



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/834,281	03/15/2013	DAVID NIGEL ARMSTRONG	646-01-CIP-009	7906
79683	7590	10/25/2019	EXAMINER	
OLIVE LAW GROUP, PLLC BENTLEY J OLIVE 125 EDINBURGH SOUTH DRIVE SUITE 220 CARY, NC 27511			SOROUSH, LAYLA	
			ART UNIT	PAPER NUMBER
			1627	
			NOTIFICATION DATE	DELIVERY MODE
			10/25/2019	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

bjolive@olivelawgroup.com
docket@OLIVELAWGROUP.COM
eofficeaction@appcoll.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte DAVID NIGEL ARMSTRONG and JUSTIN SLAGEL

Appeal 2019-003985
Application 13/834,281
Technology Center 1600

Before JEFFREY N. FREDMAN, RICHARD J. SMITH, and
DEVON ZASTROW NEWMAN, *Administrative Patent Judges*.

SMITH, *Administrative Patent Judge*.

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellant¹ appeals from the Examiner's decision to reject claims 1, 3–8, 11–14, and 17–20. We have jurisdiction under 35 U.S.C. § 6(b).

We reverse.

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 S.L.A. Pharma AG. Appeal Br. 3.

STATEMENT OF THE CASE

Claims on Appeal

Claims 1, 3–8, 11–14, and 17–20 are on appeal.² (Claims Appendix, Appeal Br. 16–17.) Claim 1, the only independent claim, is illustrative and reads as follows:

1. A method of treating skin in a patient, wherein the skin has been damaged by a second degree, a third degree, or a fourth degree burn wherein the burns are selected from the group consisting of sunburn, burns from cancer therapy radiation, chemical burns, electrical burns, and thermal burns, the method comprising:

topically applying a topical composition to the damaged skin, wherein the topical composition consists essentially of metronidazole in a therapeutically effective concentration of 10 wt % in a pharmacologically acceptable non-aqueous vehicle to treat the skin damaged by said burns, wherein the dosage of metronidazole for each application is from about 125 mg to about 375 mg.

Id. at 16.

Examiner's Rejections

1. Claims 1, 3–8, 11, 12, 17, and 20 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Seaman³ and Wahba-Yahav.⁴ Final Act. 5–6.
2. Claims 13, 14, and 19 stand rejected under 35 U.S.C. § 103(a) as

² The Claims Appendix identifies claim 21 as cancelled, and Appellant's summary of claimed subject matter does not include claim 21. Appeal Br. 5–6, 17. We treat claim 21 as cancelled and not on appeal. *See* Advisory Action Before the Filing of an Appeal Brief, dated August 15, 2018 (identifying claims 1, 3–8, 11–14, and 17–20 as rejected).

³ S. Seaman, *Management of Malignant Fungating Wounds in Advanced Cancer*, SEMINARS ONCOLOGY NURSING 22(3), 185–93 (2006) (“Seaman”).

⁴ A.V. Wahba-Yahav, MD, *Idiopathic lichen planus: Treatment with metronidazole*, J. AM. ACADEMY DERMATOLOGY 33(2), 301–02 (1995) (“Wahba-Yahav”).

unpatentable over Seaman, Wahba-Yahav, and Romer.⁵ *Id.* at 6–7.

3. Claim 18 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Seaman, Wahba-Yahav, and Brett.⁶ *Id.* at 7–8.

4. Claims 1, 3–8, 11–14, and 17–20 stand provisionally⁷ rejected on the ground of nonstatutory double patenting over claims 1–25 of US Patent No. 9,655,883. *Id.* at 9–10.

5. Claims 1, 3–8, 11–14, and 17–20 stand provisionally rejected on the ground of nonstatutory double patenting over claims 1–14 of copending Application No. 15/234,084.⁸ *Id.* at 10–11.

DISCUSSION

The common issue with respect to obviousness rejections 1–3 is whether Seaman teaches or suggests a method of treating skin that has been damaged by a burn, selected from a group of five types of burns, by topically applying metronidazole to the damaged skin. For the reasons set forth below, we find that Seaman does not teach or suggest topically applying metronidazole as claimed.

“[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability.” *In*

⁵ Romer et al., US 4,784,994, issued Nov. 15, 1988 (“Romer”).

⁶ D.W. Brett, US 5,948,400, issued Sept. 7, 1999 (“Brett”).

⁷ Because this nonstatutory double patenting rejection is based on an issued patent, the rejection is no longer provisional.

⁸ When an application on appeal is provisionally rejected based on a later-filed application, and all other rejections on appeal are reversed, the proper course is not to reach the nonstatutory obviousness-type double patenting rejection. *Ex parte Moncla*, Appeal No. 2009-006448 (BPAI 2010) (designated precedential). Accordingly, we do not reach this provisional nonstatutory double patenting rejection.

re Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992). Furthermore, a prima facie case for obviousness “requires a suggestion of all limitations in a claim.” *CFMT, Inc. v. Yieldup Int’l Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003).

Examiner’s Position

The Examiner finds that “Seaman teaches nonadherent contact layers, such as Vaseline gauze applied over a layer of metronidazole gel, for treatment of wounds (reads on recu[rr]ing edema).^[9] The dressing is changed one to two times daily.” Final Act. 5. The Examiner further finds that Seaman “describes wounds may be fragile secondary to previous radiation therapy (reads on burns), inflammation caused by tumor extension, repeated use of adhesive dressings, or maceration.” *Id.* The Examiner also quotes Seaman as teaching:

Local invasion, which occurs as the result of direct extension of a tumor to the surface of the skin, may initially manifest as inflammation with induration, redness, heat, and/or tenderness. The skin may have a peau d’orange appearance and can be fixed to underlying tissue. As the tumor spreads and more tissue destruction occurs, the skin eventually ulcerates.

Id. (quoting Seaman 186, left col.).

Appellant’s Arguments

Appellant argues that “Seaman relates to the treatment of malignant wounds, wherein the wounds that are treated are malignant cutaneous wounds caused by cancer or patients with metastatic disease.” Appeal Br. 8 (citing the Examiner’s citation to Seaman 186, left col.). Appellant further

⁹ Claim 3 recites “[t]he method of claim 1, wherein the topical composition reduces edema.” Appeal Br. 16. The Specification states that “[r]adiation burns can cause . . . edema.” Spec. ¶ 16.

argues that “Seaman expressly teaches the use of topical metronidazole for wound cleaning and the reduction or elimination of odor in the malignant wound.” *Id.* at 9. Moreover, regarding the treatment of edema, Appellant argues that a person skilled in the art, considering Seaman, “would manage the exudate only. The management of the exudate does not include the application of topical metronidazole.” *Id.* at 10–11 (citing Seaman 190 (Table 2)); *see also* Reply Br. 1–6.

Analysis

The Examiner has failed to meet the burden of showing that Seaman teaches or suggests the topical use of metronidazole for treating a patient population having skin damaged by a burn as recited in claim 1. The Examiner actually points out that the “wound” being treated in Seaman is the result of direct extension of a tumor to the surface of the skin, i.e. *not a burn*. *See* Final Act. 5. Furthermore, the Examiner’s finding that Seaman “describes wounds may be fragile secondary to previous radiation therapy (reads on burns)” (*id.*) is incorrect or incomplete. Seaman states that “[t]he skin around the wound may be fragile secondary to previous radiation therapy” (emphasis added), followed by a discussion of *protecting* the skin around the wound in the process of *treating* the wound. Seaman 190, left col.; *see also* Reply Br. 2–4. Seaman also states, with respect to edema, that “[d]ressings should be chosen to conceal and collect exudate and odor. It is essential to use dressings that contain exudate.” Seaman 189, right col. Thus, not only is the edema/exudate not a skin burn, “[t]he management of the exudate [in Seaman] does not include the application of topical metronidazole.” Appeal Br. 11.

This case is analogous to *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368 (Fed. Cir. 2005). Although arising in the context of anticipation, the court in *Perricone* considered a claim reciting “[a] method for treating skin sunburn comprising topically applying to the skin sunburn a fatty acid ester of ascorbic acid . . .” in view of a prior art disclosure (Pereira) of a cosmetic composition for topical application that included various ingredients, such as the skin benefit ingredient ascorbyl palmate. *Id.* at 1376–78. The court stated that the issue was “whether Pereira discloses the application of its composition to skin sunburn. It does not.” *Id.* at 1378. The court went on to state that the claim at issue “recites a new use of the composition disclosed by Pereira, i.e., the treatment of skin sunburn. . . . [t]he disclosed use of Pereira’s lotion, i.e., topical application, does not suggest application of Pereira’s lotion to skin sunburn.” *Id.* at 1378–79.

Similarly, although Seaman discloses the use of metronidazole on a wound “which occurs as the result of direct extension of a tumor to the surface of the skin,” it does not teach or suggest the method of treating skin damaged by a burn by topically applying metronidazole to the damaged skin. *See Seaman* 186, left col. Nor does the Examiner provide a persuasive reason, based on teachings in the prior art, to apply the teachings of Seaman to this different patient population composed of burn patients.

Accordingly, the Examiner has failed to show by a preponderance of the evidence that claims 1, 3–8, 11–14, and 17–20 would have been obvious based on the art of record. Rejections 1–3 are reversed.

Rejection No. 4 (nonstatutory double patenting)

The Examiner’s rejection of claims 1, 3–8, 11–14, and 17–20 on the ground of nonstatutory double patenting over claims 1–25 of US Patent No.

9,655,883 (“’883 patent”) also fails for reasons similar to those discussed above. *See* Final Act. 9–10. Claims 1–25 of the ’883 patent recite “[a] method of relieving pain or promoting wound healing in a patient following a surgical operation to the colon, rectum, anorectum or perianal region of patient,” the method comprising “applying directly to the colon, rectum, anorectum or perianal region of patient affected by the surgical operation a topical composition . . . [that] consists essentially of metronidazole” ’883 patent, col. 7, ll. 38–45. That is not a teaching or suggestion of a method of treating skin damaged by a burn by topically applying metronidazole to the damaged skin. *See Perricone*, 432 F.3d at 1378. Even the Examiner acknowledges that claims 1–25 of the ’883 patent “do[] not teach skin damage[] was caused by sunburn, burns from cancer therapy radiation, chemical burns, electrical burns or thermal burns.” Final Act. 10.

Accordingly, the Examiner has failed to show by a preponderance of the evidence that claims 1, 3–8, 11–14, and 17–20 are not patentably distinct from claims 1–25 of the ’883 patent. Rejection 4 is reversed.

CONCLUSION

Rejection Nos. 1–3: A preponderance of evidence of record fails to support the Examiner’s rejections of claims 1, 3–8, 11–14, and 17–20 under 35 U.S.C. § 103(a).

Rejection No. 4: A preponderance of evidence of record fails to support the Examiner’s rejection of claims 1, 3–8, 11–14, and 17–20 for nonstatutory double patenting over claims 1–25 of US Patent No. 9,655,883.

Rejection No. 5: We do not reach the Examiner’s provisional rejection of claims 1, 3–8, 11–14, and 17–20 on the ground of nonstatutory

double patenting over claims 1–14 of copending Application No.
 15/234,084. *See Moncla* at 3.

SUMMARY

Claims Rejected	35 U.S.C. §	Basis	Affirmed	Reversed
1, 3–8, 11, 12, 17, 20	§ 103(a)	Seaman, Wahba-Yahav		1, 3–8, 11, 12, 17, 20
13, 14, 19	§ 103(a)	Seaman, Wahba-Yahav, Romer		13, 14, 19
18	§ 103(a)	Seaman, Wahba-Yahav, Brett		18
1, 3–8, 11–14, 17–20		nonstatutory double patenting		1, 3–8, 11–14, 17–20
1, 3–8, 11–14, 17–20		provisional nonstatutory double patenting ¹⁰		
Overall Outcome				1, 3–8, 11–14, 17–20

REVERSED

¹⁰ As explained above, we do not reach this rejection per *Moncla*.