy 'the sample stream' limitation." *Final Written Decision*, at *16, *20. But because under the proper construction "the sample stream" may refer to one or more sample streams, Simonnet satisfies this claim limitation—regardless of whether the "split" sample stream disclosed by Simonnet is properly viewed as two different sample streams or as a singular sample stream with a gap in the middle. As the Board found that every other element of claim 1 was disclosed by Simonnet and Cytonome has not meaningfully challenged those findings on appeal, the evidence compels a finding that claim 1 is anticipated. That finding makes an inquiry into obviousness for claim 1 unnecessary.

2

The challenged dependent claims (2, 6, 8, and 9) all claim "[t]he microfluidic assembly of claim 1" with one

additional limitation each. ABS seeks reversal of the Board's determinations as to all challenged dependent claims, while Cytonome urges a remand for the Board to consider the dependent claims in the first instance under a new claim construction. We agree with Cytonome regarding claims 2, 6, and 9 and with ABS regarding claim 8.

Claim 2 requires the lateral fluid focusing feature of claim 1 to be "configured to introduce focusing fluid into the flow channel symmetrically with respect to a centerline of the sample stream." '439 patent, col. 18, lines 64–67. Claim 6 adds to claim 1 a different additional limitation: that "the sample stream and the focusing fluid . . . enter the fluid focusing region in a same plane." *Id.*, col. 19, lines 26–29. The parties continue to dispute the proper application (and perhaps interpretation) of claims 2 and 6, at least of the terms "symmetrically" in claim 2, ABS's Opening Br. at 62–63; Cytonome's Br. at 52, and "a sample plane" in claim 6, ABS's Opening Br. at 63–66; Cytonome's Br. at 53. We remand for further consideration of claims 2 and 6.

Claim 9 adds to claim 1 the limitation that "each of the fluid focusing features is in fluid communication with a first focusing fluid inlet port provided on a top surface of the substrate." '439 patent, col. 19, lines 40–43. ABS concedes that Simonnet does not disclose this limitation and instead argues that the claimed apparatus would have been an obvious combination of Simonnet and Kummrow. ABS's Opening Br. at 68–71. The Board has not decided the merits of components of ABS's obviousness challenge, including whether a relevant artisan would have had a motivation to combine Simonnet and Kummrow. We remand for further consideration of claim 9.

Claim 8 warrants different treatment. It adds to claim 1 a requirement that the "fluid flow channel . . . transition[] from a first cross section shape to a second cross section shape different from the first cross section shape." '439 patent, col. 19, lines 36–39. ABS asserts that the microfluidic

device taught by Simonnet changes cross-section shapes multiple times. ABS's Opening Br. at 66–67. But neither before the Board nor in this court has Cytonome disputed whether Simonnet discloses this limitation. Cytonome's Br. at 54. Because the uncontested evidence establishes that Simonnet discloses claim 8's additional limitation, we reverse the Board's determination and hold that claim 8 is anticipated by Simonnet.

III

The Board's claim construction, and its final written decision regarding claims 1 and 8, are reversed. The Board's final written decision regarding claims 2, 6, and 9 is vacated. The matter is remanded for further proceedings consistent with this opinion.

Costs awarded to appellants.

REVERSED IN PART, VACATED, AND REMANDED