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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/139,243	12/23/2013	Charles Gerald Connor	14597-21	3679
45473	7590	12/19/2019	EXAMINER	
BGL/RESEARCH TRIANGLE PARK P.O. BOX 110285 RESEARCH TRIANGLE PARK, NC 27709			SIMMONS, CHRIS E	
			ART UNIT	PAPER NUMBER
			1629	
			MAIL DATE	DELIVERY MODE
			12/19/2019	PAPER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte CHARLES GERALD CONNOR and
CHARLES L. HAINE¹

Appeal 2019-001465
Application 14/139,243
Technology Center 1600

Before JEFFREY N. FREDMAN, JOHN G. NEW, and
JAMIE T. WISZ, *Administrative Patent Judges*.

NEW, *Administrative Patent Judge*.

DECISION ON APPEAL

¹ We use the word “Appellant” to refer to the “applicant” as defined in 37 C.F.R. § 1.142. Appellant identifies Rhodes Pharmaceuticals, LP, as the real party-in-interest. App. Br. 3.

SUMMARY

Appellant files this appeal under 35 U.S.C. § 134(a) from the Examiner's Final Rejection of claims 14, 20–22, 27–31, and 34–35. Specifically, claims 14, 20–22, 27–31 stand rejected as unpatentable under 35 U.S.C. § 103(a) as being obvious over the combination of Connor (US 6,659,985 B2, December 9, 2003) (“Connor”) and Lubkin (Re. 34,578, April 5, 1994) (“Lubkin”).

Claims 14, 20–22, 27–31, and 34–35 stand rejected as unpatentable under 35 U.S.C. § 103(a) as being obvious over the combination of Connor, Lublin, and Dale et al. (US 2,861,920, November 25, 1958) (“Dale”).

Claims 14, 20–22, 27–31 also stand rejected as unpatentable under the doctrine of obviousness-type double patenting as being obvious over the combination of claims 1–15 of Connor and Lubkin.

Claims 14, 20–22, 27–31, and 34–35 stand rejected as unpatentable under the doctrine of obviousness-type double patenting as being obvious over the combination of claims 1–15 of Connor, Lubkin, and Dale.

We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

NATURE OF THE CLAIMED INVENTION

Appellant's claimed invention is directed to a composition and method of treating eye diseases using a composition having a therapeutically effective amount of a progestagen and a pharmaceutically acceptable carrier.
Abstr.

REPRESENTATIVE CLAIM

Claim 14 is representative of the claims on appeal and recites:

14. A method of treating dry eye comprising transdermally administering to a palpebral part of an eye of a patient in need thereof a composition comprising a therapeutically effective amount of a sex steroid and at least one pharmaceutically acceptable carrier, wherein said sex steroid is progesterone.

App. Br. 13.

ISSUES AND ANALYSES

We agree with, and adopt, the Examiner's findings, reasoning, and conclusion that the claims on appeal are obvious over the combined cited prior art and under the nonstatutory doctrine of obviousness-type double patenting. We address the arguments raised by Appellant below.

A. Rejection of claims 14, 20–22, 27–31, and 34–35 under 35 U.S.C. § 103(a)

Issue

Appellant argues that the Examiner erred in finding that the combined cited prior art neither teaches nor suggest the limitation of claim 14 reciting “wherein said sex steroid is progesterone.” App. Br. 8.

Analysis

The Examiner finds that Connor teaches a method of treating dry eye by transdermally delivering androgenic hormones, such as testosterone or dehydroepiandrosterone, in a pharmaceutically effective carrier to the adnexa of the eye. Final Act. 11. However, the Examiner finds, Connor

does not teach the use of progesterone as the active ingredient in the composition. *Id.*

The Examiner finds that Lubkin teaches application of a dry eye-treating composition to the eye, in which the active agent comprises a sex steroid. Final Act. 11 (citing Lubkin, Title, Abstr., col. 1, ll. 13–15). The Examiner finds that Lubkin expressly defines the term “sex steroid” as including progesterone, testosterone, estrogen, dehydroepiandrosterone, and derivatives thereof. *Id.* (citing Lubkin col. 1, ll. 19–22). The Examiner notes that, although 17 beta-estradiol is used in a preferred embodiment, a person of ordinary skill in the art would have understood from the teachings of Lubkin that progesterone is also a sex steroid suitable for topical application in a dry eye-treating composition. *Id.* at 11–12 (citing Lubkin, Abstr.).

The Examiner concludes that a person of ordinary skill in the art would have had a reasonable expectation of success in arriving at the claimed invention, because Connor teaches treating dry eye by transdermally delivering androgenic hormones such as testosterone or dehydroepiandrosterone to the adnexa of the eye, and Lubkin teaches treating dry eye by administering a sex hormone such as progesterone, testosterone, estrogen and dehydroepiandrosterone. Final Act. 12. The Examiner also concludes that a person of ordinary skill in the art would have recognized that the sex hormones (e.g., progesterone, testosterone, etc.) are equivalents that are interchangeable for treatment of dry eye. *Id.*

Appellant disputes the Examiner’s conclusion that a skilled artisan would substitute the androgenic hormone taught by Connor with progesterone, or would “understand that progesterone is also a suitable sex

steroid suitable for topical application in a dry eye-treating composition as described by Lubkin.” App. Br. 8 (quoting Final Act. 12). Appellant argues that, although Lubkin defines the term “sex steroid” as including estrogen, progesterone, testosterone, dehydroepiandrosterone, and chemical variants and derivatives of the same, the definition in Lubkin does not teach that these sex steroids are equivalent or interchangeable for treating dry eye, or for any other purpose. *Id.* at 9.

Appellant argues that, reading Lubkin as a whole, a skilled artisan would have understood that application of formulations of 17-beta estradiol to the ocular surface is useful for treating dry eye syndrome in postmenopausal or oophorectomized women. App. Br. 9. Appellant notes that the studies described in the background of the invention section in Lubkin include discussion of the presence of estrogen and testosterone in human tear film and the effects of anti-estrogens, such as Tamoxifen, on the lacrimal gland. *Id.* Appellant notes that the examples in Lubkin include various estrogen-containing formulations for application to the ocular surface to treat dry eye. *Id.*

Appellant further asserts that the Examiner does not articulate any reasoning as to why a person of ordinary skill in the art would look to Lubkin to modify the compositions of Connor, or why a skilled artisan would modify the compositions of Connor using the teachings of Lubkin with any reasonable expectation of success. App. Br. 9. Furthermore, argues Appellant, the Examiner’s reliance on the allegations that Lubkin teaches that sex hormones are equivalent and interchangeable are not only mischaracterizations of the teachings of Lubkin but are also scientifically nonsensical. *Id.*

According to Appellant, it was well known in the art at the time of Appellant's filing that estrogen, testosterone, and progesterone are sometimes collectively referred to as "sex steroids," nor Appellant asserts, does Lubkin teach anything different. App. Br. 9. Appellant contends that Lubkin teaches what was already known: that estrogen, progesterone, testosterone, dehydroepiandrosterone, and chemical variants and derivatives of the same are all sex steroids. *Id.* Appellant contends, additionally, that it was also well understood in the art that all sex steroids are not equivalent or interchangeable with one another in, for example, their physiological effects. *Id.* According to Appellant, there would have been no scientific rationale or reason that the skilled artisan would somehow expect that substituting one sex steroid for another would ever produce the same result. *Id.* at 10.

Furthermore, Appellant argues, the examples in Lubkin include various estrogen-containing formulations for application to the ocular surface to treat dry eye. App. Br. 10. Appellant asserts that nothing in Lubkin teaches that androgenic hormones, progesterone, or any other sex steroids are equivalent to 17-beta estradiol, or that either reference suggests that application of any composition to the ocular surface is somehow the same as application to the palpebral portion of the eye or would reasonably be expected to be effective. *Id.*

We are not persuaded by Appellant's arguments. As an initial matter, the teachings of Lubkin are not limited to the exemplary embodiments set forth in the reference. Rather, "all disclosures of the prior art, including unpreferred embodiments, must be considered." *Merck & Co., Inc. v. Biocraft Labs., Inc.*, 874 F.2d 804, 807 (Fed. Cir. 1989) (quoting *In re Lamberti*, 545 F.2d 747, 750 (C.C.P.A. 1976)). Consequently, in our

obviousness analysis we consider all of the teachings of the references cited by the Examiner.

Connor teaches:

[A] method for treating dry eye or increasing contact lens wear time through the transdermal delivery of androgenic hormones to the adnexa of the eye. More specifically, an androgenic hormone such as testosterone or dehydroepiandrosterone is solubilized in pharmaceutically effective carrier such as a facial cream or gel. The androgenic hormone in a pharmaceutically effective carrier is applied to the adnexa of the eye, which is the tissue adjacent to and surrounding the eyeball.

Connor Abstr. As Appellant notes, progesterone, as recited in Appellant's claims, although a steroid, is not an androgenic hormone.

However, Lubkin is also directed to the treatment of dry eye syndrome by the topical application of sex steroids. *See* Lubkin, Title. Specifically, Lubkin teaches: "A topical drug application for the alleviation of keratoconjunctivitis sicca (dry eye syndrome) is comprised of a solution of sex steroids or their derivatives suspended or dissolved in a vehicle, and the method of preparation and application of the same." *Id.* Abstr.

Furthermore, Lubkin teaches that:

This invention relates to drugs for the topical application of sex steroids in the treatment of human dry eye syndrome (keratoconjunctivitis sicca) In the specification and claims hereinafter the term "sex steroids" is defined to include estrogen, progesterone, testosterone, dehydroepiandrosterone and chemical variants and derivatives of the same.

Lubkin col. 1, ll. 13–22.

We do not dispute Appellant's contention that the examples of Lubkin are directed primarily to the topical application of estrogens (e.g., 17-beta-

estradiol 3-phosphate disodium) in the treatment of dry eye. *See, e.g.*, Lubkin cols. 4–6, ll. 5–63. Nevertheless, Lubkin also teaches that sex steroids generally can be used in the topical treatment of dry eye, and expressly defines progesterone as being a member of the genus of “sex steroids.” *See* Lubkin col. 1, ll. 18–22.

Nor do we dispute Appellant’s assertion that progesterone and other sex steroids, including androgens, are not universally interchangeable for all applications. Rather, we interpret the Examiner’s findings to mean that Lubkin teaches that “sex steroids,” including progesterone as well as the androgens taught by Connor, can all be used in the treatment of dry eye syndrome. Thus, we agree with the Examiner that the ordinary artisan would have found it obvious to use the known effective sex steroids of Lubkin, including progesterone, for treatment of dry eye using the dry eye treatment routes of Connor. Appellant provides no rebuttal evidence suggesting ineffectiveness of the dry eye compounds disclosed by Lubkin. “[A]ttorney argument [is] not the kind of factual evidence that is required to rebut a prima facie case of obviousness.” *In re Geisler*, 116 F.3d 1465, 1470 (Fed. Cir. 1997).

Finally, Appellant’s claim 14 recites application of the claimed composition to “a palpebral part of an eye of a patient.” Appellant’s Specification discloses that: “[a]s referred to in the instant specification, the term ‘palpebral part of an eye’ is the external portion of the upper and lower eyelids and the medial and lateral canthus.” Spec. 5.

Connor teaches that “the androgenic hormone in a pharmaceutically effective carrier is applied to the adnexa of the eye, which is the tissue

adjacent to and surrounding the eyeball. The adnexa of the eye includes the eyelid, but is not limited to the eyelids.” Connor col. 2, ll. 57–61.

We agree with the Examiner that “the external portion of the upper and lower eyelids and the medial and lateral canthus” disclosed by Appellant’s Specification constitute part of the “tissue adjacent to and surrounding the eyeball includ[ing] the eyelid, but [] not limited to the eyelids,” as taught by Connor.

We consequently affirm the Examiner’s conclusion that Appellant’s claims 14, 20–22, 27–31 are obvious over the combination of Connor and Lubkin. Furthermore, Appellant relies upon the same arguments with respect to the Examiner’s rejection of all of the claims on appeal over the combination of Connor, Lubkin, and Dale. *See* App. Br. 11. For the reasons that we have explained, we similarly affirm this rejection.

B. Rejection of claims 14, 20–22, 27–31, and 34–35 under the nonstatutory doctrine of obviousness-type double patenting

Analysis

Independent claim 1 of Connor recites:

1. A method of treating dry eye disease comprising:
 - (a) transdermally administering a composition to a subject in need of such treatment, said composition comprising a therapeutically effective amount of an androgenic hormone in a pharmaceutically effective carrier wherein said transdermally administering involves administering said compound to the adnexa of the eye of said subject and said androgenic hormone comprised between 1 to 5% by weight of said pharmaceutically effective carrier.

Appellant advances substantively the same arguments presented with respect to the Examiner's rejections under Section 103 *supra*. App. Br. 6–8. We have explained why we do not find these arguments persuasive. Furthermore, our analysis of the Section 103 rejection does not necessarily rely upon the disclosures of the Specification of Connor, nor need we do so in this instance.

Connor recites, *inter alia*, treating dry eye disease by administering a composition containing androgenic hormones, as the active agent, to the adnexa of the eye. Connor claim 1. Lubkin teaches treating dry eye syndrome by topically administering a composition containing sex hormones as the active agent, and further teaches that sex steroids are defined as including “estrogen, progesterone, testosterone, dehydroepiandrosterone and chemical variants and derivatives of the same.” Lubkin col. 1, ll. 13–22. We agree with the Examiner's conclusion that Lubkin teaches that progesterone and androgenic hormones (i.e., testosterone and dehydroepiandrosterone) can both be employed effectively in the treatment of dry eye syndrome, and that it would have therefore been obvious to substitute progesterone for the androgenic hormone of Connor's claim 1, as recited in Appellant's claim 14 with a reasonable expectation of success. We consequently affirm the Examiner's rejection of claims 14, 20–22, and 27–31 over the combination of Connor and Lubkin.

Furthermore, Appellant relies upon the same arguments with respect to the Examiner's rejection of claims 14, 20–22, 27–31, and 34–35 over the combination of Connor, Lubkin, and Dale. For the reasons we have explained, we similarly affirm the Examiner's rejection of the claims.

CONCLUSION

The Examiner's rejection of claims 14, 20–22, 27–31, and 34–35 under 35 U.S.C. § 103(a) is affirmed.

The Examiner's rejection of claims 14, 20–22, 27–31, and 34–35 under the nonstatutory doctrine of obviousness-type double patenting is affirmed.

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

AFFIRMED

Claims Rejected	35 U.S.C. §	Basis	Affirmed	Reversed
14, 20–22, 27–31	103(a)	Connor, Lubkin	14, 20–22, 27–31	
14, 20–22, 27–31, 34–35	103(a)	Connor, Lubkin, Dale	14, 20–22, 27–31, 34–35	
14, 20–22, 27–31	Obviousness-type double patenting	Connor, Lubkin	14, 20–22, 27–31	
14, 20–22, 27–31, 34–35	Obviousness-type double patenting	Connor, Lubkin, Dale	14, 20–22, 27–31, 34–35	
Overall Outcome			14, 20–22, 27–31, 34–35	