

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARDS LIFESCIENCES CORPORATION AND
EDWARDS LIFESCIENCES LLC,
Petitioner,

v.

AORTIC INNOVATIONS LLC,
Patent Owner.

Case IPR2023-01325
Patent 11,491,033

**PATENT OWNER AORTIC INNOVATIONS LLC'S
PRELIMINARY SUR-REPLY**

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EXHIBIT LIST	
2001	Declaration of Nathan Lowenstein in Support of Motion for <i>Pro Hac Vice</i> Admission
2002	Declaration of Stephen J.D. Brecker [Brecker-Decl.]
2003-2039	Reserved
2040	Excerpts from the opposition proceeding to European Patent 2982337 [Spenser-II-European-Proceeding]
2041-2051	Reserved
2052	Deposition Transcript of Nigel P. Buller In IPR2022-00034 [Buller-00034-Depo.]
2053-2100	Reserved
2101	U.S. Patent No. US6,663,667 [Dehdashtian]
2102	U.S. Patent Application No. 2006/0004442 to Spenser ['442 Application]
2103	Declaration of Stephen J.D. Brecker filed in IPR2022-00556 [Brecker-556-Decl.]
2104-2121	Reserved
2122	Transcript of April 12, 2023 Deposition of Nigel P. Buller in IPR2022-00556 [Buller-556-Reply-Depo.]
2123	Reserved
2124	Final Written Decision of IPR2022-00556 [-00556FWD]
2125	U.S. Patent No. 6,096,052 [Callister]
2126	File History of US Patent Application 2002/0151958 A1 to Chuter [Chuter-FH]
2127	Reserved

2128	Declaration of Nigel P. Buller filed in IPR2022-00556 [Buller-556-Decl.]
2129-2135	Reserved
2136	Edwards Petition for Inter Partes Review filed in IPR2023-01151 [-01151-Pet.]
2137-2139	Reserved
2140	File History of US Patent Application 2017/327,673 ['834-FH]
2141	Declaration of Dr. David Brookstein, Sc.D. Regarding Claim Construction submitted in Case No. 1-23-cv-00158 (D. Del.) [Brookstein-Decl.]
2142	Reserved
2143	U.S. Patent No. 11,337,834 ['834]
2144	Edwards Petition for Inter Partes Review filed in IPR2023-01232 [-01232-Pet.]

I. PETITIONER’S ARGUMENT HAS ALREADY BEEN REJECTED.

Petitioner’s reply concerns the “spacing” limitation. The Board, however, has already decided that Spenser II and Chuter do not satisfy the spacing limitation. *See* IPR2023-01151, Paper 12 (“-1151 ID”), 34-41 (Spenser II), 47 (Chuter). For the same reasons, the Board should reject Petitioner’s positions.

Indeed, in the 1151 IPR, Petitioner submitted a substantially similar reply arguing that (1) Patent Owner takes inconsistent positions between the district court and the Board as to “spacings” and (2) that all fibrous cloths have spacings. *Compare* IPR2023-01151, Paper 9 *with* IPR2023-01325, Paper 9. These arguments were considered and squarely rejected. As to (1), the Board found that “[w]e are not persuaded by Petitioner’s argument that Patent Owner (or Dr. Brecker) are proposing conflicting claim constructions in this IPR versus what is proposed before the district court.” -1151 ID, 37 n.14. As to (2), the Board was “unpersuaded that the claimed ‘spacing’ should be interpreted to read on all fibrous cloths attached to a frame.” *Id.*, 36.

II. PETITIONER’S DISTRICT COURT EXPERT AGREES THAT SPENSER II WAS DISCLAIMED AS NOT DISCLOSING OR RENDERING OBVIOUS “SPACINGS.”

The Petition contends that Spenser II satisfies the claimed “spacings” (Pet., 46-54) while the POPR contends, *inter alia*, that in view of a clear prosecution disclaimer, Spenser II cannot satisfy the claimed “spacings” (POPR, 2-18).

Petitioner’s district court expert, however, *fully agrees with Patent Owner’s position* (POPR, Section II.B.1) that, in view of a prosecution disclaimer, Spenser II cannot satisfy the “spacing” limitation. Specifically, Dr. Brookstein recognized that “Aortic Innovations argued that the collagen fibers in the Asserted Patents *were distinguishable from the prior art ... (including Walther and Spenser II)*” due to the “lack of ‘spacings.’” Ex. 2141 [Brookstein-Decl.] ¶35 (quoting Ex. 2140 [’834-FH] 1001). Dr. Brookstein further confirmed there is no “dispute that the Asserted Patents *do not include cloths like those described* in Walther and *Spenser II.*” *Id.*, ¶33 (Applicant “repeatedly distinguished the claimed ‘spacing(s)’ from spacings between fibers that are present in ... the cloths and materials disclosed in Walther and Spenser II”). Thus, while Petitioner here argues that Spenser II discloses or renders obvious “spacings,” Petitioner’s expert has since confirmed the opposite.

Dispositively, the Board has already found that Spenser II cannot satisfy the “spacing” limitation in view of the prosecution history:

[The] applicant contrasted the claimed “spacing” with the prior art’s “very tightly knitted outer seal made of tightly knitted fibers” and expressly cited Spenser II’s Figure 22 and Walther (Ex. 1007) as examples of designs with a “lack of spacings” between the fibers like the claimed “spacing.” ... Petitioner’s expert in related litigation also testified that “there does not appear to be any dispute that [the ’834

patent] do[es] not include cloths like those described in Walther and Spenser II. ... construing the “spacing” limitation to encompass all [] cloths would, at least on this record, appear to erase the distinction (or potential disclaimer) that applicant made during prosecution over cloths comprising “tightly knitted fibers” such as allegedly exemplified in Spenser II.

-1151 ID, 36-37.

III. UNLIKE PETITIONER, PATENT OWNER’S POSITION REGARDING “SPACINGS” IS CONSISTENT.

Ignoring its own inconsistency, Petitioner argues that “PO and its expert, Dr. Brecker, propose a [] construction in district court” “contrary” to their position in the IPR. Reply, 3. The Board, again, rejected Petitioner’s argument: “We are not persuaded by Petitioner’s argument that Patent Owner (or Dr. Brecker) are proposing conflicting claim constructions in this IPR versus what is proposed before the district court.” -1151 ID, 37 n.14.

The Board’s finding was correct. Patent Owner “propose[d]” no construction of “spacings,” much less one inconsistent with its IPR position. Patent Owner consistently applied the plain and ordinary meaning in view of the Applicant’s **undisputed** disclaimer “such that Spenser II[] cannot disclose or render obvious ‘spacings.’” POPR, 4; Ex. 2140 [’834-FH] 1001; Ex. 2141 [Brookstein-Decl.] ¶¶33, 35. Petitioner’s contrary position is founded upon Dr. Brecker’s testimony that he saw no “disavowal or disclaimer ... requiring that **all**

sleeves, layers, and cloths be excluded from the term ‘spacings.’” Reply, 3 (quoting Ex. 1145 [Breckers-Claim-Construction-Decl.] ¶92). This is a *non sequitur*. As the Board agreed, a statement about Spenser II’s compressible material is not a statement about “**all** sleeves, layers, and cloths.” See -1151 ID, 37.

The Applicant’s statement that Spenser II’s compressible material lacks the claimed “spacings” is in full harmony with the plain meaning. Dispositively, the Board noted Dr. Buller’s testimony that “Spenser II’s compressible material ... is ‘sufficiently dense to prevent blood from leaking through the cloth/fabric’” and found “Dr. Buller’s description of Spenser II as having a **dense, blood impermeable base layer** is ... more consistent with applicant’s characterization of Spenser II ...” -1151 ID, 38-39 (quoting Ex. 2128 [Buller-556-Decl.] ¶222); see also Ex. 2040, 2087-2093 (Petitioner: “compressible material is a fluid impermeable membrane”); Ex. 2124 [-556-FWD] 29-30 (Board: Spenser II’s compressible material “corresponds to an outer graft covering), 33-34 (quoting Ex. 2103 [Breckers-556-Decl.] ¶160).

Petitioner argues that Patent Owner “suggests” that the Applicant’s disclaimer was “limit[ed]” to Spenser II, arguing instead for an expansive disclaimer, broadly extending to all grafts, sleeves, and cloths. Reply, 4. The Board has already rejected this contention. -1151 ID, 37; *id.*, n.14 (citing Ex. 1146

[Brecker-556-Depo.] 185:14-186:7). Again, the Applicant distinguished the claimed “spacings” from “a very tightly knitted outer seal made of tightly knitted fibers (such as found in ... Walther ... or [Spenser II], with reference to FIG. 22 ...” Ex. 2140 [’834-FH] 1001 (quoted at POPR, 4). Thus, the disclaimer is not limited to Spenser II for it plainly extends to Walther and to a “very tightly knitted outer seal made of tightly knitted fibers.” Equally plain, the disclaimer does not extend to all “grafts,” “graft coverings,” “sleeves,” and “cloths.” Reply, 4.¹

Petitioner’s contention that the claims are indefinite is wrong and, moreover, outside the Board’s jurisdiction. *See* -1151 ID, 41; *id.*, n.17.

In accord with the -1151 ID, institution should be denied.

¹ A loosely woven/knitted cloth with “spacings” extending through its thickness to or through the frame may well satisfy the limitation. Petitioner’s contention that Ultra’s outer skirt is a “graft covering” lacking “spacings” (Reply, 3-4) is contradicted by Dr. Buller’s testimony that it is not a “graft covering” and “clearly” has “holes [] going all the way through it.” Ex. 1128, 132:14-133:10; *see also* -1151 ID, 36 (“the available (yet limited) evidence suggests there may be important differences in those designs”).

Respectfully submitted,

/ Kenneth J. Weatherwax /

Kenneth J. Weatherwax, Reg. No. 54,528

Nathan N. Lowenstein (*pro hac vice*)

Colette Woo (*pro hac vice* to be filed)

Lowenstein & Weatherwax LLP

Date: January 12, 2024

CERTIFICATE OF SERVICE

The undersigned hereby certifies that the following document was served by electronic service, by agreement between the parties, on January 12, 2024:

**PATENT OWNER AORTIC INNOVATIONS LLC'S
PRELIMINARY SUR-REPLY**

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