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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* ANDREW T. SCHIEBER and CHARLES L. EUTENEUER

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Appeal 2019-002184
Application 15/012,544
Technology Center 3700

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Before CHARLES N. GREENHUT, MICHAEL L. HOELTER, and LISA M. GUIJT, *Administrative Patent Judges.*

GREENHUT, *Administrative Patent Judge.*

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from the Examiner's decision to reject claims 1–7, 9–15, 17–25, 27, 28, 30, and 31.[2] *See* Final Act. 1. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE and enter NEW GROUNDS OF REJECTION.

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[1] We use the word Appellant to refer to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies the real party in interest as Ivantis, Inc. Appeal Br. 2.

[2] Claims 20 and 23 are included in the listing of rejected claims in the Office Action Summary. However, we do not find claims 20 and 23 specifically addressed in the Examiner's Action. Appellant does not take issue with this.

## CLAIMED SUBJECT MATTER

The claims are directed to ocular implants for increasing aqueous humor outflow. Claim 1, reproduced below, is illustrative of the claimed subject matter:

> 1. An ocular implant comprising:
>
> a longitudinally extending body having an inlet portion and a Schlemm's canal portion distal to the inlet portion, the inlet portion being configured to extend into and be in fluid communication with an anterior chamber of a human eye and the Schlemm's canal portion being configured to be inserted into Schlemm's canal adjacent to collector channels of the eye;
>
> a plurality of alternating spines and frames positioned longitudinally along at least a portion of the Schlemm's canal portion wherein the plurality of alternating spines and frames define a central channel extending therethrough, with the central channel being in fluid communication with the inlet portion;
>
> each of the spines having edges partially defining an opening across from the central channel and in fluid communication with the central channel; and
>
> each of the frames including first and second struts, the first and second struts each having an edge contiguous with the edges of adjacent spines, the edges of the first and second struts and of the spines defining the opening in fluid communication with the central channel;
>
> wherein the ocular implant is configured to provide at least a 121% increase in average outflow facility of aqueous humor from the anterior chamber through the collector channels of the eye.

## REFERENCES

| **Name** | **Reference** | **Date** |
|---|---|---|
| Neuhann | US 6,494,857 B1 | Dec. 17, 2002 |
| Bergheim | US 2006/0074375 A1 | Apr. 6, 2006 |
| Schieber | US 8,372,026 B2 | Feb. 12, 2013 |
| Wardle | US 8,657,776 B2 | Feb. 25, 2014 |
| Schieber | US 8,961,447 B2 | Feb. 24, 2015 |
| Schieber | US 9,039,650 B2 | May 26, 2015 |

| Name | Reference | Date |
|---|---|---|
| Schieber | US 9,155,655 B2 | Oct. 13, 2015 |
| Wardle | US 9,211,213 B2 | Dec. 15, 2015 |
| Wardle | US 9,358,156 B2 | June 7, 2016 |
| Schieber | US 9,402,767 B2 | Aug. 2, 2016 |
| Schieber | US 9,610,196 B2 | Apr. 4, 2017 |
| Wardle | US 9,693,899 B2 | July 4, 2017 |

REJECTIONS

Claim 30 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Final Act. 17.

Claim 1, 9, and 31 are rejected under 35 U.S.C. § 102(b) as being anticipated by Neuhann. Final Act. 17.

Claims 2–7, 10–15, 17, 18, and 30 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Neuhann. Final Act. 23.

Claims of the present 15/012,544 application indicated in each row of the following table are rejected for obviousness–type double patenting based on the application, patent, and claims indicated in that row:[3]

| Claims in 15/012,544 | Application | Patent# | Claims in Prior Case |
|---|---|---|---|
| 1, 3, 4, 6, 7, 9, 11, 12, 14, 15, 17–19, 21, 22, 24, 25, 27, 28, 31 | 12/236,225 | US 8,734,377 | 1, 21 |
| 1, 3, 4, 6, 7, 9, 11, 12, 14, 15, 17–19, 21, 22, 24, 25, 27, 28, 30, 31 | 13/160,355 | US 8,657,776 | 1, 2, 6–11, 13, 14 |

[3] The Examiner withdrew the double-patenting rejections of (1) Claim 31 under US 8,961,447, (2) Claim 31 under US 9,402,767, (3) Claim 30 under US 9,358,156, and (4) Claim 31 under US 9,610,196. Ans. 3.

| Claims in 15/012,544 | Application | Patent# | Claims in Prior Case |
|---|---|---|---|
| 1, 3, 4, 6, 7, 9, 11, 12, 14, 15, 17–19, 21, 22, 24, 25, 27, 28, 30, 31 | 13/366,073 | US 8,372,026 | 1, 2, 7, 11, 12, 17 |
| 1, 3, 4, 6, 7, 9, 11, 12, 14, 15, 17–19, 21, 22, 24, 25, 27, 28, 30 | 13/763,394 | US 9,402,767 | 1, 4–5, 8, 10, 13–14, 16 |
| 1, 3, 4, 6, 7, 9, 11, 12, 14, 15, 17–19, 21, 22, 24, 25, 27–28, 30 | 13/776,592 | US 8,961,447 | 1, 2, 9–12, 19–22, 29, 30 |
| 1, 3, 4, 6, 7, 9, 11, 12, 14, 15, 17–19, 21, 22, 24, 25, 27, 28, 30 | 13/793,638 | US 9,358,156 | 1–3 |
| 1, 3, 4, 6, 7, 9, 11, 12, 14, 15, 17–19, 21, 22, 24, 25, 27, 28, 30, 31 | 13/865,770 | US 9,211,213 | 1–4, 6–13, 15–20 |
| 1, 3, 4, 6, 7, 9, 11, 12, 14, 15, 17–19, 21, 22, 24, 25, 27, 28, 30, 31 | 14/139,403 | US 9,155,655 | 1, 2, 6–11, 13, 14 |
| 1, 3, 4, 6, 7, 9, 11, 12, 14, 15, 17–19, 21, 22, 24, 25, 27, 28, 30, 31 | 14/246,363 | US 9,039,650 | 1, 2, 10 |
| 1, 3, 4, 6, 7, 9, 11, 12, 14, 15, 17–19, 21, 22, 24, 25, 27, 28, 30 | 14/691,267 | US 9,610,196 | 1–4, 8–10 |

OPINION

*Indefiniteness of claim 30 under 25 U.S.C. § 112, second paragraph, based on "the body extending in a curved volume having a large radius side and a short radius side"*

The Examiner determined "[i]t is unclear what radii are referred to" (Final Act. 17) and "[n]ot knowing if the device is implanted or not alone renders this language unclear as the term radius is also used to describe the radius of the tube." Ans. 4. Appellant points to the Specification's disclosure:

> ocular implant 100 with a body 102 extending along a curved longitudinal axis having a radius 150. A channel 126 has an opening 124 on the side of body 102 having a radius larger than radius 150, and a plurality of openings 138 are shown on the side of body 102 having a radius smaller than radius 150.

Reply. Br. 2 (citing Spec. paras. 89–91]). The marked contrast between claim 30 and the cited portion of the Specification is that in the cited excerpt of the Specification it is clear that the longer and shorter radii are attributes of the *implant body*, and in claim 30 they appear to be attributes of the volume of Schlemm's canal. Claim 30 is directed to an implant "*adapted to* reside . . . in . . . Schlemm's canal" and the recited body of the implant is "*configured to* extend within Schlemm's canal." (Emphasis added). Hence, it is not well-defined whether the "extending in a curved volume" limitation is before or after implantation. Further, where the claim makes the requirement for an "open side disposed on the large radius side" it becomes unclear whether Appellant is attempting to claim (1) the implant in its implanted state; (2) an implant having an open side "*disposed on* a large radius side" of the *implant body*, as opposed to the large radius side of the volume of Schlemm's canal; or (3) an implant having an open side that is

*configured to be* "disposed on a large radius side [of the volume of Schlemm's canal]." The first interpretation requires no alteration to the express wording of the claim, but would likely run afoul of the prohibition against mixing statutory classes in such a way that it is unclear when infringement actually occurs. *See* MPEP 2173.05(p)(II). The second and third interpretation differ in whether there exists a requirement for curvature of the implant body itself (second interpretation) or only the capability to be curved once the implant is implanted in the curved volume (third interpretation). The Examiner was reasonably justified in requiring Appellant to resolve this ambiguity during prosecution while Appellant has the opportunity to do so. *See In re Packard*, 751 F.3d 1307 (Fed. Cir. 2014). Accordingly, we sustain the Examiner's indefiniteness rejection of claim 30.

*The recited term "adjacent," in claims 9 and 31 as it relates to the rejections under §§ 102(b) and 103(a), and the double-patenting rejections.*

The Examiner, citing Merriam-Webster's definition of the word adjacent (Ans. 7), reasons:

> the claimed language is that the opening "is adjacent a major side", so the claim does not require an opening to "face" a major side as argued. Adjacent only requires a "nearby" location and facing as argued by the Appellant.

"Nearby" may be a suitable synonym for "adjacent" in many contexts, including this one. However, "adjacent" and "nearby" are both terms highly dependent upon the context in which they are used. Here, the context in which the positioning of the implant is described in claims 9 and 31 is "in Schlemm's canal." When a structure is described as being adjacent one side of a reference frame, here an "opening . . . adjacent a major side of

Schlemm's canal," considering that language to be satisfied when the structure is on the polar opposite side of the reference frame, here the minor side of Schelmm's canal, effectively deprives the term "adjacent" of any meaning within that reference frame. We therefore agree with Appellant that, on the record presently before us, the Examiner has not adequately demonstrated how the claim language "adjacent" in claims 9 and 31 is satisfied by Neuhann. Thus, the Examiner's anticipation rejection of claims 9 and 31 cannot be sustained on the record before us. As the Examiner has not otherwise accounted for this deficiency in the obviousness rejection, the Examiner's obviousness rejection of dependent claims of 1–15, 17, and 18 also cannot be sustained.

The Examiner advances the same position regarding the term adjacent with regard to the following double-patenting rejections:

| Claims in 15/012,544 | US Patent# | Claims in Prior Case | Answer page |
|---|---|---|---|
| 9 | 8,734,377 | 1 | 13 |
| 1, 9 | 8,657,776 | 1 | 14 |
| 9 | 9,402,767 | 4 | 17 |
| 9 | 9,358,156 | 1 | 19 |
| 9 | 9,155,655 | 2 | 22 |
| 9 | 9,039,650 | 2, 3, 10, and 12[4] | 24 |
| 9 | 9,610,196 | 1, 8 | 26 |

It is unclear why the Examiner addresses the "adjacent" language with regard to the rejection of claim 1 based on US 8,657,776 (Ans. 14) because claim 1 of the present application does not include the "adjacent" language in question. We regard this as a typographical error. Although we have

[4] The Final Office Action cites only claims 1, 2, and 10 of US 9,039,650. Final Act. 16.

determined the Examiner's applied interpretation of "adjacent" was unreasonably broad, this erroneous claim construction is not by itself fatal to the double-patenting rejections of claim 9 in the table above premised on US patents 8,734,377; 9,402,767; and 9,610,196. This is because the applied claims in each of these patents contain language that, although not identical, sufficiently satisfies the "adjacent a major side" language of claim 9 in question. The pertinent language of the prior claims is indicated in the table below:

| US Patent# | Claims in Prior Case | Claim language in prior case |
|---|---|---|
| 8,734,377 | 1 | "an elongate opening disposed on an outer side of the body" |
| 9,402,767 | 4 | "the opening defined by the edges of the spines and struts being disposed on the outside of the curve" |
| 9,610,196 | 1 | "having an open side disposed on the large radius side" |

It is additionally noted that claim 6 of US 9,039,650 contains the limitation, "the elongate opening is disposed on a radially outward portion of the cylindrical volume," which would satisfy the language of claim 9 in question. However, the Examiner did not apply claim 6 of US 9,039,650 in the Examiner's rejection. We are not apprised of anything in the remaining applied patents, or of any reasoning articulated by the Examiner, for explaining why, despite the differences between the subject matter of the prior claims and present claim 9, the subject matter of claim 9 would nevertheless have been obvious over the applied prior claims. Accordingly, the obviousness-type double-patenting rejections against claim 9 premised on 8,657,776; 9,358,156; 9,155,655; 9,039,650 cannot be sustained on the basis set forth by the Examiner.

*"the channel having an open side" according to claim 30 as it pertains to the § 103(a) rejection*

Claim 30 requires both a "plurality of openings" and an "open side." In the rejection the Examiner addresses the "open side" by referring, without further explanation, to Figure 1(a) of Neuhann. Final Act. 26–27. The Examiner addresses the "plurality of openings" limitation by indicating it was "discussed supra." Final Act. 27. "[S]upra," as the term is used by the Examiner, appears to refer to the Examiner's citation to openings 2 and 3 in Figure 1(a) of Neuhann. *See* Final Act. 18. The embodiment depicted in Figure 1(a) of Neuhann clearly lacks both a "plurality of openings" and an "open side." The Examiner does not account for this difference between the claimed subject matter and the prior art with any further evidence or reasoning supported by rational underpinnings to address why, despite this distinction, the claimed subject matter would nevertheless have been obvious.

In the Examiner's Answer, the Examiner indicates the rejection of claim 30 was intended to be based on reasoning similar to that set forth by the Examiner concerning claim 2. Ans. 10. However, "provid[ing] for openings on both opposing sides of the tube" (Final Act. 23 (addressing claim 2)) is different from proving an "open side." Reply. Br. 7–8. There is no legally recognizable essential gist or heart of the invention. *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1548 (Fed.Cir.1983), *cert. denied*, 469 U.S. 851 (1984). The express language of the claim must be considered in judging the obviousness of the claimed subject matter. *See In re Wilson*, 424 F.2d 1382, 1385.

For the foregoing reasons, on the record presently before us, the Examiner's § 103(a) rejection of claim 30 cannot be sustained because the Examiner has not established the obviousness of the precise subject matter defined by claim 30.

*The "inlet" as it pertains to the double-patenting rejections*

The issue of whether Neuhann includes an "inlet portion" according to claims 1 and 30 is moot with regard to the rejections predicated under §§ 102(b) and 103(a) because we have reversed those rejections for alternative reasons as discussed above. Insofar as the "inlet" limitation is concerned with regard to the double-patenting rejections of claims 1, 19, and 30 (Appeal Br. 18–20, 22, 23, 25–29, 42–56), we agree with the Examiner that, although the term "inlet" or "inlet portion" may not be expressly recited in the applied prior claims, such a feature is necessarily present in any structure that intakes a fluid at some location and conveys it from that location to another. It is not disputed that the prior claims are directed to such a fluid-conveying structure. Ans. 4–12. Once the examiner presents evidence or reasoning tending to show inherency, the burden of production shifts to the applicant. *See* MPEP § 2112(V). Appellant's arguments do not apprise us of any possible alternatives to demonstrate why inlets are not necessarily required in the previously claimed subject matter.

*The requirement for demonstrating that it would have been obvious to omit claim elements from previous applications or patents to establish obviousness-type double patenting*

In numerous instances, Appellant argues that in order to establish obviousness-type double patenting the Examiner must demonstrate that it

would have been obvious to *omit* features from the prior claims applied in the rejection. Appeal Br. 18–21, 24, 25, 27, 30, 43, 45, 46, 48, 51, 52, 54, 57. As the Examiner points out, this is not required. Unless the claims of the present application employ closed transitional phrases (*see* MPEP § 2111.03), which they do not, they are demonstrated unpatentable for purposes of an obviousness-type double-patenting rejection in much the same way as they are demonstrated unpatentable for covering obvious subject matter under 35 U.S.C. § 103(a). MPEP § 804 (citing, *inter alia*, *In re Braat*, 937 F.2d 589, 592-93 (Fed. Cir. 1991)). "The fundamental reason for the [obviousness-type double-patenting] rule is to prevent unjustified timewise extension of the right to exclude granted by a patent no matter how the extension is brought about." *In re Schneller,* 397 F. 2d 350 (CCPA 1968) (discussed in detail at MPEP § 804). Of course, an extension can effectively be "brought about" by *omitting* elements from previous claims such that later claims encompass subject matter for which an applicant was previously conferred an exclusive right. Anyone undertaking to utilize the subject matter of the patented claims on their expiration would remain precluded from doing so notwithstanding the fact that the later claims omit elements of the previously issued claims. This would undermine the very purpose of the prohibition against obviousness-type double patenting. Accordingly, where, as here, the claims recite an open-ended transitional phrase, the Examiner need not demonstrate the obviousness of omitting additional elements of prior claims applied in an obviousness-type double-patenting rejection.

*The limitation "wherein the ocular implant is configured to provide at least a 121% increase in average outflow facility of aqueous humor from the anterior chamber through the collector channels of the eye"*

A central issue in the rejections under §§ 102(b) and 103(a) and the double-patenting rejection is the meaning of the recited phrase, "wherein the ocular implant is configured to provide at least a 121% increase in average outflow facility of aqueous humor from the anterior chamber through the collector channels of the eye" in claim 1, and that of the similar limitations in claims 9, 19, 30, and 31, which instead recite a "121%–222%" range. Although we have reversed the §§ 102(b) and 103(a) on other grounds, a discussion of the meaning of this phrase with regard to all rejections before us is warranted.

First, it is easily observed that the claims in question are directed to "ocular implant[s]" and are therefore machine or apparatus claims, as opposed to method or process claims. "[A]pparatus claims cover what a device *is*, not what a device *does*." MPEP § 2114 (quoting *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469 (Fed. Cir. 1990)). Thus, the actual *act* of "provid[ing] at least a 121% increase in average outflow facility of aqueous humor from the anterior chamber through the collector channels of the eye" is not a requirement of the claims. The question then is: what is the structural implication of reciting that the claimed "ocular implant" is "configured to" perform this function? *See K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1363 (Fed. Cir. 1999) ("[T]he functional language tells us something about the structural requirements. . ."). In certain contexts "configured to" can simply mean, or be synonymous with, "capable of" in that any structure that can actually perform the recited function satisfies the claim limitation. On the other hand, in certain contexts "configured to" can

have a narrower meaning implicating the presence of some structure or arrangement that demonstrates that the device was specifically designed, made, or adapted to accomplish the particular recited function. The Examiner repeatedly questions Appellant as to what structural meaning is implicated by this phrase. *See, e.g.*, Final Act. 13 ("With respect to the functional language 'the 121% increase in average outflow facility', as the structure is the same, so are the functions of the structure. The Examiner notes that the Applicant must claim their invention in such a way that the structural features define over the prior art."); Ans. 6–7 ("Further, the Appellant has failed to show what combination of structures are required to produce the claimed outflow facility."). Appellant simply argues Appellant is under no obligation to provide that information. Reply. Br. 4 ("Section 102 has no such requirement.").

Section 102 itself might not impose a requirement for an applicant to precisely define the subject matter claimed. However, such a burden is clearly and unequivocally imposed by 35 U.S.C. § 112, second paragraph. *In re Morris*, 127 F. 3d 1048, 1056 (Fed. Cir. 1997) ("It is the applicants' burden to precisely define the invention, not the PTO's. *See* 35 U.S.C. § 112 ¶ 2 . . . [T]his section puts the burden of precise claim drafting squarely on the applicant."). Furthermore, when functional language such as the language at issue here, is considered under 35 U.S.C. §§ 102 or 103, courts have sanctioned the PTO's use of a burden-shifting framework to require an applicant to come forward with evidence and/or explanation to demonstrate why prior-art devices that appear to be similar or identical do not exhibit the functional characteristic in question. MPEP § 2112.01; *see In re Schreiber*, 128 F. 3d 1473, 1478 (Fed. Cir. 1997) (*citing In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990)); *see also In re Swinehart*, 439 F.2d 210, 213 (CCPA 1971).

This procedural tool is used because, as a practical matter, the PTO is not equipped to obtain and test various devices and compare their functions, characteristics, and properties. *In re Best*, 562 F.2d 1252, 1255 (CCPA 1977).

In the context of §§ 102(b) and 103(a) our reviewing court and its predecessor have consistently summarized the underlying policy concern in situations such as this is that "[m]ere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. MPEP § 2145(II) (quoting *In re Wiseman*, 596 F.2d 1019 (CCPA 1979)) *accord In re Baxter Travenol Labs*, 952 F. 2d 388, 392 (Fed. Cir. 1991). An applicant should not be conferred an exclusive right to subject matter potentially in the possession of the public because that applicant has discovered an inherent but latent characteristic of that subject matter. *See id.* Under similar reasoning, an applicant-patentee should not be permitted to extend a patent monopoly by adding latent characteristics to the applicant-patentee's previously issued claims. That would be another way to "br[ing] about" an "unjustified timewise extension of the right to exclude granted by a patent" *See In re Schneller, supra*; MPEP § 804. Thus, the Examiner was not unjustified in requiring Appellant to explain the structural implications of "configured to provide at least a 121% increase in average outflow facility of aqueous humor from the anterior chamber through the collector channels of the eye" so that the Examiner may make a proper determination regarding whether the present claims should be rejected over those previously issued for obviousness-type double patenting.

Neither the Examiner nor Appellant make a very compelling case regarding the precise meaning that should be attributed to the phrase "configured to provide at least a 121% increase in average outflow facility

of aqueous humor from the anterior chamber through the collector channels of the eye" in claim 1 or the similar phrases in the other independent claims. According to the Examiner, these limitations should essentially be presumed satisfied by the prior-art or by the previously claimed subject matter unless Appellant can point to some concrete structural distinction that either *prevents* it from occurring in the subject matter of the applied references or *causes* it to occur in the present application. *See, e.g.*, Final Act. 13 & Ans. 6–7, *supra*. Appellant, on the other hand, contends the Examiner's rejection is defeated simply because the Examiner has not demonstrated the *actual act* occurs in the prior art or prior claims. Appeal Br. 9 ("the Examiner has not shown that Neuhann's structure would necessarily provide at least a 121% increase in average outflow facility of aqueous humor from the anterior chamber through the collector channels of the eye."); Appeal Br. 18 (the Examiner [must] show[] that it would have been obvious to . . . modify the configuration of the device recited . . . to provide a 121% increase in average outflow facility.").

As claims must be read in light of the Specification, we turn to Appellant's Specification for understanding. *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997) ("[T]he PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in applicant's specification."). Paragraph 234 of the Specification states:

> The average C value for the 8 mm implant was 121% greater than controls with a C value of 0.438 µl/min/mmHg and the 16 mm implant was 46% greater than the 8 mm implant (222% greater

> than controls) with a C value of 0.638 μl/min/mmHg (Table 3 above).

Where "[t]he total sum of the flow rates through the collector channels per unit ΔP is defined as the outflow facility (C)." Spec. para. 232. The referenced "Table 3" is provided on page 45 of the Specification and indicates the "Simulated Outflow Facility" for a control and two specific embodiments of the implant, an 8mm embodiment and a 16 mm embodiment. As discussed in paragraphs 217–218 of the Specification, the simulation results tabulated in Table 3 were derived from a mathematical model:

> A comprehensive mathematical model was developed in this disclosure to evaluate changes in fluid dynamics of aqueous humor outflow induced by combinations of trabecular mesh bypass and/or Schlemm's canal dilation, and to predict how the changes would affect outflow facility. . . .
>
> The mathematical model was developed to numerically simulate aqueous humor outflow based on the assumptions and physical principles that govern fluid flow.

The model relies on the following "Universal Parameters," which essentially represent assumptions about the anatomical characteristics of the patient receiving the implant, as listed on page 42–43 of the Specification in Table 1:

**Table 1: Universal Parameters**

| Parameter | Description | Value |
|---|---|---|
| $h_0$ | Intrinsic Height of SC[5] | 20 μm |
| w | Width of SC | 230 μm |
| L | Length of SC | 36 mm |
| E | Young's modulus of TM[6] | 30 mmHg |
| ΔP | IOP[7] - $P_{epi}$[8] | $5 \leq \Delta P \leq 30$ mmHg |
| $N_{CC}$ | Number of CCs[9] | 30 |
| $R_{TM}$ | TM Resistance to Flow | 9 cm mmHg/(μl/min) |
| $R_{CC}$ | Resistance to flow in CC | $2.5*N_{CC}$ mmHg/(μl/min) |
| β | Ratio of RCC in control SC vs. SC with TM bypass | 3 |
| μ | Viscosity of AH[10] | $7.5x10^{-4}$ kg/(m sec) or 0.75 cP |

The model additionally relies on the following "Geometric parameters" for the 8mm and 16mm implant embodiments as respectively indicated in Tables 2A and 2B on pages 43–44 of the Specification:

[5] Schlemm's Canal
[6] Trabecular Meshwork
[7] Intra-Ocular Pressure
[8] Pressure in the Episcleral Vein
[9] Collector Channels
[10] Aqueous Humor

**Table 2A: Geometric Parameters of 8mm implant**

| Parameter | Description | Value |
|---|---|---|
| $A_w$ | Area of window region | 17553 $\mu m^2$ |
| $A_s$ | Area of spine region | 22955 $\mu m^2$ |
| $A_{in}$ | Area of inlet region | 29841 $\mu m^2$ |
| $h_w$ | Height of window region | 76.3 μm |
| $h_s$ | Height of spine region | 99.8 μm |
| $h_{in}$ | Height of inlet region | 129.7 μm |
| $L_w$ | Length of window region | 1.1 mm |
| $N_w$ | Number of windows | 3 |
| $W_d$ | Width of device | 230 μm |
| $L_{in}$ | Length of inlet spine region | 1.1 mm |
| $L_{dev}$ | Length of device in SC | 7.2 mm |
| $L_s$ | Length of spine region | 0.9 mm |

**Table 2B: Geometric Parameters of 16mm implant**

| Parameter | Description | Value |
|---|---|---|
| $A_w$ | Area of window region | 20994 $\mu m^2$ |
| $A_s$ | Area of spine region | 32092 $\mu m^2$ |
| $A_{in}$ | Area of inlet region | 29841 $\mu m^2$ |
| $h_w$ | Height of window region | 91.3 μm |
| $h_s$ | Height of spine region | 139.5 μm |
| $h_{in}$ | Height of inlet region | 129.7 μm |
| $L_w$ | Length of window region | 1 mm |
| $N_w$ | Number of windows | 5 |
| $W_d$ | Width of device | 230 μm |
| $L_{in}$ | Length of inlet spine region | 1.1 mm |
| $L_{dev}$ | Length of device in SC | 15 mm |
| $L_s$ | Length of spine region | 1.5 mm |

Thus, with regard to the "configured to provide at least a 121% increase in average outflow facility of aqueous humor from the anterior chamber through the collector channels of the eye," the Specification discloses that an implant is *theoretically* so configured where it (1) exhibits the indicated values for each of the listed parameters indicated in Table 2A

and (2) is otherwise configured to be implanted in an eye exhibiting the indicated values for each of the parameters listed in Table 1.[11] For the recited upper limit of a 222% increase (*e.g.*, claims 9, 19, 30, 31) the implant must (1) exhibit the indicated values for each of the listed parameters indicated in Table 2B and (2) be otherwise configured to be implanted in an eye exhibiting the indicated values for each of the parameters listed in Table 1. These are very specific requirements to achieve the recited 121%, or 222%, increase in average outflow facility of aqueous humor as recited in the claims and none of the independent claims, each of which contain a recitation pertaining to this result, recites any limitations pertaining to the geometric requirements that appear to be necessary to bring these results about according to the Specification. The Specification does not indicate any specific or approximate ranges for these values that would operate to bring about the recited results and it cannot be ascertained what influence modification to one or more of these values will have on the outflow facility of aqueous humor ultimately or theoretically provided. An ocular implant may be "configured to provide" the recited outflow increase by designing it with a geometry exhibiting *all* of the tabulated parameter values. However, the question arises as to whether an implant is reasonably regarded as similarly "configured" if it exhibits the outflow increase without exhibiting all, or for that matter, any, of the tabulated parameter values. This uncertainty, in our view, unduly burdens the potential infringer with too much uncertainty when attempting to ascertain the metes and bounds of the claimed subject matter. Stated differently, when read in light of the

[11] It is noted that not all the independent claims indicate the implant is configured to be implanted in a human eye based on which the assumed "universal characteristics" appear to have been derived.

Specification, the limitation in claim 1 indicating that the claimed implant is "configured to provide at least a 121% increase in average outflow facility of aqueous humor from the anterior chamber through the collector channels of the eye," as well as the similar limitations in the other independent claims, do not point out with sufficient particularity precisely what structural arrangement is required of the claimed implant. This violates the requirements of 35 U.S.C. § 112, second paragraph. We therefore reject all the claims before us under 35 U.S.C. § 112, second paragraph, as being indefinite.

An additional problem with the "configured to provide at least a 121% [or 121%–222%] increase in average outflow facility of aqueous humor from the anterior chamber through the collector channels of the eye" limitation is that, as discussed above, Appellant's disclosure includes only a single (8 mm) embodiment theoretically exhibiting the "121% increase in average outflow facility" and a single (16 mm) embodiment theoretically exhibiting the "222% increase" These embodiments each rely on no less than twelve very specific geometric parameters coupled with the assumption of ten patient parameters to, respectively, arrive at the theoretical 121% and 222% results. The so called quid-pro-quo of the patent grant serves to ensure that the right to exclude conferred by the patent is commensurate with the patentee's contribution to the art to which the patent pertains. *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.*, 598 F. 3d 1336, 1349, 1353–4 (Fed. Cir. 2010). Both the written description and enablement requirements of 35 U.S.C. § 112, first paragraph, which often rise and fall together, help ensure that this is the case. *Ariad*, 598 F. 3d at 1350 ("[A] sufficient [written] description of a genus . . . requires the disclosure of either a representative number of species falling within the scope of the genus or

*structural features* common to the members of the genus so that one of skill in the art can "visualize or recognize" the members of the genus.") (emphasis added); *In re Moore*, 439 F.2d 1232, 1236 (CCPA 1971) ("The relevant inquiry may be summed up as being whether the scope of enablement provided to one of ordinary skill in the art by the disclosure is such as to be commensurate with the scope of protection sought by the claims.") *accord also Plant Genetic Sys., N.V. v. DeKalb Genetics Corp.*, 315 F.3d 1335, 1339 (Fed. Cir. 2003). Thus, the disclosure of structures theoretically exhibiting the characteristics of, two discrete endpoints of a range (121–222%; claims 9, 19, 30, 31), or one endpoint and one value within the range (at least 121%; claim 1), does not necessarily confer a right to claim any and all structures exhibiting characteristics that fall within the entire range.

Appellant chose to define this aspect of the claims using functional language. There is no prohibition against doing that but, as our reviewing court's predecessor observed in *In re Swinehart*, 439 F. 2d 210, 213 (CCPA 1971):

> "Functional" terminology may render a claim quite broad. By its own literal terms a claim employing such language covers any and all embodiments which perform the recited function. Legitimate concern often properly exists, therefore, as to whether the scope of protection defined thereby is warranted by the scope of enablement indicated and provided by the description contained in the specification. That is, the language may be so broad that it causes the claim to have a potential scope of protection beyond that which is justified by the specification disclosure.

More recently, our reviewing court stated, "[t]he written description requirement . . . ensures that when a patent claims a genus by its function or result, the specification recites sufficient materials to accomplish that

function — a problem that is particularly acute in the biological arts." *Ariad*, 598 F. 3d at 1352–53.

Based on Appellant's Specification, we can see no reason why a disclosure of two embodiments seemingly requiring very precise geometric parameter values operating in a very specific biological environment in order to yield a particular biological result is sufficient to support claims that cover implants having any or none of those specific parameter values but are, one way or another, by means known or unknown, somehow "configured to" exhibit those same results. Broad generic claims of this nature are examples of improper "attempt[s] to preempt the future before it has arrived." *See Ariad*, 598 F. 3d at 1353 (citation omitted). We see nothing in the dependent claims that remedies this deficiency. Accordingly, we additionally reject all the pending claims before us under 35 U.S.C. § 112, first paragraph, because the Specification does not comply with the written description and enablement requirements.

*Disposition of remaining obviousness-type double-patenting rejections*

Above, we have reached certain issues pertaining to the double-patenting rejections in an effort to advance any further prosecution. Ultimately, where we did not express other unrelated reasons for not sustaining the Examiner's double-patenting rejections, the double-patenting rejections hinge on the meaning afforded to the "configured to provide at least a 121% increase in average outflow facility of aqueous humor from the anterior chamber through the collector channels of the eye" limitation in claim 1 or the similar limitations of claims 9, 19, 30, and 31. Before a proper obviousness or inherency analysis can be performed, the subject matter encompassed by the claims on appeal must be reasonably understood

without resort to speculation. *See In re Steele*, 305 F.2d 859, 862 (CCPA 1962) (A prior art rejection cannot be sustained if the hypothetical person of ordinary skill in the art would have to make speculative assumptions concerning the meaning of claim language.). As we have determined that these phrases render the claims indefinite when read in light of the Specification, we do not make a final determination as to the merits of the remaining obviousness-type double-patenting rejections at this time. We reverse these rejections pro-forma without reaching their merits. *See In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970) ("If no reasonably definite meaning can be ascribed to certain terms in the claim, the subject matter does not become obvious-the claim becomes indefinite.")

## CONCLUSION

The Examiner's rejections are REVERSED.

Pursuant to our authority under 37 C.F.R. § 41.50(b), we enter NEW GROUNDS of rejection for claims 1–7, 9–15, 17–25, 27, 28, 30, and 31 under 35 U.S.C. § 112, first and second paragraphs, for the reasons discussed above.

DECISION SUMMARY

| Claims Rejected | 35 U.S.C. § | Reference(s)/Basis | Affirmed | Reversed | New Ground |
|---|---|---|---|---|---|
| 30 | 112(b) | Indefiniteness | | 30 | |
| 1, 9, 31 | 102(b) | Neuhann | | 1, 9, 31 | |
| 2–7, 10–15, 17, 18, 30 | 103(a) | Neuhann | | 2–7, 10–15, 17, 18, 30 | |
| 1, 3, 4, 6, 7, 9, 11, 12, 14, 15, 17–19, 21, 22, 24, 25, 27, 28, 30, 31 | | Obviousness-type double patenting | | 1, 3, 4, 6, 7, 9, 11, 12, 14, 15, 17–19, 21, 22, 24, 25, 27, 28, 30, 31 | |
| 1–7, 9–15, 17–25, 27, 28, 30, 31 | 112(b) | Indefiniteness | | | 1–7, 9–15, 17–25, 27, 28, 30, 31 |
| 1–7, 9–15, 17–25, 27, 28, 30, 31 | 112(a) | Written description, enablement | | | 1–7, 9–15, 17–25, 27, 28, 30, 31 |
| **Overall Outcome** | | | | 1–7, 9–15, 17–19, 21, 22, 24, 25, 27, 28, 30, 31 | 1–7, 9–15, 17–25, 27, 28, 30, 31 |

RESPONSE

This decision contains a new ground of rejection pursuant to 37 C.F.R. § 41.50(b). Section 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review." Section 41.50(b) also provides:

> When the Board enters such a non-final decision, the appellant, within two months from the date of the decision, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:
>
> (1) *Reopen prosecution*. Submit an appropriate amendment of the claims so rejected or new Evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the prosecution will be remanded to the examiner. The new ground of rejection is binding upon the examiner unless an amendment or new Evidence not previously of Record is made which, in the opinion of the examiner, overcomes the new ground of rejection designated in the decision. Should the examiner reject the claims, appellant may again appeal to the Board pursuant to this subpart.
>
> (2) *Request rehearing*. Request that the proceeding be reheard under § 41.52 by the Board upon the same Record. The request for rehearing must address any new ground of rejection and state with particularity the points believed to have been misapprehended or overlooked in entering the new ground of rejection and also state all other grounds upon which rehearing is sought.

Further guidance on responding to a new ground of rejection can be found in the Manual of Patent Examining Procedure § 1214.01.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv).

REVERSED; 37 C.F.R. § 41.50(b)