

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

CLEVELAND MEDICAL DEVICES INC.,	)	
an Ohio Corporation,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 22-794 GBW
	)	
RESMED INC., a Delaware Corporation,	)	DEMAND FOR JURY TRIAL
	)	
Defendant.	)	

DEFENDANT RESMED INC.’S MOTION FOR RECONSIDERATION

Pursuant to LR 7.1.5, Defendant ResMed Inc. respectfully requests that the Court reconsider in part its March 9, 2023 Oral Order denying the parties’ Stipulation and Proposed Order to Modify the Scheduling Order (D.I. 51, the “Stipulation”).

I. INTRODUCTION

ResMed seeks reconsideration of its request to eliminate the cap of ten prior art references for one of the asserted patents in this case, U.S. Patent No. 10,076,269 (“the ’269 patent”). The Stipulation did not articulate the reasons why the ten-reference prior art limit has become unworkable for that patent and why ResMed would be unfairly prejudiced in defending itself if the Court limits ResMed’s invalidity challenge on the ’269 patent to only ten prior art references at this stage of the case.

When the Court entered the scheduling order in November 2022, Plaintiff CleveMed was only asserting one claim of the ’269 patent—claim 15. However, since then, CleveMed has added nine more asserted claims from the ’269 patent, including three new independent claims, each reciting different limitations requiring different prior art references and combinations of prior art. This is why ResMed sought and obtained CleveMed’s agreement to remove the caps on prior art references for all patents. However, if the Court is not inclined to reconsider its Oral

Order and enter the Stipulation, ResMed respectfully requests that the Court increase the number of prior art references for the '269 patent from ten to 25 references, which would mitigate the significant prejudice to ResMed due to CleveMed's assertion of additional claims. CleveMed has stated it opposes this motion.

II. BACKGROUND

CleveMed filed its original complaint (D.I. 1) on June 16, 2022, asserting eight patents, including the '269 patent and a group of seven other patents that CleveMed calls the "Home Sleep Testing" or "HST" patents. The '269 patent is directed to what CleveMed calls a "Positive Airway Pressure" ("PAP") solution. D.I. 1 ¶¶ 49, 84. CleveMed characterizes the '269 patent as "generally disclos[ing] systems for enabling sleep disorder treatment systems ..." (D.I. 1 ¶ 33), but as demonstrated below, the independent claims of the '269 patent are directed to four different sleep disorder treatment systems and recite unique and different claim limitations. Appendix A shows the four independent claims with exemplary unique limitations highlighted.

In its original complaint, CleveMed alleges infringement of one claim per patent, including claim 15 of the '269 patent. *See* D.I. 1, ¶ 81. Thus, at the time the parties negotiated and filed the proposed scheduling order on September 26, 2022 (D.I. 28), ResMed understood that its invalidity defense to the '269 patent was limited to asserted claim 15. At the Rule 16 conference on October 6, 2022, the Court adopted ResMed's proposal to limit the number of asserted claims and prior art references on a per-patent and aggregate basis. However, the Court set limits of ten asserted claims and ten prior art references for each patent, and a total of 64 claims and references across all eight asserted patents. *See* D.I. 40, ¶ 3(g).

On January 9, 2023, CleveMed served its initial infringement contentions, which it then corrected on January 13, 2023. In its initial infringement contentions, CleveMed asserted for the

first time nine additional claims of the '269 patent (ten total), including three new independent claims—claims 1, 5, and 8, bringing the number of independent claims to four. Also, CleveMed asserted for the first time in a discovery response, served after the parties' submission of the proposed scheduling order, a conception date for the '269 patent that is eight months earlier than the priority date shown on the face of the patent. *See* Ex. 1 at 13-14. Although ResMed disputes CleveMed's new alleged conception date, resolution of that dispute may affect whether certain prior art references qualify as prior art.

After seeing CleveMed's initial infringement contentions, ResMed asked CleveMed to agree to raise the limit on prior art references for the '269 patent from ten to 25, but told CleveMed that ResMed did not need to raise the 64-reference overall cap. *See* Ex. 2. As a compromise, CleveMed proposed that the parties agree to eliminate entirely the per-patent caps on the number of asserted claims and prior art references. *Id.* ResMed agreed to that compromise. *Id.* On February 17, 2023, the parties filed the Stipulation to that effect (*see* D.I. 51), which the Court rejected in its March 9, 2023 Oral Order.

On February 21, 2023, ResMed served its initial invalidity contentions. For the '269 patent, ResMed served six invalidity charts citing a total of 31 references, including references establishing the state of the art, five invalidating ResMed systems, and two references (the Rasid Thesis and ResMed S8 AutoSet Vantage system) that may not qualify as prior art if CleveMed is able to establish its alleged conception date. If the Court grants the alternative relief requested in this motion, ResMed will reduce its asserted prior art references from 31 to 25 for its initial contentions. Then, if permitted, the parties will work to propose claim and prior art reference limits for the '269 patent for their respective final contentions due in July and August 2023.

III. LEGAL STANDARDS

A motion for reconsideration is governed by Local Rule 7.1.5. See *Helios Software, LLC v. Awareness Techs., Inc.*, C.A. No. 11-1259-LPS, 2014 WL 906346, at *1 (D. Del. Mar. 5, 2014). A motion for reconsideration “must rely on one of three grounds: (1) an intervening change in controlling law; (2) the availability of new evidence; or (3) the need to correct a clear error of law or fact or to prevent manifest injustice.” *Parkell v. Frederick*, C.A. No. 15-718-LPS, 2019 WL 1435884, at *1 (D. Del. Mar. 31, 2019). Reconsideration is warranted where “the Court has patently misunderstood a party, or has made a decision outside the adversarial issues presented to the court by the parties, or has made an error not of reasoning but of apprehension.” *Wood v. Galef-Surdo*, Civ. No. 11-777-GMS, 2015 WL 479205, at *1 (D. Del. Jan. 26, 2015). The decision to grant reconsideration “lies squarely within the discretion of the district court.” *Wi-Lan Inc. v. Sharp Elecs. Corp.*, Civ. No. 15-379-LPS, 2018 WL 6445548, at *1 (D. Del. Dec. 10, 2018).

Federal Rule of Civil Procedure 16 governs pretrial management and scheduling orders. Under Federal Rule 16(b)(4), a scheduling order “may be modified only for good cause and with the judge’s consent.” The burden is on the moving party to “demonstrate good cause and due diligence.” *Race Tires America, Inc. v. Hoosier Racing Tire Corp.*, 614 F.3d 57, 84 (3d Cir. 2010). Good causes exists “when the schedule cannot reasonably be met despite the diligence of the party seeking the [modification].” *Dickerson v. KeyPoint Gov’t Sols., Inc.*, C.A. No. 16-657-RGA-MPT, 2017 WL 2457457, at *4 (D. Del. June 7, 2017).

IV. ARGUMENT

For the following reasons, reconsideration is warranted to (1) eliminate the cap on asserted prior art references for the ’269 patent (but not the other asserted patents), as requested

in the Stipulation, or (2) in the alternative, raise the limit on prior art references for the '269 patent from ten to 25 for initial invalidity contentions.

A. Reconsideration Is Warranted Based On The Availability Of New Evidence; Namely, CleveMed's Assertion Of Nine Additional Claims Of The '269 Patent.

Under Local Rule 7.1.5, reconsideration is warranted based on the availability of new evidence that (a) did not exist when the Court entered its scheduling order and (b) the Court did not have when it rejected the parties' Stipulation—namely, that CleveMed increased the asserted claims of the '269 patent from one to ten, including three new independent claims that are each directed to unique system configurations. As demonstrated below and in Appendix A, the four asserted independent claims of the '269 patent are directed to four different sleep disorder treatment systems, each reciting limitations that are materially different from one another. In this way, the '269 patent is actually four patents rolled into one.

For instance, asserted claim 15 recites a treatment system comprising a PAP device, a processor, a base station/cellular phone/PDA, and two radio frequency wireless module transceivers used to transmit and retransmit data to a remote internet site. No other independent claim recites this system. In contrast, newly asserted independent claim 1 recites a treatment system comprising a signal processing module connected to a pulse oximeter, a PAP device, and a module transceiver for transmitting data to a remote location. Independent claim 5 recites a system comprising a data acquisition system receiving data from a pulse oximeter, a PAP device, and a “non-volatile memory to be used for later transmission” of data to a remote location. Independent claim 8 recites a treatment system using a pharmaceutical agent and comprising a data acquisition system, and a PAP apparatus that performs “dosing and chemically treating a subjects sleep disorder or symptoms with a pharmaceutical agent.”

Thus, newly asserted claim 1 recites a signal processing module and a module transceiver that transmits to a remote location that are not recited in the other claims. Newly asserted claim 5 recites a data acquisition system and nonvolatile memory limitations that are not recited in the other independent claims. Newly asserted claim 8 recites a dosing and chemical treatment system using a pharmaceutical agent that is not recited in the other independent claims. And newly asserted claims 1 and 5 recite a pulse oximeter and related calculations that are not recited in the other independent claims. These four unique system configurations require different prior art for anticipation purposes and different combinations of prior art for obviousness purposes. The additional recited features, such as a pulse oximeter, non-volatile memory, and RF wireless transceivers, also require additional prior art references in combination with one another.

The same is true of the asserted dependent claims. Claim 16 (which depends from claim 15) recites using the Bluetooth wireless protocol, while claim 17 recites calculating a respiratory disturbance index (RDI) and claim 18 recites an electronic component for remotely adjusting the PAP device. None of those features are recited in any other asserted claims. Dependent claim 4 (which depends from claim 1) recites the application of a “one or more of the signal processing techniques” from a group including a short-time Fourier transform and a wavelet analysis. This feature is also not recited in any other asserted claim. These limitations therefore require other prior art references in combination with the independent claim references.

CleveMed’s interrogatory response also identified for the first time an alleged conception date that is eight months earlier than the priority date shown on the face of the ’269 patent. In response to that new contention, ResMed went to great lengths to identify prior art that would qualify as prior art even if CleveMed can establish its earlier alleged conception date. However, the uncertainty surrounding CleveMed’s new alleged conception date means that some prior art

references may not qualify as prior art if CleveMed is successful on that issue. To date, CleveMed has not identified a specific date for its conception or reduction to practice, nor has it supported its interrogatory response with a single document. Ex. 1 at 14.

Thus, ResMed respectfully submits that CleveMed's increase from one asserted claim to ten—including three new independent claims that each require different prior art references and combinations of prior art—constitutes “new evidence” warranting reconsideration of the parties' Stipulation or an increase of the prior art reference cap on the '269 patent to 25 references. *See Parkell*, 2019 WL 1435884, at *1; *see also Pac. Biosciences of California, Inc. v. Oxford Nanopore Techs., Inc.*, No. CV 17-1353-LPS, 2019 WL 2453780, at *1 (D. Del. June 12, 2019) (granting motion for reconsideration where court concluded that “it misapprehended certain factual arguments and would benefit from the presentation of additional evidence before making a final determination”).

B. Reconsideration Is Warranted To Prevent Manifest Injustice To ResMed's Ability To Present A Complete Invalidity Defense To The '269 Patent.

For similar reasons, reconsideration is warranted “to prevent manifest injustice” in ResMed's ability to present a complete invalidity defense to the '269 patent. *See Parkell*, 2019 WL 1435884, at *1; *see also Cooper Notification, Inc. v. Twitter, Inc.*, 867 F. Supp. 2d 485, 501 (D. Del. 2012), *aff'd*, 545 F. App'x 959 (Fed. Cir. 2013). As another judge in this District has observed:

In the usual case, an obviousness combination requires the identification of two or sometimes three references that disclose the requisite claim elements, and (usually) additional references, which can be multiple references to show the state of the art, that, considered as a whole, support a motivation to combine and a reasonable expectation of success in doing so.

Exelixis, Inc. v. MSN Lab's Priv. Ltd., No. CV 19-2017-RGA, 2022 WL 6697645, at *1 (D. Del. Apr. 20, 2022); *see also In re Gorman*, 933 F.2d 982, 986 (Fed. Cir. 1991) (“[W]e have

upheld reliance on a large number of references to show obviousness”); *In re Fulton*, No. 2020-1384, 2020 WL 7230522, at *2 (Fed. Cir. Dec. 8, 2020) (affirming finding of obviousness based on “the combination of three prior-art references”).

Here, as shown in Appendix A, three of the four independent claims of the ’269 patent recite eight or more unique limitations. Because the claims have so many limitations, ResMed’s current invalidity contentions rely on just over three prior art references per claim. If the Court accepts ResMed’s proposed alternative relief to assert no more than 25 references against the ’269 patent, the number of references would drop to an average of 2.5 references per asserted claim. This reasonable limitation will permit ResMed to assert combinations of multiple prior art references while setting a manageable limit on the number of prior art references.

In contrast, limiting ResMed to ten prior art references across ten very different claims of the ’269 patent would severely hinder ResMed’s ability to litigate its invalidity defense, a manifestly unjust result. Fact discovery is in its early stages, the Court has not yet issued a claim construction ruling, and expert discovery is months away. CleveMed’s infringement theories are in flux and poorly supported, and CleveMed only recently disclosed its new contention that certain claims are entitled to an earlier conception date. Simply put, a limit of ten prior art references is not sufficient to cover all ten asserted claims with their numerous different limitations, plus the potential for two different invention dates, plus the fact that obviousness law permits the combination of two or more references. Thus, ResMed respectfully submits that raising the limit on prior art references for the ’269 patent to 25 will prevent manifest injustice to ResMed in fully presenting its invalidity defense. *See Parkell*, 2019 WL 1435884, at *1.

C. Good Cause Exists To Amend The Scheduling Order To Raise The Limit On Prior Art References For The '269 Patent.

For the same reasons discussed above, good cause exists to raise the limit on prior art references for the '269 patent to 25 at this stage of the case. ResMed was diligent in seeking this amendment after CleveMed (1) asserted nine additional claims from the '269 patent in its infringement contentions, and (2) asserted a different alleged conception date than the priority date on the face of the '269 patent. Before receiving CleveMed's infringement contentions, ResMed had no notice that CleveMed would assert nine new claims and three new independent claims with unique claim limitations. And upon receiving the Court's Oral Order rejecting the parties' Stipulation, ResMed promptly sought reconsideration through this motion.

Moreover, CleveMed will not be prejudiced by raising the prior art reference cap on the '269 patent from ten to 25 references. First, CleveMed already agreed to eliminate the cap entirely, as evidenced by the parties' Stipulation, so a 25-reference limit is lower than what CleveMed already agreed to. Second, CleveMed already has ResMed's initial invalidity contentions asserting 31 prior art references against the ten claims of the '269 patent, so ResMed's proposed 25-reference cap will actually lower the number of references in ResMed's contentions. Third, ResMed has been selective in identifying fewer than eight total prior art references across the seven HST patents. Permitting ResMed to redirect a number of prior art references from the total prior art allotment over to the '269 patent will prevent injustice to ResMed without prejudicing CleveMed.

V. CONCLUSION

For the foregoing reasons, ResMed respectfully requests that the Court grant ResMed's motion for reconsideration and adopt the parties' Stipulation or, in the alternative, increase the

prior art reference cap for ResMed's initial invalidity contentions for the '269 patent from ten to 25 references.

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Sean Cunningham
Tiffany Miller
David Knudson
DLA PIPER LLP (US)
401 B Street Suite 1700
San Diego, California 92101-4297
Telephone: 619-699-4787
Facsimile: 619-764-6787
sean.cunningham@dlapiper.com
tiffany.miller@dlapiper.com
david.knudson@dlapiper.com

Nancy Braman
DLA PIPER LLP (US)
33 Arch Street 26th Floor
Boston, Massachusetts 02110-1447
Telephone: 617-406-6000
Facsimile: 617-406-6100
nancy.braman@dlapiper.com

Respectfully submitted,

/s/ Brian A. Biggs
Brian A. Biggs (Bar No. 5591)
Angela C. Whitesell (Bar No. 5547)
Matthew S. Middleton (Bar No. 6877)
DLA PIPER LLP (US)
1201 North Market Street, Suite 2100
Wilmington, DE 19801-1147
Telephone: 302.468.5700
Facsimile: 302.394.2341
brian.biggs@us.dlapiper.com
angela.whitesell@us.dlapiper.com
matthew.middleton@us.dlapiper.com

Attorneys for Defendant ResMed Inc.