UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

MIRACOR MEDICAL SA,	)	
	)	
Plaintiff,	)	Case No. 1:23-cv-16257
	)	
v.	)	Hon. Judge Sunil R. Harjani
	)	Hon. Magistrate Judge M. David Weisman
ABBOTT LABORATORIES, and THORATEC LLC,	)	
	)	
	)	**JURY TRIAL DEMANDED**
Defendants.	)	
	)	

PLAINTIFF'S SUPPLEMENTAL INITIAL RESPONSE TO DEFENDANTS' SUPPLEMENTAL INITIAL INVALIDITY AND UNENFORCEABILITY CONTENTIONS

Pursuant to Local Patent Rule (LPR) 2.5 and the Scheduling Order (D.I. 33, as modified, D.1.38), Plaintiff Miracor Medical SA ("Miracor" or "Plaintiff") hereby serves its Supplemental Initial Response to Defendants' Supplemental Initial Invalidity and Unenforceability Contentions concerning U.S. Patent Nos. Nos. 11,351,356 ("the '356 patent"), 11,351,357 ("the '357 patent"), 11,376,415 ("the '415 patent"), 11,572,879 ("the '879 patent"), 11,674,517 ("the '517 patent"), and 11,754,077 ("the '077 patent") (together, the "patents-in-suit" or "Asserted Patents"). For at least the reasons disclosed herein, each of the claims asserted by Miracor are not invalid under 35 U.S.C. §§ 102, 103, and/or 112, and are not unenforceable for prosecution laches, unclean hands, and/or patent misuse.

I. Preliminary Statement

Miracor's Supplemental Initial Response to Defendants' Invalidity Contentions are based on information and discovery currently available to it. Fact discovery is ongoing, claim construction has not yet occurred, deposition discovery is in its beginning stages, and expert

discovery has not yet begun in this case. Miracor's investigation is ongoing. Miracor therefore reserves the right to amend, alter, or, supplement its Supplemental Initial Response to Defendants' Invalidity Contentions based on further investigation and discovery as the case progresses, any claim construction from the Court, or as a result of any amendment, supplementation or modification by Defendants of their Invalidity Contentions.

The information set forth in these contentions is provided without waiving: (1) the right to object to the use of any statement for any purpose, in this action or any other, on the grounds of privilege, relevance, materiality, or any other appropriate grounds; (2) the right to object to any request involving or relating to the subject matter of the statements herein; or (3) the right to revise, correct, supplement, or clarify any of the statements provided below at any time.

These contentions should not be taken as an indication of Miracor's positions on the proper construction of any claim term. As noted below, Defendants have failed to provide constructions for many of the claim elements that it challenges as lacking written description or enablement. Miracor will provide its positions regarding claim constructions in a time and manner consistent with the schedule set by the Court.

These contentions should not be taken as an indication of Miracor's positions on the qualifications of a person having ordinary skill in the art relevant to the Asserted Patents. As noted below, Defendants have failed to explain the particular level of skill of a person of ordinary skill in the art in their obviousness challenges for the Asserted Claims, as well as in their challenges to the written description, enablement, and definiteness support for the Asserted Claims.

Miracor's initial responses to Defendants' Invalidity Contentions are provided without prejudice to Miracor's right to introduce at trial or any other proceeding in this or another matter any subsequently-discovered evidence, or evidence or expert opinions relating to currently- known

facts and to produce and introduce at trial all evidence, whenever discovered. Furthermore, nothing in these contentions limits any of Miracor's experts from relying upon any information in this case, in support of any defense, or from providing opinions and testimony in support of any defense.

II. Miracor's Initial Response to Defendants' Supplemental Initial Invalidity Contentions and Charts under Pre-AIA 35 U.S.C. §§ 102 and 103 Pursuant to LPR 2.5

On July 19, 2024, Defendants served their Supplemental Initial Invalidity and Unenforceability Contentions consisting of 144 separate charts purporting to map the elements of each Asserted Claim to 24 different alleged prior art references. Miracor previously served Plaintiff Miracor Medical SA's Supplemental LPR 2.2 Initial Infringement Contentions asserting infringement of claims 5, 6 and 12 of the '356 patent, while withdrawing assertion of claim 1 of the '357 patent and claims 1 and 2 of the '879 patent. For the reasons set forth herein, in Miracor's April 26, 2024 responsive claim charts for the '357 patent, '415 patent, '879 patent, '517 patent and '077 patent and in the accompanying supplemental responsive '356 patent charts, Miracor denies that any Asserted Claim is invalid as anticipated under 35 U.S.C. § 102(a) and/or obvious under 35 U.S.C. § 103(a) over the prior art.

In their Invalidity Contentions, Defendants assert that they apply the apparent claim constructions set forth in Miracor's Initial Infringement Contentions. Defendants appear not to apply those apparent claim constructions, not to apply any apparent claim constructions set forth in Defendants' Initial Noninfringement Contentions or Supplemental Initial Noninfringement Contentions, and not to apply the plain and ordinary meaning of the claim terms.

Defendants' Invalidity Contentions and accompanying charts fail to comply with LPR 2.3(b)(2). In particular, Defendants provide no detailed statement of whether the prior art references, individually or in combination, renders any asserted claim invalid under 35 U.S.C. §§ 102 or 103. For example, in many instances, Defendants simply assert that a claim element is

disclosed, and if an element is not disclosed it is inherent, and if it is not inherent it can be found in one of the other cited references in Defendants' Initial Invalidity Contentions. Defendants' Supplemental Initial Invalidity Contentions and accompanying charts also fail to comply with LPR 2.3(b)(3). In particular, Defendants do not identify where specifically in each alleged item of prior art each element of the asserted claims is allegedly disclosed. All of the elements are met with a conclusory recitation that the reference discloses the claim element by parroting the claim language. Some of these recitations are followed by quotes from the reference or figures, without even attempting to identify where specifically each element of the asserted claims is allegedly disclosed. At best, Defendants simply identify portions of the various references that they apparently believe disclose or render obvious various claim elements, without identifying where specifically in each alleged item of prior art each element of each asserted claim is allegedly found or explaining how these disclosures allegedly correspond to the claim elements. Next, each element is met with a conclusory assertion that even if the element is not disclosed, it is inherent or obvious in combination with any of the other references cited in Defendants' Invalidity Contentions and/or in combination with the knowledge of the skilled artisan, without any reasons given in support of this assertion and without any explanation or analysis of the particular level of knowledge or skill they attribute to the skilled artisan.

Because of Defendants' failure to explain or support their purported invalidity positions as required under LPR 2.3, Miracor is limited in its ability to respond to them. Miracor reserves all rights to further respond should Defendants be allowed to amend, alter, modify or expand then-contentions. In the responsive charts attached to Miracor's Initial Response to Defendants' Invalidity Contentions and those supplemental responsive '356 patent charts served herewith,

Miracor states as best it can, given Defendants' contentions, whether the reference includes the relevant claim element.

III. Miracor's Initial Response to Defendants' Supplemental Initial Invalidity Contentions under Pre- AIA 35 U.S.C. §§ 112

Miracor denies that any Asserted Claim is invalid based on indefiniteness, lack of enablement, or lack of written description under 35 U.S.C. § 112.

A. Miracor denies that any Asserted Claim is invalid for lack of written description.

Defendants' contentions that certain claim elements of the Asserted Claims lack written description support are improperly based reading the claims to be limited to the exact exemplary embodiments disclosed in the specification. It is black letter patent law that a claim may be broader than the specific embodiments in the specification. *In re Rasmussen,* 650F.2d 1212,1215 (CCPA 1981).

Defendants do not provide any explanation as to the level of skill for a person of ordinary skill in the art.

Defendants do not provide any explanation as to the predictability or unpredictability of the art.

Contrary to Defendants' contentions, the specification, including references to specific prior art patents and applications as well as description of the state of art, reasonably conveys to a person of ordinary skill in the art (who has knowledge of the prior art) that the inventor had possession of the full scope of the Asserted Claims. For example, the specification expressly refers to devices in AT 407 960 B and WO 01/703000 Al.

Defendants' contentions misunderstand the law. An adequate written description does not require that every claimed element be described in an embodiment or illustrated in the figures. *Hologic, Inc. v. Smith & Nephew, Inc.,* 884 F.3d 1357, 1362-63 (Fed. Cir. 2018). Nor does the

specification need to describe every conceivable and possible future embodiment of the invention. *Cordis Corp. v. Medtronic AVE, Inc.,* 339 F.3d 1352, 1365 (Fed. Cir. 2003).

Defendants fail to point to anything that indicates the features of the exemplary embodiments are critical to the invention or provide novelty over the prior art. *Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.,* 93 F.3d 1572, 1582 (Fed. Cir. 1997). The specification of each of the Asserted Patents provides ample support for the breadth of the Asserted Claims, including, for example, the "heart assist pump device" and its claimed structure and functionality. Nothing in the specification limits the scope of the Asserted Claims to the exemplary embodiments.

Defendants' contentions rely on citations to genus/species case law that is inapposite to the art here. For example, the exemplary embodiment of an intravasal rotary pump does not limit the Asserted Claims. Contrary to Defendants' contentions, the claims and the written description are not analogous to unsupported species in a generic claim to chemical compounds. *United Therapeutics Corp. v. Liquidia Technologies, Inc.,* 74 F.4th 1360, 1370-71 (Fed. Cir. 2023). Moreover, a specification may properly contain a written description of a broadly claimed invention without describing all species encompassed by the claim. *Cordis,* 339F.3datl365.

B. Miracor denies the Asserted Claims are invalid for lack of enablement

In their Invalidity Contentions, Defendants state in conclusory fashion that the specification fails to satisfy the enablement requirement of § 112 because it does not describe the manner and process of making and using the claimed "heart assist pump device," "inflow tube," "blood outflow port,' "second magnetic device," "gap sized for the passage of blood," and/or "surrounding rotor housing." However, Defendants provide no analysis whatsoever for their contentions, including, for example, how or why a POSA would not understand from the disclosures in the Asserted Patents how to make or use the claimed invention or what alleged undue

experimentation would be required. The enablement requirement is met if the description enables any mode of making and using the invention, and the description of the Asserted Patents meets that requirement. With regard to the claim elements which recite a "gap sized for the passage of blood"—the only claim elements Defendants actually discuss here—Defendants recite an excerpt from the specification and conclude, without explanation or analysis, that "the specification does not enable a POSA to practice the full scope of the claimed invention without undue experimentation." However, this cited excerpt refers to known design principles for a rotor as described in WO 01/70300 Al. Defendants fail to explain or even attempt to show why the claims of the Asserted Patents are not enabled or what undue experimentation would be required.

For all other claim elements alleged to lack enablement support in the specification, Defendants provide no explanation or analysis whatsoever, such that these remaining allegations lack anything that warrants a substantive response from Miracor. Although Defendants cite the *Wands* factors, they provide no explanation as to how those factors support their contentions. For example, Defendants do not explain what quantity of experimentation is needed, or the predictability or unpredictability of the art. Moreover, the *Wands* factors only come into play after the challenger (here Defendants) shows at least some experimentation is needed to make the full scope of the inventions. Defendants' unsubstantiated conclusory statements are not sufficient. *Alcon Research Ltd. v. Barr Laboratories, Inc.,* 745 F.3d 1180, 1189-90 (Fed. Cir. 2014).

C. Miracor denies that any Asserted Claim is invalid for indefiniteness.

A patent claim is invalid for indefiniteness if the claim, "read in light of the specification delineating the patent, and the prosecution history, fail[s] to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.,* 572 U.S. 898,901 (2014). Defendants' indefiniteness contentions fail to meet this heavy burden

Defendants do not explain the level of skill for a person of ordinary skill in the art, from which the question of whether a claim term is indefinite is determined.

Defendants' indefiniteness contentions ignore the claim language itself. For example, the claim language provides sufficient structural clarity to understand the scope of the invention. The claims also include functional language that promotes definiteness by helping bound the scope of the claims, specifying the operations the claimed invention must undertake. *Nevro Corp. v. Boston Scientific Corporation,* 955 F.3d 35, 39 (Fed. Cir. 2020).

Defendants' complaint that they do not understand Miracor's Supplemental Initial Infringement Contentions—for example, "what Miracor contends is the alleged 'magneto coupling' in the accused HeartMate 3 device"—is not a basis for indefiniteness. Definiteness does not require that an infringer (here Defendants) be able to determine *ex ante* if a particular act infringes the claims. Defendants' indefiniteness contentions merely reflect an effort to inject uncertainty where none exists in the claim language or disclosure, as would be understood by a person of ordinary skill in the art.

IV. The Asserted Patents Are Not Unenforceable

The Asserted Patents are not unenforceable for any of the reasons set forth by Defendants, including prosecution laches, unclean hands, and patent misuse as alleged in Defendants' unenforceability contentions and Defendants' Answer to Miracor's Complaint. Miracor has filed a combined Motion to Dismiss and Motion to Strike Defendants' prosecution laches counterclaim and defense, as well as their defenses of unclean hands and patent misuse (D.I. 34), and have replied in support of that motion (D.I. 42). Miracor incorporates by reference its arguments and support set forth in that motion (D.I. 34) and reply (D.I. 42). The Court has not yet ruled.

Dated: September 20, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing document was served on the following counsel of record for Defendants via email on September 20, 2024:

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Dated: September 20, 2024 *<u>/s/ Kathleen Murphy</u>*