

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DEXCOM, INC.,
Petitioner,

v.

ABBOTT DIABETES CARE INC.,
Patent Owner.

Case No. IPR2023-01251

U.S. Patent No. 11,298,056

**PATENT OWNER'S SUR-REPLY IN SUPPORT OF THE
PATENT OWNER PRELIMINARY RESPONSE**

The phrase, “re-populated *in* the insulin pump,” refers to storing CGM data *in* the memory of the pump so that it can “be downloaded for historical analysis.” Ex. 1011 at 7-8. This interpretation is supported by explicit disclosure in Exs. 1011 and 2007. By contrast, Petitioner’s interpretation of this phrase—that it refers to backfilling a data gap on the insulin pump’s display with CGM data—is supported by *no textual description* and *no figures* in any of the evidence of record. Petitioner instead relies on its expert’s opinions about CGMs and its self-serving view of what is “logical.” Petitioner’s interpretation is neither logical nor supported by evidence. Because Ex. 1011 does not disclose the claimed display backfilling ([1.K] and [1.L]), Petitioner has not shown that every element of claim 1 is disclosed in the prior art.

I. PATENT OWNER’S INTERPRETATION IS BASED ON THE PLAIN LANGUAGE OF THE EVIDENCE

The MiniMed Paradigm® REAL-Time System includes the CareLink™ Personal Software. As shown on the right, the website navigation panes in Ex. 1011 include a link to the CareLink™ Personal Software nested among other links for the system. Ex. 1011 at 3. Moreover, the linked “Frequently Asked Questions” include FAQs about CareLink™ (*id.* at 11-12), and the linked “User Guides” include the “Carelink™ Personal Getting Started Guide” (*id.* at 3-4). That Guide is Ex. 2007, which Petitioner sought leave to address but mentions only twice in passing in its Reply. Reply at 1.



The phrase in dispute appears in a response to one of the FAQs:

When the MiniLink REAL-Time Transmitter is separated from the insulin pump for more than six feet (approximately 2 meters), the transmission is considered “out of range.” The transmitter holds 40 minutes worth of memory, so even though your system is “out of range,” continuous glucose monitoring (CGM) data can be re-populated in the insulin pump.

If your system is out-of-range for longer than 40 minutes, when reviewing historical reports you would notice “data gap” where information is missing during this period of time.

Ex. 1011 at 8. This passage does not say that “re-populated” data is ***displayed on*** the insulin pump. In fact, the word “display” is not used at all. The passage only says that “when reviewing historical ***reports***,” the user would see a data gap for a portion of an out-of-range period longer than 40 minutes. Thus, if the transmitter and receiver were out of range, data would be “re-populated ***in*** the insulin pump” and “historical ***reports***” would include the re-populated data.

The analysis therefore shifts to what is a “historical report.” The specific phrase, “historical report,” appears three times in Exhibit 1011. The first two instances are effectively identical: “When reviewing ***historical reports*** you would notice [a] ‘data gap’ where information is missing during this period of time.” *Id.* at 8 (twice). In the third instance, Ex. 1011 says: “While in flight, you need to manually test your glucose levels using a standard meter. ... When downloading and reviewing

historical reports, you will notice ‘data gap’ where information is missing during this period of time.” *Id.* at 13. Thus, Ex. 1011 explicitly says that “historical reports” must be “download[ed]” before they can be “review[ed].” That is what the CareLink™ Personal Software was for. The CareLink™ User Guide explains how to understand, generate, view, save, print, and e-mail reports. See Ex. 2007 at 11-20.

The word “report” also appears 7 other times in Exhibit 1011 (once as a verb):

- “CareLink software ... can be used to ... generate treatment **reports** integrating insulin pump, CGM, meter and logbook data.” (*id.* at 11)
- “How do I create **reports**?
From the main **Reports** page, select a **report** from the menu on the left-hand side of the screen. Select the date or date range from the **report** and click the Go button. Your **report** is displayed as a PDF file in a separate window.” (*id.* at 12)
- “Once calibrated, the Guardian RT **reports** glucose values every 5 minutes.” (*id.* at 83 (using “report” as a verb in unrelated context))

In every *relevant* instance, the words “historical report” and “report” are used in Ex. 1011 only to refer to a report generated by the CareLink™ Personal Software.

II. PETITIONER’S INTERPRETATION IS NOT BASED ON, AND IS CONTRADICTED BY, THE RECORD EVIDENCE

Nowhere does Ex. 1011 refer to anything displayed (history or otherwise) on the insulin pump as a “report,” or use “in” to refer to displaying information **on** the pump. Instead, every time Ex. 1011 refers to the insulin pump displaying information, it always refers to displaying information **on** a screen, graph, or pump.

Id. at 8 (“either a ‘WEAK SIGNAL’ or ‘LOST SENSOR’ message will appear **on the screen**”), 8 (“data will be displayed **on the insulin pump’s screen**”), 27 (“Icons appear **on every screen**”), 53 (“The pump ... displays a sensor glucose reading **on your pump screen**”), 61 (“to see the first glucose reading **on the pump screen**”), 64 (“a marker will appear **on your graph**”), 65 (“Your glucose value will be shown **on your graph**”), 65 (“Each data point **on the graph**”), 72 (“an alarm message shows **on the screen**”), 73 (“Weak Signal recorded **on the sensor graphs**”), 80 (“You should see the sensor icon [] **on the pump**”), 80 (“ISIG value **on this screen**”).

Petitioner disregards this plain language of Ex. 1011 and resorts to relying on unsupported opinions from its expert and purported “logic” to misinterpret the disputed phrase. *See* Reply at 1-3, 5, 6. Such reliance is a tacit concession that Ex. 1011 does not disclose the claimed display backfilling. In any event, none of it is relevant, and it is contradicted by the record evidence.

Petitioner argues that Patent Owner’s interpretation “def[ies] logic by suggesting that the described system withholds important data from a user.” Reply at 2. Petitioner is disguising a new inherency argument as purported “logic” by suggesting that all CGMs, including the insulin pump of Ex. 1011, must *necessarily* backfill later-acquired data on a display. Petitioner, however, has not, and cannot, prove this. Indeed, that Patel-2008 discloses a data gap, but not backfilling it, shows that backfilling a data gap on a CGM display is **not** inherent. *See* POPR at 35.

Petitioner further argues that the disputed phrase should be interpreted in light of its expert's opinion about an alleged "purpose of CGM" and statements in the FAQs about the purported emphasis "on providing continuous real time data to users." Reply at 1, 3, 5-6. Petitioner's arguments fail at least because the re-populated data would not be provided in real time. Moreover, at the time of Ex. 1011, "[t]he diabetes community [wa]s just beginning to learn about" continuous glucose monitoring. Ex. 1011 at 9. FDA clearance for the Paradigm "require[d] patients to take a fingerstick measurement before adjusting therapy, as well as for calibrating the CGM system." *Id.* Thus, the system described in Ex. 1011 was neither intended nor cleared by the FDA to be used as a lifeline to manage diabetes, which undermines Petitioner's rationale about the purported criticality of the data.

Lastly, the additional FAQ that Petitioner relies on changes nothing. Reply at 2. The phrase in the FAQ, "data will be displayed **on** the insulin pump's screen," is not referring to data repopulated **in** the insulin pump, nor is there a connection to "re-populated" data. *Id.* Petitioner also ignores the last sentence of this FAQ, which supports Patent Owner: "When reviewing **historical reports**, you would notice a 'data gap' where information is missing during this period of time." *Id.* The consistent use of different phrases, "displayed **on** the insulin pump's screen" versus "re-populated **in** the insulin pump" leaves no doubt that Ex. 1011 does not disclose displaying backfilled data in place of a data gap "**on the insulin pump's screen.**"

III. PETITIONER MISCHARACTERIZES ITS PRIOR ARGUMENTS

The Petition speaks for itself. It used “historical [glucose] graphs” when referring to Ex.1011 to conflate the pump’s trend graph with historical **reports** generated by CareLink™. For example, the Petition argued “the Paradigm® Insulin Pump displays 3 and 24-hour **historical glucose graphs**.” Pet. at 25. In addressing only Ex. 1011, the Petition argued that “when transmission is out-of-range for less than 40 minutes, gaps in continuous glucose monitoring (CGM) data are entirely re-populated and do not persist in **historical graphs**.” *Id.* at 45. Petitioner also argued that “Paradigm® REAL-Time discloses that data gaps in continuous glucose monitoring (CGM) data are re-populated with glucose data stored by the transmitter such that these gaps do not appear in **historical graphs**.” *Id.* at 47.

Petitioner is now attempting to re-write the Petition by arguing that references therein to “**historical graphs**” “merely explain[] what results when Paradigm’s teachings ... are applied to a historical graph as disclosed by Patel-2009.” Reply at 4-5. Petitioner’s attempt to rewrite its prior arguments is disingenuous and should be rejected as a new argument. *Intelligent Bio-Sys. v. Illumina Cambridge*, 821 F.3d 1359, 1369-70 (Fed. Cir. 2016). While Petitioner relies on the combination for Ground 1, it exclusively relied on Ex. 1011 for backfilling displayed data gaps. But Ex. 1011 does not disclose backfilling data gaps on the insulin pump’s display. Thus, Petitioner has not shown that the combination meets every element of claim 1.

Date: December 18, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that Patent Owner's Sur-Reply In Support of The Patent Owner Preliminary Response pursuant to 37 C.F.R. § 42.107 in connection with *Inter Partes* Review Case IPR2023-01251 was served on this 18th day of December, 2023 by electronic mail to the following:

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