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Paper No. 48
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DEXCOM, INC., Petitioner,

v.

WAVEFORM TECHNOLOGIES, INC., Patent Owner.

Case IPR2017-01051 Patent 7,529,574 B2

Before BENJAMIN D. M. WOOD, JON B. TORNQUIST, and ELIZABETH M. ROESEL, *Administrative Patent Judges*.

ROESEL, Administrative Patent Judge.

FINAL WRITTEN DECISION 35 U.S.C. § 318 and 37 C.F.R. § 42.73



In this *inter partes* review, instituted pursuant to 35 U.S.C. § 314, Dexcom, Inc. ("Petitioner") challenges the patentability of claims 1–19 of U.S. Patent No. 7,529,574 B2 (Ex. 1001, "the '574 patent"), owned by WaveForm Technologies, Inc. ("Patent Owner").

We have jurisdiction under 35 U.S.C. § 6. This final written decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

For the reasons that follow, we determine that Petitioner has shown by a preponderance of the evidence that claims 1, 4–12, and 15–19 of the '574 patent are unpatentable. We determine that Petitioner has not shown by a preponderance of the evidence that claims 2, 3, 13, and 14 of the '574 patent are unpatentable. We grant Patent Owner's Contingent Motion to Amend as to claims 21, 24, and 25 (proposed substitutes for claims 10, 13, and 14 of the '574 patent) and deny the motion as to claims 20, 22, 23, and 26–29 (proposed substitutes for claims 9, 11, 12, 15–17, and 19 of the '574 patent). We dismiss Patent Owner's Motion to Exclude as moot.

I. BACKGROUND

A. Procedural History

Petitioner filed a Petition seeking *inter partes* review of claims 1–19 of the '574 patent. Paper 1 ("Pet."). Patent Owner filed a Preliminary Response. Paper 5 ("Prelim. Resp."). We instituted *inter partes* review of all challenged claims, based on only one of the five grounds of unpatentability presented in the Petition. Paper 7 ("Institution Decision" or "Dec."), 2, 4, 32.

Patent Owner filed a Response and a Contingent Motion to Amend.

Paper 17 ("PO Resp."); Paper 18 ("Mot."). Petitioner filed a Reply and a

Response to the Motion to Amend. Paper 23 ("Pet. Reply"); Paper 22 ("Pet.



Opp."). Patent Owner filed a Reply to Petitioner's Response to the Motion to Amend. Paper 27 ("PO Reply"). With prior authorization of the Board, Petitioner filed a Sur-Reply to the Motion to Amend (Paper 29, "Pet. Sur-Reply"), and Patent Owner filed Responses to Observations of Dr. Smith's testimony (Paper 36).

Following the Supreme Court's decision in *SAS Institute Inc. v. Iancu*, 138 S. Ct. 1348 (2018), we modified our Institution Decision to include review of all grounds presented in the Petition. Paper 30. With the Board's prior authorization, Petitioner filed a Reply regarding the subsequently instituted grounds (Paper 37), and Patent Owner filed a Sur-Reply (Paper 42).

Patent Owner filed a Motion to Exclude Exhibit 1037 filed with Petitioner's Reply (Paper 37) and portions of the Reply discussing that exhibit. Paper 41. Petitioner filed a response (Paper 44), and Patent Owner filed a reply (Paper 45) concerning the Motion to Exclude.

With the Petition, Petitioner filed a Declaration of David Vachon, Ph.D. Ex. 1006. Patent Owner cross-examined Dr. Vachon and filed a transcript of his deposition testimony as Exhibit 2009.

With the Preliminary Response, Patent Owner filed a declaration of John L. Smith, Ph.D. Ex. 2001. With the Patent Owner Response, Patent Owner filed a second declaration of Dr. Smith. Ex. 2008. With its Reply to Petitioner's Response to the Motion to Amend, Patent Owner filed a third declaration of Dr. Smith. Ex. 2024. Petitioner cross-examined Dr. Smith three times and filed transcripts of his deposition testimony as Exhibits 1021, 1031, and 1032.



Oral argument was held July 13, 2018, and a transcript was entered in the record. Paper 47 ("Tr.").

B. Related Matters

The parties identify the following district court proceeding involving the '574 patent: *WaveForm Technologies, Inc. v. Dexcom, Inc.*, No. 3:16-cv-536-MO (D. Or., filed March 28, 2016). Pet. 88; Paper 3 (Patent Owner Mandatory Notices—37 C.F.R. § 42.8).

In addition, Patent Owner identifies the following *inter partes* review proceedings involving Dexcom, Inc. as Petitioner and WaveForm Technologies, Inc. as Patent Owner: IPR2016-01679, involving U.S. Patent No. 7,146,202 B2, and IPR2016-01680, involving U.S. Patent No. 8,187,433 B2. Paper 3, 2.

C. The '574 Patent (Ex. 1001)

The '574 patent was issued May 5, 2009 from Application No. 10/640,980, filed August 14, 2003. Ex. 1001, [45], [21], [22].

The '574 patent relates to an indwelling analyte sensor, for example, a glucose sensor. Ex. 1001, 1:18–19. According to the '574 patent, the problem addressed is that of producing a dip coating of curable viscous material to form, e.g., a glucose oxidase enzyme layer, over an electrochemically active surface, where the coating has a thickness sufficient to produce an adequate response to the presence of glucose. *Id.* at 1:6–14, 2:8–10. The solution described by the '574 patent is to provide at least one nub of dielectric material that extends outwardly from the electrochemically active surface to allow a greater portion of curable viscous liquid to adhere to the electrochemically active surface and provide a supportive structure for



the curable liquid before and during the curing and for the resulting membrane system. *Id.* at 1:22–25, 1:29–34, 2:6–10.

An embodiment is shown in Figures 1 and 2, which are reproduced below:

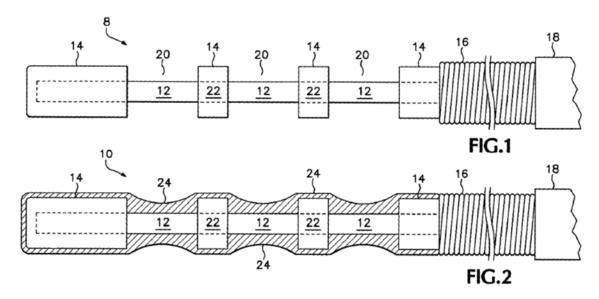


Figure 1 of the '574 patent shows a work piece formed as part of the construction of a biosensor, and Figure 2 shows a sensor constructed from the work piece of Figure 1. Ex. 1001, 1:43–47.

As shown in Figure 2, analyte (typically glucose) sensor 10, includes platinum wire 12, polyimide layer 14, silver wire 16 wrapped about a portion of layer 14, and stainless steel retractor lead 18. *Id.* at 1:53–56. Referring to the structures shown in Figures 1 and 2, the '574 patent provides the following disclosure regarding construction of a biosensor:

Three cavities 20, each 2 mm long, are formed by laser ablating polyimide layer 14 to form a work piece 8 (FIG. 1). The polyimide between the cavities 20, forms a set of annular plates 22, that are supported by the adherence of the polyimide 14 onto wire 12. In an embodiment, nubs, such as annular plates 22, may be spaced longitudinally from the active surface of wire 12. After the laser machining operation, the work piece



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