

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEW WORLD MEDICAL, INC.,
Petitioner,

v.

MICROSURGICAL TECHNOLOGY, INC.,
Patent Owner.

IPR2020-01573
Patent 9,107,729 B2

Before JAMES A. TARTAL, ROBERT A. POLLOCK, and
RYAN H. FLAX, *Administrative Patent Judges*.

FLAX, *Administrative Patent Judge*.

DECISION

Denying Patent Owner's Request for Rehearing of Final Written Decision
37 C.F.R. § 42.71(d)

I. INTRODUCTION

MicroSurgical Technology, Inc. (“Patent Owner”) is the owner of U.S. Patent 9,107,729 B2 (“the ’729 patent,” Ex. 1001). Paper 29, 1 (“Response” or “Resp.”). New World Medical, Inc. (“Petitioner”) filed a Petition for an *inter partes* review of claims 1–10 (all claims) of the ’729 patent. Paper 1 (“Pet.”). Trial was instituted on March 16, 2022. Paper 22 (“Institution Decision” or “DI”). The parties presented their positions and arguments on patentability and the evidence of record in a Petition (Paper 1), Patent Owner’s Response (Paper 29), Petitioner’s Reply (Paper 35), and Patent Owner’s Sur-Reply (Paper 44). After considering the parties’ positions and arguments, and the evidence of record, we concluded that Petitioner proved by a preponderance of the evidence that claims 1–10 of the ’729 patent are unpatentable because they would have been obvious under 35 U.S.C. § 103 over Quintana and Lee.^{1, 2} Paper 64 (“Final Decision” or “FD”).

Patent Owner timely filed a request for rehearing of our Final Decision. Paper 65 (“Request” or “Req.”). Patent Owner argues we erred in concluding the claims are unpatentable because: (1) Quintana fails to teach “first and second cutting edges concurrently cutting, from the trabecular meshwork, a strip of tissue,” as recited by claim 1; (2) it was impermissible hindsight to rely on Exhibits 1031–1033 (“the Netland videos”); (3) there would not have been motivation for the ordinarily skilled artisan to combine

¹ Manuel Quintana, *Gonioscopic Trabeculotomy. First Results in DOCUMENTA OPHTHALMOLOGICA PROCEEDINGS SERIES 43, SECOND EUROPEAN GLAUCOMA SYMPOSIUM 265–71* (E.L. Greve et al. eds. 1985). Ex. 1004 (“Quintana”).

² U.S. Patent 4,900,300 (issued Feb. 13, 1990). Ex. 1006 (“Lee”).

Quintana and Lee; (4) Quintana and Lee fail to teach “a dual blade device” (that concurrently cut trabecular meshwork) as recited by claim 1; (5) we substituted expert witness assertions for claim elements missing from Quintana and Lee; and (6) we substituted our own analysis regarding Lee teaching an angled tip of its device where that fact was not raised by Petitioner. *See generally* Req. Our discussion below addresses these issues with the understanding that Patent Owner presents specific arguments on these points throughout its Request.

II. STANDARD OF REVIEW

The standard applicable to a request for rehearing of a Board decision is provided in Rule 42.71(d), which states in pertinent part:

The burden of showing a decision should be modified lies with the party challenging the decision. The request must specifically identify all matters the party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed in a motion, an opposition, or a reply.

37 C.F.R. § 42.71(d) (2021). A request for rehearing is not an opportunity to present new arguments or evidence or merely to disagree with the panel’s assessment of the arguments or weighing of the evidence.

III. DISCUSSION

For the reasons that follow, we find Patent Owner has not shown we misapprehended or overlooked any matter in the Final Decision. We address Patent Owner’s arguments below.

A. QUINTANA TEACHES “FIRST AND SECOND CUTTING EDGES CONCURRENTLY CUTTING, FROM THE TRABECULAR MESHWORK, A STRIP OF TISSUE”

Patent Owner argues that that Quintana does not teach the successful removal of a strip of trabecular meshwork. Req. 3–4.³ Patent Owner further argues there is no evidence in the record to support that Quintana teaches “creating a strip of TM using a slightly, bent hypodermic needle tip, much less by the concurrent cutting of the beveled sides of the needle tip.” *Id.* at 5.

We address in the Final Decision the question of whether Quintana teaches “first and second cutting edges concurrently cutting, from the trabecular meshwork, a strip of tissue,” as recited by claim 1, which is an issue previously raised by Patent Owner. FD 45–47; *see also id.* at 33–43 (addressing whether and determining that Quintana and Lee teach “obtaining a dual blade device,” as also recited by claim 1, upon which this limitation is

³ Patent Owner’s argument focuses on whether Quintana teaches the claimed subject matter and ignores (1) that Petitioner’s ground for unpatentability is based on obviousness and a combination of Quintana and Lee, (2) that it is over this ground that we found the claims unpatentable as obvious, and (3) that we found Lee, like Quintana, teaches a trabecular meshwork stripping device having two cutting edges, as claimed. *See* FD 15–18, 32–43; *see also* DI 10–12, 21–23 (discussing such teachings of Quintana and Lee). “Non-obviousness cannot be established by attacking references individually where [unpatentability] is based upon the teachings of a combination of references. . . . [The references] must be read, not in isolation, but for what [they] fairly teach[] in combination with the prior art as a whole.” *In re Merck & Co.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). Nevertheless, we address here Patent Owner’s arguments as presented. Patent Owner also argues that we were incorrect in finding the ordinarily skilled artisan would have been motivated to combine Quintana and Lee; we address this argument below.

based). As addressed in the Final Decision, Petitioner asserts Quintana teaches a dual blade device having first and second cutting edges as a bent-tip needle having a beveled tip with two sharp sides and further teaches a process where that device is advanced through Schlemm's canal resulting in a strip of trabecular meshwork tissue having a width matching the distance between the cutting edges. *Id.* at 45. The Final Decision also addresses Petitioner's assertion that such a procedure was well known by 2003 and that Lee also teaches such a procedure, which cuts and extracts segments of trabecular meshwork. *Id.*

In the Final Decision we address Patent Owner's argument that Quintana did not teach these limitations, as Patent Owner repeats in its Request. *Id.* at 45–46. The same points that Patent Owner makes in its Request now were addressed in the Final Decision. For example, we address Quintana's use of the term “stripped” in several portions of the Final Decision. *Id.* at 37, 45–46. The Final Decision identifies that Quintana's procedure teaches “the TM is stripped slowly, gently, and easily from the canal's lumen . . . as the needle progresses.” *Id.* at 37 (citing Ex. 1004, 4); *see also id.* at 45–46. We found that Quintana's disclosure that “TM is stripped . . . from the canal's lumen” evidences the tissue's removal.⁴ *See id.* at 37 (citing Ex. 1004, 4, caption to Figure 2; crediting Ex. 1030 ¶¶ 7–10). We further explain Quintana's reference to “acheiv[ing] a section of the trabecular meshwork,” and to conducting studies “of the sectioned trabecular

⁴ Further, we found that Lee's disclosure supported our determination and that Dr. Netland's experiments confirmed that Quintana's disclosed procedure functions to cut a strip of trabecular meshwork from the eye. FD 46.

meshwork,” to similarly evidence cutting a strip of tissue and tissue removal.⁵ *Id.* at 13 (citing Ex. 1004, 3), 14 (citing Ex. 1004, 8). Quintana (and, for that matter, Lee) teaches creating a strip of trabecular meshwork using an instrument with blades on two (dual) sides as described above and as discussed in the Final Decision. *See id.* at 42–43.

We do not find Patent Owner’s argument persuasive for the reasons stated in our Final Decision. *See id.* at 45–47. Accordingly, we did not overlook or misapprehend the plain language of the challenged claims or the evidence that Quintana, individually and also in view of Lee, discloses creating a strip of trabecular meshwork with a bent-tip needle comprising a dual blade.

B. EXHIBITS 1031–1033 (“THE NETLAND VIDEOS”)

Patent Owner argues that we used the Netland videos (Exhibits 1031–1033) to justify our decision based on a hindsight reading of Quintana. Req. 6. Patent Owner further states it is “ambiguous at best whether the Netland videos show the creation of a strip of TM.” *Id.* at 10.

Dr. Netland’s testimony that Quintana discloses cutting and removal of TM tissue (i.e., Quintana’s goniotrabeculotomy) is consistent with a plain reading of the reference, and we credit Dr. Netland’s explanation of how Quintana would have been understood by the ordinarily skilled artisan. *See* FD 33, 37–43, 46–47. Quintana discloses that, using the tip of the bent needle, “*the TM is stripped* slowly, gently and easily *from* the canal’s

⁵ Additionally, we found that Lee discloses a procedure it calls “goniectomy, which includes using a dual-bladed, hollow tool to excise and remove tissue from the eye’s trabecular meshwork via access through the eye’s anterior chamber.” FD 32 (Ex. 1006, Abstract, 1:54–2:7, 3:50–57, 4:18– 48, 5:61–65, 6:14–27, Figs. 2, 3; Ex. 1003 ¶¶ 101–103).

lumen.” FD at 45–46 (citing Ex. 1004, 4) (emphasis added). That “TM is stripped . . . from the canal’s lumen” evidences tissue cutting and removal. *See id.* at 13 (citing Ex. 1004, 8, caption to Figure 2). We further view Quintana’s reference to “acheiv[ing] a section of the trabecular meshwork,” and conducting studies “of the sectioned trabecular meshwork,” to similarly evidence *cutting a strip* of tissue and tissue removal, rather than merely slicing through or pushing aside TM tissue. *Id.* at 13 (citing Ex. 1004, 3), 14 (citing Ex. 1004, 8, caption to Figure 2).

We are not persuaded by Patent Owner’s suggestion that, in crediting Dr. Netland’s experimental evidence, we improperly “substitut[e] the assertions of an expert witness for a missing element.” Req. 8. Rather, we looked first to what Quintana expressly discloses, and further considered Dr. Netland’s testimony on how one of ordinary skill in the art would have understood Quintana’s teachings, which corroborated the reference’s express disclosure.

We also credit Dr. Netland’s experimental evidence (Exs. 1031–1033) and related testimony (Ex. 1030). His video-recorded experiment sought to perform the procedure taught by Quintana, and bolstered his original testimony by showing that Quintana’s bent needle, when used in Quintana’s procedure, cuts and removes a strip of trabecular meshwork from a human eye, just as he testified. *See, generally*, FD 39–42 (discussing Exs. 1031–1033). Patent Owner argues that, rather than showing a strip of tissue cut from the TM by the opposing beveled edges of the bent hypodermic needle, Dr. Netland’s demonstration *could* show “merely incising the TM and creating a separation between the TM and Schlemm’s canal.” Req. 9–10. Patent Owner bases this conjecture on the disclosure of a bent hypodermic

needle in the of-record, but secondary and unasserted Johnstone reference, which discussed “push[ing] a strip of meshwork ahead of itself *in the manner of a plow*.” *Id.* (citing Ex. 1005, 907).

In raising Johnstone, Patent Owner presents a new argument—one unsupported by evidence—regarding how one of ordinary skill in the art would have understood Johnstone’s plow analogy. Thus, to the extent we were to credit Patent Owner’s theory, it appears to be attorney argument unsupported by record evidence. We note, however, that Patent Owner mischaracterizes Johnstone because the preceding sentences in Johnstone explain that the instrument was positioned to

present[] a triangular shape with its base facing the external wall of Schlemm's canal, and a sharp slanting edge engaging the trabecular meshwork. This was *intended to cut* the inner wall of the canal and the *trabecular sheets* from within the canal while limiting damage to the external wall of the canal.

Ex. 1005, 907 (emphasis added); *see also* Ex. 2021, 129:10–133:14 (Dr. Netland testifying that Johnstone used a bent needle to excise a strip of trabecular meshwork). We read Johnstone’s suggestion that the “sharp slanting edge” of the instrument would “cut the inner wall of the canal and the trabecular sheets from within the canal” as consistent with our conclusion that the beveled edges of Quintana’s bent needle tip would cut a strip of TM tissue from the eye, just as Dr. Netland’s testifies and as his evidentiary videos illustrate. Whether Johnstone’s tool thereafter pushes the cut tissue is immaterial.

The determinations in the Final Decision are based on the disclosure of Quintana, individually and in view of Lee. *See generally* FD. We did not rely on impermissible hindsight.

C. THERE WERE REASONS FOR THE ORDINARILY SKILLED ARTISAN TO
COMBINE QUINTANA AND LEE

Patent Owner argues that the devices of Quintana and Lee are not used for the same purpose because Quintana does not teach creating a strip of trabecular meshwork. Req. 6. Patent Owner further states that we identified that Quintana teaches “goniotomy” and Lee teaches “goniectomy” and then dismissed this nomenclature to arrive at our decision. *Id.* at 7. Patent Owner states the difference in terms “is critical and cannot be overcome without resorting to impermissible hindsight.” *Id.*

In the Final Decision, the use of different terms in the art is addressed and, regardless of the term used in Quintana, the term “stripped” is also used to describe how Quintana’s procedure cuts and removes trabecular meshwork tissue. FD 46 (citing Ex. 1004, 4). Quintana clearly states “the TM is stripped slowly, gently and easily from the canal’s lumen.” *Id.* Not only does Quintana state “the TM is stripped,” but Quintana also specifically indicates this stripping is “from the canal’s lumen,” evidencing that a strip of tissue is created and removed. *See Id.*

The Final Decision also addresses the ordinarily skilled artisan’s motivation to combine Quintana and Lee. *Id.* at 26–31. Both the modified hypodermic needle of Quintana and the tool taught by Lee are used in a substantially identical procedure and the Final Decision states that one of skill in the art would look to Lee “for details for a trabecular meshwork stripping tool and method because that is exactly what Lee teaches designing and using a tool for.” *Id.* at 30. Furthermore, the Decision also identifies that one of skill in the art would have modified Quintana in view of Lee based on “advantages expressed by the references themselves, such as providing sharp cutting edges to better excise tissue.” *Id.* at 29.

As discussed above, both Quintana and Lee teach using their tools to create a strip of trabecular meshwork. *Id.* at 26–31. Indeed, we noted that Lee expressly illustrates this process. *Id.* 33 (citing Ex. 1006, 1:50–54, 5:55–6:45, Fig. 5). The Final Decision addresses the arguments Patent Owner raises now and we do not find the arguments persuasive for the reasons stated in the Final Decision. *Id.* at 45–47. Accordingly, the motivation to combine Quintana and Lee was previously addressed; we found there would have been motivation to combine the prior art references.

D. THE QUINTANA AND LEE COMBINATION TEACHES “A DUAL BLADE DEVICE”

Patent Owner further argues Lee does not teach a “dual blade,” but instead “a single more or less U-shaped cutting edge 14 integral with the sides of the shaft 10.” Req. 8. Patent Owner argues our finding “stands in direct contravention to its plain and ordinary meaning construction that ‘*dual*’ refers to *two*.” *Id.* (citing FD 16).

Patent Owner inaccurately characterizes Lee and does not consider the full description of Lee as discussed in the Final Decision. *See* FD 15–18 (citing Ex. 1006, 7:34–35 (claim 1 reciting “rim is sharpened so as to form a cutting blade having side cutting edges and a distal tip”)). The Final Decision identifies that Lee teaches “edges,” plural, and thus two sides or a dual blade. *See id.*

Patent Owner argues that Quintana also does not teach a dual blade, but instead a “typical *single* bevel at the needle tip.” Req. 9. Patent Owner also argues that our characterization of the “needle tip as cutting edges . . . does not comport with the intended use of a standard hypodermic needle for medicament delivery.” *Id.* Patent Owner also argues that our characterization is inconsistent with the prior art. *Id.*

Contrary to Patent Owner’s position, Quintana does not disclose “the intended use of a standard hypodermic needle.” *See, e.g., id.* at 13–14. Quintana’s *bent* needle tip, used to strip trabecular meshwork, is addressed in the Final Decision and Dr. Netland, and even Dr. Condon (Patent Owner’s witness), described the bent needle tip as having two sides. FD 38 (reproducing diagrams annotated by Dr. Netland and Dr. Condon, each pointing to two sides).

As discussed above, both Quintana and Lee teach a dual blade device, each used for essentially the same purpose—cutting and stripping Trabecular Meshwork. *Id.* at 37–39. The Final Decision addressed the arguments Patent Owner now raises and we do not find these arguments persuasive for the reasons stated in the Final Decision. *Id.* As such, Patent Owner identifies no argument or evidence overlooked or misapprehended in the Final Decision.

E. WE DID NOT SUBSTITUTE EXPERT WITNESS ASSERTIONS FOR CLAIM ELEMENTS MISSING FROM QUINTANA AND LEE

Patent Owner argues that there is no teaching of “excising TM in Quintana, much less any disclosure of creating a strip of TM.” Req. 11. Patent Owner states that there is nothing in Quintana to suggest a section was removed because no data was collected regarding tissue removal. *Id.* Patent Owner further argues that we relied on “Petitioner’s expert that the words ‘achieving a section’ and ‘stripped slowly, gently and easily from the canal’s lumen’ must mean a strip of TM was created, and ignores all contrary evidence of record.” *Id.* Patent Owner also argues that the beveled sides of the Quintana bent needle would not be able to cut the trabecular meshwork as opposed to the sharp point of the needle tip. *Id.*

Dr. Netland’s testimony that Quintana discloses removal of TM tissue (i.e., a goniotrabeculotomy), is consistent with our reading of the reference, and we credit Dr. Netland’s explanation of how Quintana would have been understood by the ordinarily skilled artisan. Quintana discloses that when using the tip of the bent needle, “*the TM is stripped* slowly, gently and easily *from* the canal’s lumen.” FD at 45–46 (citing Ex. 1004, 4) (emphasis added). Again, that “TM is stripped . . . from the canal’s lumen” evidences tissue is cut and removed. *See id.* at 13 (citing Ex. 1004, 8, caption to Figure 2). We further view Quintana’s reference to “achiev[ing] a section of the trabecular meshwork,” and conducting studies “of the sectioned trabecular meshwork,” to similarly evidence cutting a strip of tissue and tissue removal, rather than merely slicing through or pushing aside TM tissue. *Id.* at 13 (citing Ex. 1004, 3), 14 (citing Ex. 1004, 8, caption to Figure 2).

For the reasons set forth in the Final Decision, we find that Quintana teaches cutting a strip of trabecular meshwork from the eye within the four corners of the reference. *See id.* at 13, 45–47. As such, Patent Owner identifies no argument or evidence overlooked or misapprehended in the Final Decision.

F. WE DID NOT SUBSTITUTE OUR OWN ANALYSIS REGARDING LEE
TEACHING AN ANGLED TIP OF ITS DEVICE

Patent Owner argues that our “substitution of [our] own analysis regarding the purported angle cutting edge 14 in Lee is also improper” because it was not raised by Petitioner. Req. 13. Patent Owner further states that we disregarded Petitioner’s expert stating that a roughly 90° bend would not achieve the same results. *Id.* at 14. Patent Owner also asserts that our

conclusion regarding the bend angle based on the surgeon’s desires and surgical requirements is contradicted by the record. *Id.*

As an initial matter, we did not rely on Lee’s teaching of bending its devices tip at any certain angle to render the claims obvious. The Final Decision explains that Quintana teaches “bending its needle’s tip up to 30°, which is less than the claimed 90°.” FD 54. As further explained, Lee is combined with Quintana to provide “supporting information” and a teaching that the tip of the device can be bent at any angle needed for the particular surgery. *Id.* at 30. Quintana teaches and renders obvious the limitations of claims 9 and 10, and our Final Decision takes note that Lee is fully supportive of teaching bending the end of a trabecular meshwork excising device at any necessary angle. *Id.* at 54–56.

Our determination regarding claims 9 and 10 does not amount to a new ground of unpatentability not raised by Petitioner in the Petition.

IV. CONCLUSION

Having considered Patent Owner’s arguments, we are unpersuaded that the Request for Rehearing demonstrates that we misapprehended or overlooked any matters. See summary charts below:⁶

Outcome of Decision on Rehearing:

Claims	35 U.S.C. §	References	Denied	Granted
1–4, 7–9	102	Quintana		

⁶ As reflected in these charts, Petitioner’s grounds for unpatentability based on Quintana’s anticipation, obviousness over Quintana alone, and over the Jacobi reference were not reached because all claims were found to be unpatentable as obvious over Quintana and Lee.

Claims	35 U.S.C. §	References	Denied	Granted
4-6, 10	103	Quintana		
1-4, 7-9	103	Quintana, Lee	1-4, 7-9	
4-6, 10	103	Quintana, Lee	4-6, 10	
1-4, 7, 8	102	Jacobi		
5, 6, 9, 10	103	Jacobi		
Overall Outcome			1-10	

Outcome of Final Written Decision after Rehearing:

Claims	35 U.S.C. §	References	Claims Shown Unpatentable	Claims <u>Not</u> Shown Unpatentable
1-4, 7-9	102	Quintana		
4-6, 10	103	Quintana		
1-4, 7-9	103	Quintana, Lee	1-4, 7-9	
4-6, 10	103	Quintana, Lee	4-6, 10	
1-4, 7, 8	102	Jacobi		
5, 6, 9, 10	103	Jacobi		
Overall Outcome			1-10	

IPR2020-01573
Patent 9,107,729 B2

ORDER

Accordingly, it is hereby:

ORDERED that Patent Owner's Request for Rehearing is *denied*.

IPR2020-01573
Patent 9,107,729 B2

For PETITIONER:

Todd R. Tucker
Kyle T. Deighan
CALFEE, HALTER & GRISWOLD LLP
ttucker@calfee.com
kdeighan@calfee.com

For PATENT OWNER:

Lawrence M. Sung
Mary Sylvia
Teresa M. Summers
WILEY REIN LLP
lsung@wileyrein.com
msylvia@wileyrein.com
tsummers@wileyrein.com