IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Richmond Division

PRE HOLDING, INC., *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civil Action No. 3:09CV458–HEH
	)	
MONAGHAN MEDICAL CORPORATION, *et al.*,	)	
	)	
	)	
Defendants.	)	

MEMORANDUM OPINION
(Plaintiffs' Motion for Preliminary Injunction)

This is a patent infringement case involving a device known as a valved holding chamber which essentially aids in the delivery of aerosolized medication to patients though inhalation. The core dispute between the parties is whether the air expulsion features of the accused device, the AeroChamber MAX mouthpiece valved holding chamber ("MAX VHC"), infringe Plaintiffs' valved holding chamber, known as the Vortex. The Vortex was designed pursuant to U.S. Patent No. 7,562,656 ("the '656 patent"), which is owned by the Plaintiffs.

The matter is presently before the Court on Plaintiffs' request for "a narrowly tailored preliminary injunction" to prohibit Defendants from distributing the MAX VHC pending resolution of this case on the merits. Both parties have fully briefed all pertinent issues and the Court heard evidence and oral argument on October 16, 2009. For the

reasons that follow, Plaintiffs' request for preliminary injunctive relief will be denied at this stage of the proceedings.

The analytical framework for reviewing motions for preliminary injunctive relief, as articulated by the United States Supreme Court and the United States Court of Appeals for the Federal Circuit, is familiar and well settled. This standard was recently restated and clarified by the United States Supreme Court in *Winter v. Nat'l Res. Defense Council, Inc.*, 129 S. Ct. 365 (2008). "A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Id.* at 374. In applying these well-established criteria, the Court in *Winter* accentuated several points. First, that a plaintiff seeking preliminary relief must demonstrate "that irreparable harm is *likely* in the absence of an injunction." *Id.* at 375. Further, the Chief Justice, speaking for the Court, emphasized that "injunctive relief [is] an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Id.* at 375–76 (internal citations omitted).

Obviously, this standard governs the case at hand. In order to satisfy the first element, namely likelihood of succeeding on the merits, PRE Holding, Inc. and PARI Respiratory Equipment, Inc.[1] (collectively "Plaintiffs") must demonstrate that in light of the presumptions and burdens that will inhere at trial on the merits, Plaintiffs will *likely*

[1]By Order dated October 13, 2009, this Court granted Plaintiff PRE Holding's motion to join PARI Respiratory Equipment, Inc. as a party plaintiff.

prove that Defendants' product infringes the '656 patent and that it will withstand Defendants' challenges to the validity and enforceability of the '656 patent. *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1374 (Fed. Cir. 2006). In *Altana Pharma AG v. Teva Pharms. USA, Inc.*, 566 F.3d 999 (Fed. Cir. 2009), the Federal Circuit further observed that, "[t]he precedent of this court holds that if the accused infringer 'raises a substantial question concerning validity, enforceability, or infringement (i.e., asserts a defense that [the movant] cannot show 'lacks substantial merit') that preliminary injunction should not issue.'" *Id.* at 1006 (citations omitted).

Plaintiffs maintain that the accused product was fashioned from U.S. Patent No. 6,848,443 ("the '443 patent"). Plaintiffs contend that the MAX VHC infringes claims 14 and 30 of the '656 patent. Claim 14 describes a duck-bill valve. "The apparatus of claim 1, wherein the first valve element is a duck-bill valve." ('656 Patent, Col. 9:8–9.) Claim 30 teaches a delivery member and an adapter member which are releasably connected. "The apparatus of claim 2, wherein the adapter member is substantially frustoconical in shape." (Col. 9:58–59.) Both claims 14 and 30, in effect, are dependent on claim 1. Claim 14 includes all the elements of claim 1, and its first valve element is a duck-bill valve. Claim 30, in turn, is dependent on claim 2, which is dependent on claim 1. Particularly pertinent to the immediate action is the language in claim 1 which recites, "and permits the flow of air to the outside of the housing from the passage during

exhalation, wherein the first valve element extends axially away from the housing when the apparatus is in a rest position." (Col. 8: 26–32.)

The path of exhalation is critical to the Court's infringement analysis. The Defendants, Monaghan Medical Corporation and Trudell Medical International (collectively "Defendants") deny that the accused product, the MAX VHC, infringes the '656 patent. Defendants maintain that the MAX VHC was not developed from the '443 patent. In fact, Defendants insist that the '443 describes a positive expiratory device ("PED"), rather than a valved holding chamber ("VHC"). The Defendants identify a number of differences between the MAX VHC and the asserted claim elements in the patent-in-suit. First, Defendants maintain that the MAX VHC does not have an opening in the sidewall extending to outside of the housing. Defendants further allege that in order to obtain registration over the prior art, the U.S. Patent and Trademark Office ("PTO") required the inclusion of the language, "the first valve element extends axially away from the housing when the apparatus is in a rest position" in claim 1 of the application. (Col. 8:26–32.)

According to Defendants, the primary distinction between the MAX VHC and the '656 Vortex is the different pathway of exhaled air. The MAX VHC vents gases around, not through the housing. Exhaled air does not exit to ambient air through an opening in the sidewall of the mouthpiece. Instead, in the MAX VHC, the exhalation flows down and around the housing rather than through it. More particularly described, in the MAX

VHC, the exhaled air causes the outer portion of the valve to deflate, allowing air to travel into a pathway created between the inside of the mouthpiece sidewall and the outside of the dome-shaped end of the holding chamber.

Plaintiffs counter that the gap between the housing and the holding chamber constitute an opening in the sidewalls of the housing, which structurally extends away from the housing unit. In Plaintiffs' view, the feature reads directly on the limitation, "the first valve extends axially away from the housing." In the final analysis, this debate turns on what constitutes the "housing" and whether the limitation requires the exhaled air to be expelled into ambient air or a holding chamber.

Aside from the absence of a critical opening in the sidewall of the housing, Defendants contend that the delivery member and the adapter member features of the MAX VHC are not releasably connected, but are fused into one piece. Plaintiffs dismiss this contention by pointing out that the dome structure at the end of the holding chamber is an adapter consistent with the structural configuration of the '656.

To bolster their request for a preliminary injunction, Plaintiffs point out that in 2007, the Defendants filed a reissuance application to add additional claims to the '443 patent. One of the accompanying embodiments depicts a gap between the section through which the gases may leave the device. Plaintiffs allege that in their reissuance application, Defendants represented to the PTO that the duck-bill valve of the '656 was structurally similar to the '443. In addition to seeking an enlargement of the '443 patent

to include claims 14 and 30 of the '656, Defendants asked the PTO to excise these claims from an application for the '656 patent, which was then pending registration. After a thorough review, the examiner denied Defendants' request and issued the '656 patent to Plaintiffs. The newly-issued '656 patent is presumed to be valid under 35 U.S.C. § 282. Plaintiffs therefore argue that Defendants' representations to the PTO attest to the validity of its claims in this lawsuit.

Consistent with Defendants' argument that the MAX VHC is not modeled after the '443 patent, they contend that the requested addition of the claims to the '443 patent did not pertain to the MAX VHC. Moreover, they argue that nowhere in the request for reissuance did the Defendants mention the MAX VHC device. The single embodiment in their reissuance application (Figures 22(a)–(c)), which arguably depicts the expulsion of gases through a gap in the outer wall of the housing, was never practiced or developed according to Defendants. Finally, Defendants contend that the '656 patent is invalid on both anticipation and obviousness grounds.[2]

With respect to irreparable harm, Plaintiffs cite a loss of ability to enjoy market expansion, participation in clinical trials and receive recognition for innovation. According to Plaintiffs, the valved holding chamber produced from the '656 patent competes head-to-head with Defendants' products. Both parties are presently competing for a contract to supply 75,000–300,000 devices to Sepracor, Inc. Sepracor has

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[2]Defendants have filed a request for *inter parte* re-examination of the '656 patent, which is currently pending before the PTO, alleging invalidity on anticipation and obviousness grounds.

previously favored the MAX VHC over the Vortex in competitive bidding. Plaintiffs further note that Defendants also market a host of other products and would suffer minimal harm from a preliminary injunction to the MAX VHC.

Defendants disagree and counter that any harm potentially suffered by Plaintiffs can be adequately addressed by legal remedies. In other words, assuming Plaintiffs prevail, their alleged losses can be sufficiently requited through monetary damages.

At this juncture, the Court's initial task entails a careful assessment of the evidence and record to determine whether Plaintiffs have demonstrated a likelihood of both success on the merits and proof of consequent irreparable harm in the absence of preliminary injunctive relief. *Winter*, 129 S. Ct. at 374. To warrant such extraordinary relief, Plaintiffs must make a "clear showing" of entitlement. *Id.* at 376. And all four requirements for preliminary injunctive relief must be satisfied. *Id.* at 374.

As discussed above, the issue of infringement in this case turns on several critical limitations of the '656 patent. Most prominent at this stage is the pathway of exhaled air. Claim 1 of the '656 patent, on which the claims at issue are dependent, recites "and permits the flow of air to the outside of the housing from the passage during exhalation, wherein the first valved element extends axially away from the housing when the apparatus is in a rest position." (Col. 8:26–32.) Structurally, the MAX VHC appears to have a port in the housing unit through which exhaled gases flow. Unlike the Vortex, produced from the '656 patent, the MAX VHC does not vent exhaled air into the ambient

atmosphere. In the MAX VHC, the exhalation flows down and around the housing unit, rather than through it. Both sides have presented expert testimony supporting their divergent positions. Final resolution of this case-dispositive dispute will require more detailed claim construction as contemplated by *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388 (1996).

While the evidence appears to tilt in Plaintiffs' favor, the Court must conclude at this preliminary stage that the evidence, when collectively viewed, still raises a substantial question as to whether the exhalation pathways are sufficiently similar structurally to warrant a finding of infringement. As the United States Court of Appeals for the Fourth Circuit noted in *Real Truth About Obama v. Fed. Election Comm'n*, 575 F.3d 342 (4th Cir. 2009), "[b]ecause a preliminary injunction affords, on a temporary basis, the relief that can be granted permanently after trial, the party seeking the preliminary injunction must demonstrate by 'a clear showing' that, among other things, it is likely to succeed on the merits at trial." *Id.* at 345 (citations omitted). Plaintiffs' evidence fails to meet this standard at this stage.

Turning to the issue of irreparable harm, Plaintiffs contend that in the absence of preliminary injunctive relief, it will lose the opportunity for market expansion, participation in clinical trials, and a level playing field in contract competition. Each of these forms of loss can be probative of irreparable harm, particularly when such lost opportunities cannot be quantified or adequately compensated monetarily. This is not,

however, a case where Plaintiffs' existing marketing share is at risk or an existing contract is in jeopardy. *See Polymer Techs., Inc. v. Bridwell*, 103 F.3d 970, 975–76 (emphasis added). Furthermore, the accused product has a clearly recognized medical need, an established user base, and an acknowledged market position.

In their Memorandum of Law in Support of PRE-Holding, Inc.'s Motion for a Preliminary Injunction, Plaintiffs lament that despite the recognized quality of their products, "[they have] yet to be invited to participate in a single VHC clinical trial. This is likely so because Defendants' infringing product is perceived to have a superior drug delivery capability." (Mem. in Supp. Mot. Prel. Inj. p. 17.)

With respect to the Sepracor contract, Plaintiffs appear to argue that in the absence of the MAX VHC as a competitor, the Vortex will prevail. This supposition is based primarily on a study commonly referred to as the Rau Paper, which featured a comparative analysis of similar holding chamber devices. The Rau Paper rated the Vortex second behind the MAX VHC. But it is important to note that the Vortex is considerably more expensive than the MAX VHC and presumably other devices.

Plaintiffs' evidence demonstrates that it may suffer potential harm from Defendants' alleged infringement, but Plaintiffs have failed to clearly prove such harm is likely or that it is irreparable. *Winter*, 129 S. Ct. 374–76. Assuming that Plaintiffs can prove infringement and overcome Defendants' claims of invalidity, any consequent damages appear to be adequately compensable monetarily.

For the foregoing reasons, Plaintiffs' Motion for Preliminary Injunction will be denied at this stage of the proceedings.

An appropriate Order will accompany this Memorandum Opinion.

/s/
Henry E. Hudson
United States District Judge

Date: Nov. 17, 2005
Richmond, VA