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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

CLEVELAND MEDICAL DEVICES INC.,
an Ohio Corporation,

Plaintiff,

vs.

RESMED INC., a Delaware Corporation,

Defendant.

Case No.: 1:22-cv-00794-GBW

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[REDACTED]
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[REDACTED]

REBUTTAL EXPERT REPORT OF DR. DAVID A. BORKHOLDER

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(though it does use “conditioning and processing” not found in the ‘269 claims), “data acquisition device,” or “first signal.” Schmidt also does not disclose, nor does Exhibit 3 highlight, other terms in the same claim elements with the highlighted terms (e.g., in Claim 1: “adapted for connecting to a pulse oximeter sensor with a signal,” or “an output adapted for outputting pulse oximetry sensor data”). Thus, this highlighting does not show copying or materiality of Schmidt.

2. Truitt

1784. Summary of the content and scope. The Truitt reference is a patent that issued on November 11, 2003, to Respironics, Inc., entitled “Monitoring Fluid Flow in a Pressure Support System.” The specification explains that the patent is directed to “a pressure support system,” such as a CPAP machine, “in which a flow or volume of gas is measured without using a dedicated flow sensor used in a conventional flow meter.” Abstract of Truitt reference. The claims accomplish this by providing “a tortuous gas flow path in which a pressure differential is created between two points” in the path. *Id.* This pressure differential “provides the necessary pressure drop for measuring the gas flow and/or gas volume passing through the pressure support system.” *Id.* The specification makes no mention of using the CPAP in the context of sleep-related disorders.

1785. Differences and gaps compared to ‘269 Patent. Given the differences in content and scope described above, there is no dispute that Truitt does not teach or suggest many aspects of the claims of the ‘269 Patent, including for example:

- Pulse oximeter sensor
- Processor for calculating sleep disorder symptom data of a level of severity and/or an index of a level of severity of a subject’s sleep disorder symptoms

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- Module transceiver for receiving and transmitting this sleep disorder symptom data to a remote location
 - Signal processing techniques
 - Removal of artifacts from signals
 - Controller adapted to adjust a pharmaceutical agent
 - Cellular phone or PDA

1786. ResMed's experts provide no motivation for a POSITA to use the background portions of Truitt, which is directed to a flow/volume sensing system for a pressure support system like a CPAP, and teaches away from use of a "conventional flow sensor" of Figure 1, with the various other components of the '269 Patent for diagnosing and treating sleep disorders

1787. Analysis of the language that ResMed claims corresponds to '269 Patent. Mr. Irving and Dr. Jensen cite to Figure 1 of Truitt, along with three paragraphs describing Figure 1 in Truitt (at 1:44-2:11), as corresponding to Figure 7 of the '269 Patent, along with three paragraphs describing Figure 7 (at 22:45-23:17). Notably, Figure 1 of Truitt is not described in the patent as the invention, but rather as "prior art," and a "conventional" pressure support system. The '269 Patent also describes Figure 7 as a "conventional" pressure support system (at 22:47-48). For this reason, I disagree with any argument by ResMed's experts that there was any attempt to pass off this pressure support system as the invention of the '269 Patent. See, e.g., Irving, ¶80. The '269 Patent further refers to Figure 7 as "one embodiment of a device that can be used to physically treat a subject's sleep disorder, which can be further adjusted using the output of the level of severity of the subject's sleep disorder," and as "a particular type of physical treatment device known as a [CPAP] device." With this language, which differs from

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the language in Truitt, the ‘269 Patent specification adapts the depiction at Figure 7 to specific aspects of the claimed invention.

1788. In further describing its Figure 1, Truitt explains that a “[m]ore sophisticated” pressure support device includes a flow sensor (shown as 20), pressure sensor (shown as 22), or both. Similarly, in further describing its Figure 7, the ‘269 Patent explains that a “more sophisticated” pressure support device “of the present invention” includes a flow sensor (shown as 320), pressure sensor (shown as 322), or both. Thus, this is not a passing off of the Truitt invention as the invention of the ‘269 Patent. In other words, this language in the ‘269 Patent explains that it is this “more sophisticated” pressure support device that includes a flow sensor (or pressure sensor or both) that is used as part of the claimed invention. This is consistent with the claim language that requires “an airflow sensor...”

1789. Rebuttal regarding file history. Mr. Irving and Dr. Jensen argue that statements that CleveMed made in response to ResMed’s IPR petition somehow support materiality of the disclosure of Truitt. Irving Report, ¶¶82-84; Jensen Report, ¶445. I disagree with these opinions. In attempting to support these opinions, Mr. Irving and Dr. Jensen cite to the portion of CleveMed’s response to ResMed’s IPR petition where CleveMed provided background describing the ‘269 Patent, which included cites to portions of the ‘269 Patent that Mr. Irving and Dr. Jensen argue correspond to portions of Truitt (i.e., Figure 7 and 23:7-17 of the specification), and where CleveMed described Figure 7 as an “exemplary embodiment of the CPAP device.” POPR, 4-6. This description is consistent with the ‘269 Patent specification, which as explained above, makes clear that that Figure 7 shows “a conventional pressure support system,” and “a particular type of physical treatment device known as [CPAP] device.” Thus, these statements in the IPR proceeding provide no support for materiality of Truitt.

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1790. I note that while both Mr. Irving and Dr. Jensen misleadingly argue that CleveMed described Figure 7 in the IPR proceeding as an “exemplary embodiment of the CPAP device” of the “claimed invention,” this “claimed invention” language appears multiple sentences before the “exemplary embodiment of the CPAP device” language and thus is not part of the same statement. In any event, as explained above, Figure 7 does provide an exemplary embodiment of the CPAP device that can be used with the claimed invention. CleveMed does not refer to Figure 7 as the claimed invention itself as ResMed’s experts seem to imply. Thus, there is nothing incorrect or improper about this statement. Mr. Irving and Dr. Jensen also cite in purported support of their opinions CleveMed’s statement during the IPR that the claims are “patentable because the combination of references does not disclose ‘an airflow sensor internal to the PAP device adapted for measuring the respiratory airflow of a subject.’” However, they do not explain how this statement supports their opinions. To the extent they provide any explanation in a supplement or reply, I reserve the right to respond. As discussed above, Truitt provided Figure 7 as a conventional pressure support system and sets forth an invention that does not require a conventional flow sensor, and thus this language in the claims does not reflect the Truitt invention.

1791. Dr. Jensen and Dr. Irving further argue that during prosecution, the applicant amended the claims to add that the airflow sensor was “internal to the PAP device” and “adapted for measuring the respiratory airflow data of a subject using the PAP device,” and that applicant emphasized “airflow sensor internal to the PAP device” as a feature missing from the prior art, citing the October 12, 2017 Amendment, at 2, 4, and March 27, 2018 Amendment at 10. Irving Report, ¶81; Jensen Report, ¶446. Mr. Irving does not explain how these portions support his opinion, while Dr. Jensen simply adds that “[t]hese features were not CleveMed’s invention---

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they were copied from Truitt,” without explaining how this language was somehow “copied” from Truitt when this language does not appear in Truitt. To the extent they provide any further explanation in a supplement or reply, I reserve the right to respond. As explained above, Truitt provided Figure 7 as a conventional pressure support system, along with language describing such a system (which is the portion that ResMed’s experts claim corresponds to language of the ‘269 Patent), and then further sets forth an invention that does not require a conventional flow sensor. Thus this language in the claims does not reflect the Truitt invention.

1792. Cumulative references considered by examiner during prosecution. Truitt, including at a minimum the portions of Truitt that ResMed claims overlap with the ‘269 Patent and/or the portions cited in Dr. Jensen’s Exhibit 4, is cumulative with at least the following references considered by the examiner during prosecution:

- Farrell (CPAP machine and a flow sensor, including a Figure 1 depicting them)
- Wright (CPAP system used for the treatment of patients with strokes)
- Miles (system that can automatically control the nasal CPAP pressure)

1793. Rebuttal regarding highlighted claim language at Exhibit 3 of Mr. Irving’s Report: Exhibit 3 to Mr. Irving’s report highlights certain claim terms as “From Truitt.” I disagree that this language is “From Truitt.” The highlighting includes incomplete phrases and words from the claim elements without the surrounding claim language that provides the context for what the invention entails. Truitt also does not use terms that Exhibit 3 highlights as “From Truitt,” including “airflow sensor,” “internal,” or “respiratory airflow.” Truitt also does not disclose, nor does Exhibit 3 highlight, various other terms in the same claim as these highlighted terms. Thus, this highlighting does not show copying or materiality of Truitt.

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F. Embletta PDS and Somnologica software

1897. I disagree with Dr. Schwartz's contention and Embletta PDS and Somnologica software are viable noninfringing alternatives for the HST Patents. Notably, Dr. Schwartz does not assert any noninfringing alternative for the Diagnostic Patents. Embletta PDS and Somnologic software would not be technologically acceptable to ResMed's customers because, for example, it is unable to confirm the adequacy of the data prior to transmission. See Borkholder Opening Report at ¶ 81. Reverting back to the Embletta PDS and Somnologica, would require ResMed to move back in time to a system that was abandoned by it. Because, Dr. Schwartz does not provide any analysis of why this abandoned system would be technologically acceptable, he has failed to meet his burden.

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I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct. Executed on January 5, 2024 in Tampa, Florida..



Dr. David A. Borkholder