Paper No. 53 Entered: February 28, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

DEXCOM, INC.,

v.

Petitioner,

WAVEFORM TECHNOLOGIES, INC., Patent Owner.

Case IPR2016-01679 Patent 7,146,202 B2

Before ERICA A. FRANKLIN, JON B. TORNQUIST, and ELIZABETH M. ROESEL, *Administrative Patent Judges*. <sup>1</sup>

ROESEL, Administrative Patent Judge.

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

<sup>&</sup>lt;sup>1</sup> Administrative Patent Judge Erica A. Franklin replaces former panel member Brian P. Murphy, who is no longer with the Patent Trial and Appeal Board.



In this *inter partes* review, instituted pursuant to 35 U.S.C. § 314, Dexcom, Inc. ("Petitioner") challenges patentability of claims 1–3, 5, 6, and 8–11 of U.S. Patent No. 7,146,202 B2 (Ex. 1001, "the '202 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 1–3, 6, 8, and 11 of the '202 patent are unpatentable. We determine that Petitioner has not shown by a preponderance of the evidence that claims 5, 9, and 10 of the '202 patent are unpatentable.

## I. BACKGROUND

## A. Procedural History

Petitioner filed a Petition seeking *inter partes* review of claims 1–3, 5, 6, and 8–11 of the '202 patent. Paper 1 ("Pet."). Patent Owner filed a Preliminary Response. Paper 7 ("Prelim. Resp."). We instituted *inter partes* review of all challenged claims. Paper 10 ("Institution Decision" or "Dec.").

Patent Owner filed a Response. Paper 29 ("PO Resp."). Petitioner filed a Reply. Paper 37 ("Pet. Reply").<sup>2</sup>

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 2036.

<sup>&</sup>lt;sup>2</sup> We rely on the public, redacted versions of Patent Owner's Response and Petitioner's Reply.



With the Preliminary Response, Patent Owner filed declarations of John L. Smith, Ph.D. (Ex. 2001) and Matthew J. Schurman, Ph.D. (Ex. 2003). With the Patent Owner Response, Patent Owner filed declarations of Dr. Smith (Ex. 2027),<sup>3</sup> Dr. Schurman (Ex. 2029), Ellen M. Anderson (Ex. 2035), and Serena Morones (Ex. 2053). Petitioner cross-examined each of these witnesses and filed transcripts of each witness's deposition testimony as follows: Dr. Smith (Ex. 1037), Dr. Schurman (Ex. 1039), Ms. Anderson (Ex. 1041), and Ms. Morones (Ex. 1033).

Oral argument was held December 7, 2017, and a transcript was entered in the record. Paper 52 ("Tr.").

As further discussed below, each party filed a motion to exclude evidence submitted by the opposing party.

## B. Related Matters

The parties identify the following district court proceeding involving the '202 patent: *WaveForm Technologies, Inc. v. Dexcom, Inc.*, No. 3:16-cv-00536-MO (D. Or.). Pet. 64–65; Paper 14, 2 (Patent Owner's updated mandatory notices).

In addition, the parties identify the following *inter partes* review proceedings: *Dexcom, Inc. v. WaveForm Technologies, Inc.*, IPR2016-01680, involving U.S. Patent No. 8,187,433 B2 ("the '433 patent");<sup>4</sup> and *Dexcom, Inc. v. WaveForm Technologies, Inc.*, IPR2017-01051, involving

<sup>&</sup>lt;sup>4</sup> The '433 patent (Ex. 2028) was issued from U.S. Application No. 11/538,340, filed October 3, 2006, which is a division of U.S. Application No. 10/869,133, filed June 16, 2004, which issued as the '202 patent (Ex. 1001).



<sup>&</sup>lt;sup>3</sup> We rely on the public, redacted version of Exhibit 2027.

U.S. Patent No. 7,529,574. Paper 14, 2; Paper 44, 2 (Petitioner's updated mandatory notices).

## C. Instituted Grounds of Unpatentability

We instituted *inter partes* review on the following three grounds of unpatentability asserted in the Petition:

Reference[s]	Statutory Basis	Challenged Claims
Wilson <sup>5</sup> and Rosenblatt <sup>6</sup>	§ 103(a)	1–3, 5, 6, and 9–11
Hagiwara <sup>7</sup>	§ 102(b)	1–3, 6, 8, 10, and 11
Hagiwara and Rosenblatt	§ 103(a)	5

### C. The '202 Patent

The '202 patent, titled "Compound Material Analyte Sensor," was issued December 5, 2006. Ex. 1001, at (54). The '202 patent relates to a sensing element adapted to be inserted, at least in part, into a mammalian body. *Id.* at Abstract, 1:42–44. The '202 patent discloses that the sensing element includes a core of a structurally robust material and a plated portion comprising an electrochemically active metal. *Id.* at Abstract, 1:44–46. The sensing element may be used in a method for continuous sensing of an

<sup>&</sup>lt;sup>7</sup> Japanese Unexamined Patent Application Publication No. S57-110236, published July 9, 1982. Ex. 1007. Exhibit 1007 includes an English translation (pages 1–16), a translation certificate (page 17), a certified copy of the Japanese publication (pages 19–30), and a cover letter (page 18).



<sup>&</sup>lt;sup>5</sup> G. S. Wilson et al., *Progress toward the Development of an Implantable Sensor for Glucose*, 38(9) Clin. Chem. 1613–17 (1992). Ex. 1004.

<sup>&</sup>lt;sup>6</sup> U.S. Patent No. 2,719,797, issued October 4, 1955. Ex. 1005.

analyte, such as glucose, within a mammalian body. *Id.* at Abstract, 1:47–52.

According to the '202 patent, the disclosed sensing element addresses problems with platinum wire sensors, including: (1) platinum is a weak metal that is susceptible to sensor fatigue and breakage when subjected to flexure caused by bodily movement; and (2) platinum is expensive and can strain the budget for sensor production. *Id.* at 1:12–38.

An embodiment of a sensing element is depicted in Figure 1, which is reproduced below:

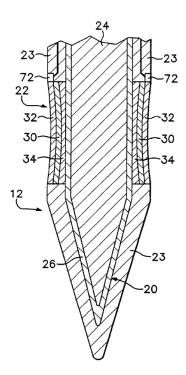


Figure 1, above, shows sensing element 12 including bimetallic wire 20, membrane system 22 coated on at least a portion of wire 20, and protective layer 23, e.g., polyimide, coated on portions of wire 20 not coated with membrane system 22. Ex. 1001, 2:10–23. Wire 20 includes core 24 and electrochemically active layer 26. *Id.* at 2:24–28. Membrane system 22, also referred to as sensing region 22, includes reactive layer 30



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