| Ground | Claims Challenged | 35 U.S.C. §[2] | Reference(s)/Basis |
|---|---|---|---|
| 5a[7] | 6, 7, 12, 13 | 103 | Dixon, Hecht[8] |
| 5b | 6, 7, 12, 13 | 103 | Regeneron 2008, Hecht |
| 5c | 6, 7, 12, 13 | 103 | NCT-795, Hecht |
| 5d | 6, 7, 12, 13 | 103 | NCT-377, Hecht |

*See* Pet. 12.

In support of these grounds for unpatentability Petitioner submits, *inter alia*, the Declaration of Angelo P. Tanna, MD (Ex. 1002). In the absence of evidence to the contrary, we find Dr. Tanna competent to testify on the subject matter of his declaration. *See infra* Section II.A; *see* Ex. 1002 ¶¶ 3–11, 15–18; Ex. 1003. We understand that Patent Owner has not submitted a similar witness declaration specifically directed to this proceeding, nor was it required to do so. Patent Owner has, however, submitted witness declarations from related proceedings before the Board, including the Declaration of Lucian V. Del Priore, MD, PhD, which was submitted in related matters IPR2021-00880 and IPR2021-00881 (and notes that IPR2022-00257, IPR2022-00258, IPR2022-00298, and IPR2022-00301 were joined therewith). *See* Ex. 2021; *see also* Prelim. Resp. viii, 37, 40; *see*

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*Investigation of Efficacy and Safety in Wet AMD (VIEW 2)* (Nov. 28, 2014), accessed Dec. 29, 2020, at https://clinicaltrials.gov/ct2/history/NCT00637377?A=1&B=1&C=merged#StudyPageTop (Ex. 1011, "NCT-377").

[7] Grounds 5a–5d listed here are presented by Petitioner as a single "Ground 5"; however, because that ground actually asserts four separate challenges for unpatentability premised on separate combinations of the references of Grounds 1–4 in combination with Hecht, we separate these into separate grounds.

[8] Gerald Hecht, PhD, *Ophthalmic Preparations*, in II REMINGTON: THE SCIENCE AND PRACTICE OF PHARMACY, 19th ed., Ch. 89, 1563–76 (Alfonso R. Gennaro ed., 1995) (Ex. 1025, "Hecht").

*supra* Section I.B (Related Matters). In the absence of evidence to the contrary, we also find Dr. Del Priore to be competent to testify on the subject matter of his declaration, which is related to the subject matter of this proceeding. *See* Ex. 2021 ¶¶ 3–10, 16–18; *see also infra* Section II.A (identifying the parties' proposed definition of the ordinarily skilled artisan, which is the same as that addressed by Dr. Del Priore).

## II. DISCUSSION

### A. LEVEL OF ORDINARY SKILL IN THE ART

In determining the level of ordinary skill in the art, we consider the types of problems encountered in the art, the prior art solutions to those problems, the rapidity with which innovations are made, the sophistication of the technology, and the educational level of active workers in the field. *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986).

Petitioner states,

> A POSA here would have: (1) knowledge regarding the diagnosis and treatment of angiogenic eye disorders, including the administration of therapies to treat said disorders; and (2) the ability to understand results and findings presented or published by others in the field, including the publications discussed herein. Typically, such a person would have an advanced degree, such as an M.D. or Ph.D. (or equivalent, or less education but considerable professional experience in the medical, biotechnological, or pharmaceutical field), with practical academic or medical experience in (i) developing treatments for angiogenic eye disorders (such as AMD),

> including through the use of VEGF antagonists, or (ii) treating of same, including through the use of VEGF antagonists.

Pet. 23 (citing Ex. 1002 ¶ 16).[9] Patent Owner neither contests this proposed definition of the ordinarily skilled artisan nor offers its own. *See generally* Prelim. Resp.

For the purposes of this decision, we accept Petitioner's proposed definition of the person of ordinary skill in the art (or ordinarily skilled artisan), which appears to be consistent with the level of skill in the art reflected in the prior art of record and the disclosure of the '572 patent. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) ("the prior art itself [may] reflect[]" evidence of the ordinary level of skill in the art) (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985)).

B. CLAIM CONSTRUCTION

The Board interprets claim terms in an *inter partes* review using the same claim construction standard that is used to construe claims in a civil action in federal district court. 37 C.F.R. § 42.100(b). In construing claims, district courts and the Board here, by default, give claim terms their ordinary and customary meaning, which is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc).

Should claim terms require express construction, sources for claim interpretation include "the words of the claims themselves, the remainder of the specification, the prosecution history [i.e., the intrinsic evidence], and extrinsic evidence concerning relevant scientific principles, the meaning of

[9] Petitioner uses "POSA" to refer to the person of ordinary skill in the art.

technical terms, and the state of the art." *Id.* at 1314 (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004)). "[T]he claims themselves [may] provide substantial guidance as to the meaning of particular claim terms." *Id.* However, the claims "do not stand alone," but are part of "'a fully integrated written instrument' . . . consisting principally of a specification that concludes with the claims," and, therefore, the claims are "read in view of the specification." *Id.* at 1315 (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 978–79 (Fed. Cir. 1995) (en banc)). Any special definition for a claim term must be set forth in the specification "with reasonable clarity, deliberateness, and precision." *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994). Without such a special definition, however, limitations may not be read from the specification into the claims. *In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993).

"[W]e need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy.'" *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

We now turn to the parties' positions on claim construction.

*1. "initial dose," "secondary doses," and "tertiary doses"*

One or all of the terms "initial dose," "secondary doses," and "tertiary doses," appear in claims 1, 4, 9, 15, 16, 20, 24–27, and 29 (as noted, not all of these claims are challenged). *See* Ex. 1001, 23:1–25:5 (claims).

Petitioner asserts that the '572 patent expressly defines the claim terms "initial dose," "secondary doses," and "tertiary doses," in its Specification, as follows:

> The terms "initial dose," "secondary doses," and "tertiary doses," refer to the temporal sequence of administration of the VEGF antagonist. Thus, the "initial dose" is the dose which is administered at the beginning of the treatment regimen (also referred to as the "baseline dose"); the "secondary doses" are the doses which are administered after the initial dose; and the "tertiary doses" are the doses which are administered after the secondary doses. The initial, secondary, and tertiary doses may all contain the same amount of VEGF antagonist, but will generally differ from one another in terms of frequency of administration. In certain embodiments, however, the amount of VEGF antagonist contained in the initial, secondary and/or tertiary doses will vary from one another (e.g., adjusted up or down as appropriate) during the course of treatment.

Pet. 16 (quoting Ex. 1001, 3:51–65; citing Ex. 1002 ¶ 62).

Patent Owner "does not propose a construction of 'initial dose,' 'secondary dose[s],' or 'tertiary dose[s]' that is different than that proposed by Petitioner," although it also does not concede Petitioner's proposal is correct. Prelim. Resp. 18.

"When the specification explains and defines a term used in the claims, without ambiguity or incompleteness, there is no need to search further for the meaning of the term." *Multiform Dessicants Inc. v. Medzam Ltd.*, 133 F.3d 1473, 1478 (Fed. Cir. 1998). We agree with Petitioner's unopposed position that the Specification of the '572 patent expressly and unequivocally defines the claim terms "initial dose," "secondary doses," and "tertiary doses," as set forth in the quote above, as meaning, respectively, (1) *the dose which is administered at the beginning of the treatment regimen*; (2) *the doses administered after the initial dose*; and (3) *the doses*

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