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Paper 61
Entered: March 28, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ALLERGAN, INC. and ALLERGAN SALES, LLC,
Petitioners,

v.

1474791 ONTARIO, LTD.,
Patent Owner.

Case IPR2016-00102
Patent 6,806,251

Before SHERIDAN K. SNEDDEN, TINA E. HULSE, and ELIZABETH A. LAVIER, *Administrative Patent Judges*.

SNEDDEN, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. INTRODUCTION

Allergan, Inc. and Allergan Sales, LLC ("Petitioners") filed an Amended Petition (Paper 24; "Pet.") to institute an *inter partes* review of claims 1–7 of US 6,806,251 B2 (Ex. 1001; "the '251 patent"). Patent Owner 1474791 Ontario, Ltd. ("Patent Owner") filed a corrected Patent Owner Preliminary Response. Paper 25 ("Prelim. Resp.").

Based on these submissions, we instituted trial on the following grounds of unpatentability asserted by Petitioners:

Ground	References	Basis	Claims Challenged
1	Travell[1]	§ 102(b)	1–4, 6, and 7
2	Travell	§ 103(a)	1–4, 6, and 7
3	Travell and Cheshire[2]	§ 103(a)	5

Decision to Institute (Paper 26, "Dec.").

After institution of trial, Patent Owner filed a Patent Owner Response (Paper 33, "PO Resp."), to which Petitioners filed a Reply (Paper 37, "Reply").

Petitioners rely on the Declarations of Dr. Edgar L. Ross, M.D. (Ex. 1039, Ex. 1053) in support of the proposed grounds of unpatentability.

Patent Owner relies on the Declaration of Dr. Antoine Chami (Ex. 2034).

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[1] Simons et al., *Travell & Simons' Myofascial Pain and Dysfunction: The Trigger Point Manual Volume 1. Upper Half of Body* (2d ed. 1999). Ex. 1034 ("Travell").

[2] Cheshire et al., "Botulinum toxin in the treatment of myofascial pain syndrome," 59 PAIN 65–69 (1994). Ex. 1004 ("Cheshire").

Patent Owner filed a motion to exclude certain of Petitioners' evidence. Paper 47. Petitioners filed an opposition (Paper 48), and Patent Owner filed a reply (Paper 50).

Oral argument was conducted on February 1, 2017. A transcript is entered as Paper 58 ("Tr.").

This Final Written Decision is entered pursuant to 35 U.S.C. § 318(a). We conclude for the reasons that follow that Petitioners have shown by a preponderance of the evidence that claims 1–7 of the '251 patent are unpatentable.

A. The '251 Patent (Ex. 1001)

The '251 patent discloses administering botulinum toxin (BT) "to treat herniated disks, spinal neuropathy, compressed and degenerated disks of the spine, and facet joint disease of the spine as caused by intrinsic spinal muscle dysfunction, and the complications thereof." Ex. 1001, 2:3–9. The disclosed invention "is based on the concept that injury over time can cause the deep/intrinsic muscles to become very tight and scarred, which, in turn, causes compression of the spine." *Id.* at 3:16–19.

The '251 patent describes the "intrinsic spinal muscles" as follows:

> The deepest set of muscles are the rotator brevis and longus **20**. In combination, these deep muscles, which comprise primarily the multifidus and the rotator brevis and longus muscles, support the spine and allow it to move without falling apart. The multifidus **18** and rotator **20** muscles, referred to herein as the intrinsic muscles, are very strong but also very small.

Id. at 3:11–15.

The '251 patent discloses methods for treating pain involving injection of BT to the intrinsic spinal muscles. *Id.* at 2:11–15. The injection

causes intrinsic spinal muscles to relax. *Id.* at 4:10–19. This facilitates decompression of the vertebral segments and spinal disks, which "allows the canals through which the dorsal nerve roots travel to become unimpinged," leading "to a reduction of neuropathy and radiculopathy and their complications and side effects." *Id.*

The claims of the '251 patent are directed to methods of treating a disorder associated with spinal compression. The '251 patent discloses that "conditions associated with myofascial compression neuropathies include migraine headaches, temporomandibular joint disease, tinnitus, vertigo, sciatica, radiculopathy, carpal tunnel syndrome, ulnar neuritis, tennis elbow, golfers elbow, RSI, rotator cuff injury, heartburn and reflux." *Id.* at 5:19–25.

To perform the disclosed methods, toxin is injected into the "intrinsic spinal muscles," which are deep spinal muscles surrounding the vertebrae and disks. *Id.* at 1:26–31, 2:19–21. The toxin is administered in an amount sufficient to paralyze the muscles. *Id.* at 2:11–15. "The toxin may be administered as a single dose or in a number of injections." *Id.* at 2:17–18.

B. Challenged Claims

Challenged claims 1–7 of the '251 patent are reproduced below:

> 1. A method of treating a disorder associated with spinal compression comprising administering an effective dose of botulinum toxin directly and solely to the intrinsic muscles of a patient in need of such therapy.
>
> 2. A method according to claim 1, wherein said disorder associated with spinal compression is selected from the group consisting of compression neuropathies, facet joint disease of the spin, sciatica, disc herniation, and degenerated discs.

> 3. A method according to claim 2, wherein the disorder is disc herniation or degenerated discs.
>
> 4. A method according to claim 1, wherein said botulinum toxin paralyzing agent is botulinum toxin A.
>
> 5. A method according to claim 1, wherein said toxin is administered in a dose between 1 and 30 mouse units of toxin per injection site.
>
> 6. A method according to claim 1, wherein said toxin is administered in a single injection.
>
> 7. A method according to claim 1, wherein said toxin is administered via a plurality of injections.

II. ANALYSIS

A. Claim Interpretation

In an *inter partes* review, the Board interprets a claim term in an unexpired patent according to its broadest reasonable construction in light of the specification of the patent in which it appears. 37 C.F.R. § 42.100(b); *see Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under that standard, and absent any special definitions, we assign claim terms their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention, in the context of the entire patent disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Only terms that are in controversy need to be construed, however, and then only to the extent necessary to resolve the controversy. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

We interpret the following terms of the challenged claims as part of our analysis. The Petition does not require explicit construction of any other claim term. *See id*.

1. "a disorder associated with spinal compression"

The challenged claims of the '251 patent are directed to methods of treating "a disorder associated with spinal compression." Claims 2 and 3 specify that such disorders include "compression neuropathies" (claim 2), "facet joint disease of the spin" (claim 2), "sciatica" (claim 2), "disc herniation" (claims 2 and 3), and "degenerated discs" (claims 2 and 3). The '251 patent does not expressly define the phrase "a disorder associated with spinal compression." Our construction of the phrase "a disorder associated with spinal compression" is discussed below in connection with patentability of claims 1–4, 6, and 7 over Travell.

2. "directly and solely"

In our Decision to Institute, we construed the terms "directly" and "solely," in the context of the challenged claims, to mean that BT is delivered precisely to the intrinsic muscles. Dec. 6–8. Furthermore, as stated in our Decision to Institute, we do not construe the claims, when read as a whole, to exclude additional steps taken during the course of any treatment regimen or session. *Id.* We reach this conclusion due to the use of the open language "comprising" in independent claim 1, which has the effect of permitting additional steps associated with the claimed method. *Id.*

While some dispute remains between the parties as to the exact meaning of the terms "directly" and "solely," we note that both parties agree that maintaining our construction for the terms "directly" and "solely" would not meaningfully impact our analysis of Petitioners' proposed grounds of unpatentability. Reply 2; Tr. 65:13–14. Accordingly, we determine that

further explicit construction of the terms "directly" and "solely" is not required for us to resolve the issues between the parties.

B. Person of Ordinary Skill in the Art

The parties generally agree that a person of ordinary skill in the art would have had a medical degree with at least three years of experience in treating patients, particularly patients with pain disorders, and would have been familiar with injecting BT, even if they had not done so themselves. PO Resp. 7–9 (citing Ex. 2034 ¶¶ 16, 18, 29; Ex. 2033, 83:1–8); Reply 1 (citing Ex. 1039 ¶¶ 28–32; Ex. 1053 ¶ 4).

Based upon their stated qualifications, we consider both Dr. Ross and Dr. Chami qualified to opine from the viewpoint of a person of ordinary skill in the art regarding the subject matter of the '251 patent. Ex. 1039 ¶¶ 2–14, Appendix A (Ross CV); Ex. 2034 ¶¶ 2–9; Ex. 2016 (Chami CV).

C. Petitioners' Asserted Grounds

1. Obviousness of Claims 1–4, 6, and 7 over Travell

a. Travell

Travell is a textbook made up of several chapters that generally discloses myofascial pain syndromes referred from myofascial trigger points ("TrPs" or "trigger points") and treatment methods for releasing the TrPs. Ex. 1034, 11, 14, 17–18;[3] Ex. 1039 ¶¶ 124–125. Chapter 1 of Travell provides a glossary. Ex. 1034, 7–16. Chapter 3 of Travell describes myofascial pain referred from TrPs applicable to all muscles. *Id.* at 17.

[3] We cite the page numbers provided by Petitioner at the bottom right of the exhibit.

Chapters 16 and 48 describe myofascial pain referred more specifically from TrPs in paraspinal muscles, such as multifidi and rotatores. *Id.* at 101–27 (Chapter 16), 146–172 (Chapter 48).

In Chapter 1, Travell defines the term "myofascial trigger point" or "trigger point," as follows:

> A hyperirritable spot in skeletal muscle that is associated with a hypersensitive palpable nodule in a taut band. The spot is painful on compression and can give rise to characteristic referred pain, referred tenderness, motor dysfunction, and autonomic phenomena.

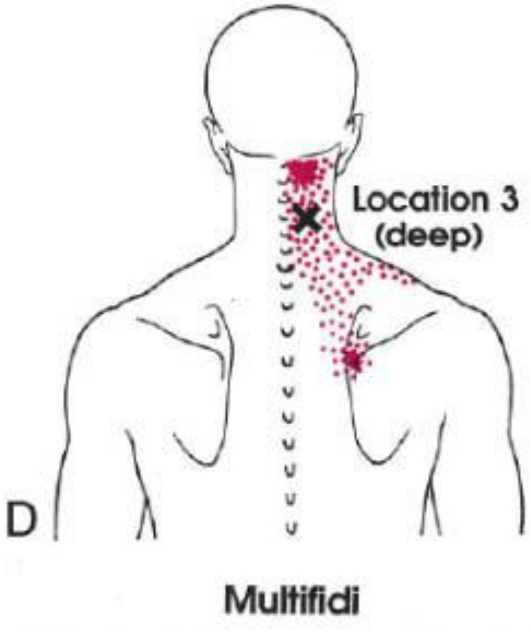
Id. at 11, 14.

In Chapter 3, of Travell discloses "[c]onsiderations that apply generally to all the muscles." *Id.* at 17. Travell discloses that increased irritability due to nerve compression (e.g., spinal radiculopathy caused by a ruptured intervertebral disc) can cause development of myofascial trigger points. Ex. 1034, 35, 112, 158.

Travell discloses the use of botulinum toxin A ("BTA") to inactivate trigger points. *Id.* at 73; *see also id.* at 78 ("BTA injection for the treatment of myofascial TrPs has been reported by several authors to be clinically effective."). Travell discloses that "[w]hen myotoxic drugs [such as BTA] are considered unavoidable for injection of TrPs, it is much better to inject *small* amounts *precisely* where the contraction knots of the TrP are located." *Id.* at 73–74; Ex. 1039 ¶ 127. Travell further discloses that "[i]t is important when using BTA to inject the minimum amount necessary and only in the TrP, since BTA destroys normal and dysfunctional TrP endplates alike." Ex. 1034, 78.

Chapter 16 of Travell discloses considerations that apply to the posterior cervical muscles, which include the multifidi and rotatores. *Id.* at 101. Travell describes that trigger points can be found in the multifidi and rotatores. *Id.* at 103, 111, 122–23. Travell discloses injection of trigger point in the multifidi and rotatores. *Id.* at 119, 122–23; *see also id*. at Fig. 16.9 ("Injection of the location in the left posterior cervical muscles near the C4 level where one may encounter trigger points of the middle semispinalis capitis, semispinalis cervicis, multifidi, and rotatores muscles."); Ex. 1039 ¶¶ 134–38.

Figure 16.1D of Travell is reproduced below:



Ex. 1034, 103.

Travell explains that

> Location 3 of Figure [16.1D] illustrates a common location and pain pattern of TrPs in the multifidi. When injecting this TrP, to reach it one must penetrate several layers of muscle (the semispinalis capitis and cervicis, after first passing through the trapezius and splenius capitis muscles). The TrP is usually

> encountered at least 2 cm (3/4 in) deep to the skin, and may lie beyond the reach of a 3.8-cm (1 1/2-in) needle. A 5-cm (2-in) needle may be needed (Fig. 16.8).

Id. at 122.

b. Analysis

Petitioners contend that claims 1–4, 6, and 7 would have been obvious over Travell. Pet. 45–56. In support of their assertion that Travell teaches each element of the challenged claims, Petitioners set forth the foregoing teachings of Travell and also provide a detailed claim chart explaining how Travell discloses each element of claims 1, 2, 4, 6, and 7. *See id.* Petitioners contend that Travell discloses a method of treating several disorders associated with spinal compression such as nerve compression. Pet. 49; Ex. 1039 ¶¶ 128–30. Petitioners' obviousness rationale is summarized in the following excerpt from the Petition:

> To the extent it is argued any further disclosure is required to meet the preamble [of claim 1], the preamble would at minimum have been obvious to a [person of ordinary skill in the art] from the disclosures of Travell in light of the knowledge of a [a person of ordinary skill in the art], who would know to apply the method disclosed in Travell to treat a disorder associated with spinal compression. This would have been obvious especially because, among other things, disorders associated with spinal compression were well known to involve pathophysiological changes in the muscles (*e.g.*, development of TrPs), similar to myofascial pain treated in Travell and thus would have been reasonably expected to respond to similar treatment. *See* Ex. 1039 ¶ 130.

Pet. 50.

Patent Owner asserts that Travell fails to teach every limitation of the challenged claims. Specifically, Patent Owner argues that Travell fails to

disclose treating a disorder associated with spinal compression, as recited in the preamble of claim 1 (PO Resp. 39–42) and also injecting BT solely into an intrinsic muscle (*id.* at 28–39). Patent Owner further argues that Travell fails to disclose accurate localization of trigger in the intrinsic spinal muscles. *Id.* at 47–59.

With reference to the preamble language, Patent Owner argues that

> The challenged claims of the '251 patent are directed to the treatment of the underlying disorders that are associated with spinal compression by addressing their root cause, i.e. the shortening and scarring of intrinsic muscles pulling on spinal segments that in turn impinge spinal nerves. The '251 patent is not directed to treating the pain symptoms that may or may not occur downstream of these disorders and conditions.

PO Resp. 40. Patent Owner further argues that

> Trigger points cause "referred pain" (as that term is used in Travell) by impingement of a nerve within that muscle, while the pain associated with spinal compression is radicular pain that originates in a spinal nerve or nerves that are impinged but may be felt in distant muscles. (Ex. 2034, at ¶ 22).

Id. at 41. Thus, according to Patent Owner, "pain caused by trigger points and pain caused by disorders associated with spinal compression are different things." *Id*. (citing Ex. 2034 ¶ 22; Ex. 2033, 189:3–23).

Patent Owner's expert, Dr. Chami, further directs our attention to the following paragraph of the '251 patent to support his testimony that the preamble phrase, "a condition associated with spinal compression," should be limited to targeting the root cause of spinal compression:

> The present invention is based on the concept that injury over time can cause the deep/intrinsic muscles to become very tight and scarred, which, in turn, causes compression of the spine. The deep muscles likely contribute to many cases of spinal pain,

> yet very few treatments have been developed involving these muscles due to the fact that they are very small and difficult to manipulate. The present invention discloses a method of specifically treating these muscles thereby enabling the spine to relax and healing to occur.

Ex. 2034 ¶ 22 (quoting Ex. 1001, 3:16–24); *see also id.* ¶ 108 ("[Travell] does not disclose that *a TrP in an intrinsic muscle* could cause spinal compression or any disorders associated with spinal compression. As discussed above, an intrinsic muscle with a TrP cannot be the cause of spinal compression.").

Petitioners respond that the '251 patent does limit the claims to "treatment of the underlying causes of spinal compression." Rather, Petitioners argue the '251 patent "describes treating 'downstream symptoms' of spinal compression and broadly describes an array of disorders that cause, coincide with, or result from compression of the spine, *i.e.*, 'disorder[s] associated with spinal compression.'" Reply 20 (citing Ex. 1001, 1:5–7, 2:5–9, 5:12–24, 6:12–13, 6:26–67, 7:2–26; Ex. 1053 ¶ 19). Notably, the examples set forth in the '251 patent treated patients with pain syndromes, e.g., sciatica, low back pain, carpal tunnel, tennis and golfer's elbow. *Id.* (citing Ex. 1001, 6:25–8:2; Ex. 1039 ¶ 25; Ex. 1053 ¶ 19).

Petitioners further argue that "TrPs and spinal compression associated disorders can both be symptoms of, and causes of, one another." Reply 10, 20–21 (citing Ex. 1053 ¶¶ 12–13, 19, 21, 23; Pet. 13–14 ("self-perpetuating circle"); Ex. 1034, 7–8, 109; Ex. 1039 ¶¶ 41–44, 127–30). Thus, "TrPs—as described in Travell—are 'a disorder associated with spinal compression.'" Reply 20–21.

We find the preponderance of evidence support Petitioners' position. The '251 patent generally discloses methods of treating pain, "[p]articularly, . . . the application of Botulinum toxin to treat herniated disks, spinal neuropathy, compressed and degenerated disks of the spine, and facet joint disease of the spine as caused by intrinsic spinal muscle dysfunction, and the complications thereof." Ex. 1001, 2:1–10. We further note that the '251 patent expressly states that targeting the intrinsic muscles "allows decompression of the specific vertebral segments surrounded by these paraspinal muscles," thereby resulting in "the reversal of compression at the vertebral segments around which are injected by Botulinum toxin," and "leads to a decrease in local or *referred pain syndromes* caused by chronic pain from the intrinsic muscles of the spine either directly or indirectly." *Id.* at 5:63–6:12 (emphasis added). Thus, contrary to Patent Owner's position, the '251 patent discloses treating the pain symptoms, including pain associated with referred pain syndromes.

We further agree with Petitioners that Travell discloses that myofascial pain arising from TrPs may be associated with spinal compression. Ex. 1034, 46; Ex. 1039 ¶¶ 128–30; Ex. 1045, 4 ("Radicular muscle pain may develop as the first sign of nerve root compression by disc herniation or by foraminal osteophytic nerve root compression. . . . Muscle pain from TrPs may occur at any time in the course of radiculopathy . . . ."). Here, we credit the testimony of Petitioners' expert, Dr. Ross, who testifies that Travell discloses association of treating TrPs with treatment of nerve compression, radiculopathy, ruptured intervertebral disc, nerve irritability, ruptured disc, and disc herniation, which are all associated with spinal

compression. Ex. 1039 ¶¶ 129, 139–50 (citing Ex. 1034, 35, 108, 123, 158). For example, Travell discloses as follows:

> Nerve compression, such as in the radiculopathy caused by a ruptured intervertebral disc, favors the development of TrPs in the muscles supplied by the compressed nerve root (postdisc syndrome). Less severe radiculopathy also can activate TrPs.

Ex. 1034, 35 (footnotes omitted). Travell further discloses that radiculopathy may be caused by pressure from a ruptured disc. *Id.* at 158. Accordingly, we find that Travell discloses the recited element of treating a disorder associated with spinal compression, including the treatment of trigger points associated with nerve entrapment (or nerve compression) and disc herniation. Ex. 1034, 108, 149, 158; Ex. 1039 ¶¶ 128–29, 139–50.

Patent Owner argues that there is no express teaching of BT injection solely into intrinsic muscles. PO Resp. 28–39, 45–47. This argument is premised on the fact that although Travell discloses BT injection in muscles generally as a means to treat trigger points in Chapter 3, which is titled *Apropos of All Muscles.* (*id.* at 28–30; Ex. 1034, 77–78), and, in Chapter 16, discloses the injection of trigger points located in intrinsic muscles generally, Travell does not expressly disclose injection of BT to the intrinsic muscles. We find this argument unpersuasive in our obviousness analysis. Rather, we are persuaded by Petitioners' argument that the teachings of the distinct chapters in Travell are directly related to each other, and thus conclude that Travell teaches or suggests BT injection into trigger points located within the intrinsic muscles. Reply 16–17; Ex. 1034, 77–78, 119–123. Furthermore, we are persuaded by Petitioners' argument that,

> [t]o the extent it is argued these chapters from Travell do not constitute a single reference, a [person of ordinary skill in the art] would certainly have been motivated and found it obvious to look to these related teachings in Chapters 3, 16 and 48 together to understand myofascial pain syndromes associated with the paraspinal muscles.

Pet. 46 (citing Ex. 1039 ¶ 126).

Alternatively, Patent Owner argues that "[n]either Petitioners nor Dr. Ross points to anywhere in the Travell reference, or any other reference for that matter, that discloses or even suggests that *TrPs in an intrinsic muscle*, alone, could cause myofascial pain that required treatment." PO Resp. 39 (citing Ex. 2034 ¶ 108). Patent Owner asserts that "[w]ithout that disclosure, a teaching of 'injecting into TrP' does not translate into 'injecting solely into an intrinsic muscle.'" *Id.*

Petitioners respond by arguing that Travell discloses that trigger points can cause myofascial pain, and that

> BT injection into a single TrP can effectively treat myofascial pain. Ex. 1034[, 73] ("It is essential to clearly define just what is meant by one injection. The number of injections should be . . . the number of TrP sites injected, not the number of times some solution has been deposited within one TrP site."); *id*. [at 78] ("It is important when using BTA to inject the minimum amount necessary and only in the TrP . . . ."); *see also* Pet. 45–58; Ex. 1039 ¶¶ 134–138.

Reply 19.

We find that the preponderance of evidence supports Petitioners' position that trigger points cause myofascial pain. Dr. Chami does not cite to any objection evidence to support his testimony that "an intrinsic muscle

with a TrP cannot be the cause of spinal compression." Ex. 2034 ¶ 108.[4] On the other hand, Travell and evidence cited by Petitioners support the conclusion that trigger points cause myofascial pain and can be associated with disorders associated with spinal compression, such as disc herniation. Ex. 1034, 158; Ex.1039 ¶¶ 41, 126–30; Ex. 1045, 2; Ex. 1046, 1; Ex. 1049, 4; Ex. 1053 ¶ 13; Reply, 11 ("TrPs cause referred, myofascial, and radicular-like pain (*i.e.*, 'radicular pain')."").

Further, to the extent that Patent Owner is arguing that more than one injection is required to treat a disorder associated with spinal compression, we find that the treatment of a single trigger point in the intrinsic muscles satisfies this element of the claims, which, as discussed above, is taught by Travell. *See e.g.*, Ex. 1034, 73 (explaining the process by which a single trigger point is treated by injection for the purposes of reducing myofascial pain).

Finally, Patent Owner argues that Travell teaches away from the claimed invention or otherwise fails to provide a person of ordinary skill in the art with a reasonable expectation of success in practicing the invention. PO Resp. 47–59. Specifically, Patent Owner argues that "no trigger points are to be located in the intrinsic spinal muscles because the muscles cannot be palpated, and thus, Travell would discourage a [person of ordinary skill in the art] to try to inject BT into an intrinsic muscle to treat any disorder or pain symptoms." *Id.* at 47 (citing Ex. 2034 ¶ 152). Thus, according to

[4] Absent some underlying facts or data to support this testimony, such testimony is entitled to little, if any, weight. *See* 37 C.F.R. § 42.65 ("Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight.").

Patent Owner, "accurate localization of trigger points in intrinsic muscles is neither taught nor enabled by the Travell reference." *Id.* at 59.

Again, however, we find that the preponderance of evidence supports Petitioners' position, which we adopt as our own. Reply 3–8, 13–15, 24–27. Briefly, Travell discloses expressly how to locate trigger points in the multifidi and rotatores. Ex. 1034, 110–11. For the multifidi, Travell discloses:

> Trigger points of cervical **multifidi** can be located approximately halfway between a spinous process and a lower transverse process . . . .

Id. at 111. For the rotatores, Travell discloses:

> The deepest muscles in the fourth layer, the **rotatores**, are often not as fully developed in the cervical region as they are in the thoracic region. These muscles lie too deep for the fiber direction of their taut bands to be identified by palpation. They must be identified by characteristic deep tenderness to pressure applied deep in the groove lateral to spinous processes, and by tenderness to applied pressure or tapping on the spinous process. The pain distribution of the rotatores is essentially midline pain at the segmental level.

Id. We also note that Travell explains that trigger point injection to the intrinsic muscle is difficult, requiring patience and skill. *Id.* at 119–20. In particular, Travell provides the following explanation and guidance:

> Trigger points in the posterior cervical muscles[5] are frequently bilateral, so it is often necessary to inject them on both sides of the body. A common mistake is the failure to inject deeply enough because of the possibility of penetrating the vertebral artery in the posterior cervical triangle or the dura mater

[5] Chapter 16 of Travell is devoted to the treatment of trigger points in the posterior cervical muscles, which include the multifidi and rotatores.

> of the spinal cord. These are significant concerns, so these deep TrPs should not be injected by beginners and should never be injected in a hurry. The vertebral artery is avoided by noting carefully the spinal level and *avoiding* injections deep into the lateral posterior neck at, or above, the level of the C_2 spinous process (Fig. 16.5).
>
> . . . .
>
> In general, penetration into the spinal canal is avoided by always angling the needle slightly laterally when injecting the deeper paraspinal muscles. However, in some patients, the cervical spinal cord may not be covered by bone between vertebrae as far as 1 cm or more lateral to the edge of a cervical spinous process. Penetration of the dura in this space can be avoided by establishing the depth of the lamina at 2 cm lateral to the lateral edge of a cervical spinous process, and *not* inserting the needle to a greater depth whenever it must be directed more medially.

Id. at 119–20; *see also id.* at 122–23 (providing specific guidance on how to inject the multifidi and rotatores).

Despite this difficulty, however, we are not persuaded by Patent Owner's arguments that Travell's notes of caution amount to a teaching away. Travell does not "criticize, discredit, or otherwise discourage" a person of ordinary skill in the art from practicing the disclosed methods. *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1327 (Fed. Cir. 2009). Rather, Travell urges the need for care and skill when performing the disclosed injection procedures and provides sufficient disclosure of those procedures to provide a skilled clinician with a reasonable expectation of success in accomplishing injection of trigger points located in the intrinsic muscles.

In view of the above, we determine that Petitioners have shown, by a preponderance of the evidence, that claims 1–4, 6, and 7 are unpatentable under 35 U.S.C. § 103(a) as obvious over Travell.

2. Anticipation of Claims 1–4, 6, and 7 over Travell

For the reasons discussed above, we determine that Petitioners have demonstrated by a preponderance of the evidence that claims 1–4, 6, and 7 of the '251 patent are unpatentable under 35 U.S.C. § 103(a) as obvious over Travell. It is therefore unnecessary for us to address whether the same claims are unpatentable under 35 U.S.C. § 102 as anticipated by Travell.

3. Obviousness of Claim 5 over the Combination of Travell and Cheshire

Petitioners contend that claim 5 is obvious over the combination of Travell and Cheshire. Pet. 57–58. Claim 5 recites the method of claim 1, "wherein said toxin is administered in a dose between 1 and 30 mouse units of toxin per injection site." Cheshire discloses BT injection of trigger points using "a total dose of 50 mouse units of botulinum toxin in 4ml normal saline divided equally among 2 or 3 sites." Ex. 1004, 67; Pet. 58; Ex. 1039 ¶¶ 160–164. Petitioners' rationale for combining Travell and Cheshire is set forth in the following:

> Travell specifically cites Cheshire, stating that "BTA injection for the treatment of myofascial TrPs has been reported by several authors to be clinically effective." Ex. 1034 at 155, 174. Thus, a POSITA reading Travell would have been motivated to look to Cheshire's teachings in order to learn a specific way of administering botulinum toxin A that was found effective. A POSITA would have known that Cheshire expressly identifies a specific dose of botulinum toxin A that was effective to treat myofascial pain. Ex. 1004 at 68 ("a total dose of 50 mouse units

> of botulinum toxin . . . divided equally among 2 or 3 sites.")[.] Thus, a POSITA would have been motivated to apply teachings of Cheshire in implementing Travell and would have had a reasonable expectation that such application would work. *See generally* Ex. 1039 ¶ 164.

Pet. 57.

Patent Owner's responses to Petitioners' obviousness grounds focus largely on Travell, not Cheshire, and recapitulate arguments made with respect to the grounds involving Travell alone. PO Resp. 45–59. Patent Owner asserts that Cheshire's disclosure of finding muscles to inject by palpation, for example, teaches away from injecting into the deeper intrinsic muscles. *Id.* at 51. This argument is not persuasive, because Petitioners rely on Cheshire only for a very narrow purpose, i.e., dosage for BT injections (Pet. 57), not the identification of the injection site. Thus, we are not persuaded that Cheshire's teaching of palpation would have dissuaded one of skill in the art from considering Cheshire's dosage disclosure in view of Travell's disclosure regarding injection of intrinsic muscles.

For these reasons, we determine that Petitioners have shown, by a preponderance of the evidence, that claim 5 is unpatentable under 35 U.S.C. § 103(a) as obvious over the combination of Travell and Cheshire.

III. PATENT OWNER'S MOTION TO EXCLUDE

A. Exs. 1003, 1010–1016, 1020–1033, 1040, 1041, 1044, 1055–1060

Patent Owner seeks to exclude Exs. 1003, 1010–1016, 1020–1033, 1040, 1041, 1044, and 1055–1060 under FRE 401, 402, and/or 403. Paper 47, 1–2, 4–5, 15. Because we do not rely on any of these exhibits to reach

the final decision, we dismiss Patent Owner's motion to exclude Exs. 1003, 1010–1016, 1020–1033, 1040, 1041, 1044, and 1055–1060 as moot.

B. Ex. 1034

Patent Owner seeks to exclude portions of Travell (Ex. 1034) on the basis of inadmissible hearsay. Paper 47, 3–4. In particular, Patent Owner seeks to exclude what Patent Owner calls a "'personal communication' with a Dr. Gerwin in 1996" on page 467 of Travell (Ex. 1034, 123). *Id.* Because we have considered the entirety of Travell (Ex. 1034) for what is disclosed, and not as proof of the truth of the matter asserted, we deny Patent Owner's motion seeking to exclude portions of Travell on the basis of inadmissible hearsay.

C. Ex. 1039

Patent Owner seeks to exclude ¶¶ 45–123 of the Corrected Declaration of Edgar Ross (Ex. 1039) as irrelevant. Paper 47, 4. Because we do not rely on any of paragraphs identified by Patent Owner to reach the final decision, we dismiss Patent Owner's motion to exclude portions of Ex. 1039 as moot.

D. Ex. 1053

Patent Owner seeks to exclude the entirety of the Second Declaration of Edgar Ross (Ex. 1053) because "this declaration is irrelevant under FRE 401 and 402 (because Dr. Ross did not follow, and in fact contradicts, the *Travell* definition of 'TrP' in his declaration), overly confusing and misleading under 403, impermissible under 35 U.S.C. § 311(b), and unreliable under FRE 702 and 37 C.F.R. §42.65(a)." Paper 47, 6.

We have reviewed the testimony provided by Dr. Ross and see no credible basis that would warrant its exclusion. Patent Owner's objections go to the weight and sufficiency of the testimony, rather than its admissibility. We are capable of discerning from the testimony, and the evidence presented, whether the witness' testimony should be entitled to any weight, either as a whole or with regard to specific issues. We weigh such testimony on an issue-by-issue basis, as appropriate. Furthermore, Patent Owner had the opportunity to address any alleged deficiencies in the testimony of Dr. Ross in its Patent Owner's Response, and we are capable of weighing that testimony accordingly. Thus, we deny Patent Owner's motion seeking to exclude the testimony of Dr. Ross in this proceeding.

IV. CONCLUSION

Petitioners have demonstrated by a preponderance of the evidence that claims 1–4, 6, and 7 of the '251 patent are unpatentable under 35 U.S.C. § 103(a) as obvious over Travell.

Petitioners have demonstrated by a preponderance of the evidence that claim 5 of the '251 patent is unpatentable under 35 U.S.C. § 103(a) as obvious over the combination of Travell and Cheshire.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–7 of the '251 patent are held unpatentable;

FURTHER ORDERED that Patent Owner's Motion to Exclude Evidence is *denied-in-part and dismissed-in-part as moot*;

FURTHER ORDERED that, because this is a Final Written Decision, the parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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