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.
12/146,976	06/26/2008	Wayne H. Knox	P04595	6120

23702 7590 02/27/2013

Bausch & Lomb Incorporated
One Bausch & Lomb Place
Rochester, NY 14604-2701

EXAMINER	
CRANDALL, LYNSEY P	
ART UNIT	PAPER NUMBER
3769	

NOTIFICATION DATE	DELIVERY MODE
02/27/2013	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):

patents@bausch.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte WAYNE H. KNOX, LI DING,
KRYSTEL R. HUXLIN, and JAY F. KUNZLER

Appeal 2011-002230
Application 12/146,976
Technology Center 3700

Before TONI R. SCHEINER, FRANCISCO C. PRATS, and
JEFFREY N. FREDMAN, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method for modifying the refractive index of ocular tissue. The Examiner rejected the claims as anticipated and as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm-in-part.

Statement of the Case

Background

"The invention is directed to a method for modifying the refractive index of ocular tissue. The method comprises irradiating select regions of biological tissue with a focused, visible or near-IR laser" (Spec. 3 ¶ 0010). According to the Specification, the "irradiation results in the formation of refractive structures characterized by a change in refractive index, and which exhibit little or no scattering loss. The types of biological tissues that can be modified include ocular tissues such as corneal stromal layer and the lens cortex" (Spec. 3 ¶ 0010).

The Claims

Claims 13-19, 27-31, and 36-38 are on appeal. Claim 13 is representative and reads as follows:

> 13. A method for modifying the refractive index of ocular tissue, the method comprising:
>
> irradiating select regions of the ocular tissue with a focused, visible or near-IR laser below the optical breakdown threshold of the tissue to provide refractive structures that exhibit a change in refractive index, and exhibit little or no scattering loss; and
>
> scanning over the select regions with the laser such that ablation or removal of the tissue is not observed in the irradiated region.

The issues[1]

A. The Examiner rejected claims 13, 16, 17, and 30 under 35 U.S.C. § 102(b) as anticipated by Hänsel[2] (Ans. 4-6).

---

[1] The Examiner's objection to claims 13-19, 27-31, and 36-38 for certain informalities is a petitionable (rather than appealable) matter.

B. The Examiner rejected claims 14, 15, 19, 27, 28, 31, and 36-38 under 35 U.S.C. § 103(a) as obvious over Hänsel (Ans. 6-7).

C. The Examiner rejected claims 18 and 29 under 35 U.S.C. § 103(a) as obvious over Hänsel and Seiler[3] (Ans. 7-8).

A. 35 U.S.C. § 102(b) over Hänsel

The Examiner finds that Hänsel teaches that "[s]elect regions of the ocular tissue are irradiated with a focused, visible or near-IR laser (greater than 600 nm or greater than 1300 nm; Col 5, lines 12-18) below the optical breakdown threshold of the tissue to provide refractive structures" (Ans. 4). The Examiner finds that Hänsel "discloses that the radiation used is therapeutic (Col 3, lines 44-58) and the method avoids the use of high-energy radiation" (*id.* at 4-5). The Examiner finds that Hänsel "discloses the use of a scanner" (*id.* at 5).

The Examiner also contends that "the mere allegation of non-enablement is insufficient to overcome the presumption of validity afforded a patented claim" (*id.* at 8).

Appellants contend that the "primary issue on Appeal is whether Hansel is an enabling disclosure, that is, whether the complete disclosure of Hansel in combination with the knowledge of an ordinary person in the relevant art has placed in the possession of the public the claimed invention sought by Appellants" (App. Br. 5). Appellants contend that the ordinary artisan "would not know where to begin with respect to the irradiation conditions necessary to modify the refractive index of ocular tissue by

---

[2] Hänsel, H., US 6,478,792 B1, issued Nov. 12, 2002.
[3] Seiler et al., US 5,461,212, issued Oct. 24, 1995.

forming refractive structures that exhibit little or no scattering loss and which does not result in the ablation or destruction of the tissue in the irradiated regions" (App. Br. 8).

The issue with respect to this rejection is: Does the evidence of record support the Examiner's conclusion that Hänsel is an enabled reference which anticipates the claims?

Findings of Fact

1. Hänsel teaches that changes "in the refractive index of the various eye lens regions are achieved efficiently and in a simple manner, using a device for irradiation of the eye" (Hänsel, col. 3, ll. 59-61).

2. Hänsel teaches

> a light source **10** which emits therapeutic radiation **11** for the radiation of the eye lens at any wavelength which is clearly above the operating wavelength of excimer lasers, advantageously greater than 600 nm, and for the radiation of the cornea with a wavelength, which is above a near infra-red wavelength of 1.3 micrometers.

(Hänsel, col. 5, ll. 14-18.)

3. The Specification teaches that a "wavelength of 800 nm is useful; preferable ranges include 600-1,000 nm" (Spec. 9 ¶ 0051).

4. Hänsel teaches that the "refractive index variations have to be created in microscopically small dimensions (about 1 micron/micrometer or even less)" (Hänsel, col. 7, ll. 5-7).

5. The Specification teaches that the "laser pulses were focused to a spot size of about 1 µm" (Spec. 9 ¶ 0048).

6. Hänsel teaches that the "time specifications of therapeutic exposure (cw, qcw or pulse mode, pulse duration and repeat frequency) must

be selected in accordance with the examinations to be specified for each individual application" (Hänsel, col. 7, ll. 12-15).

7. Hänsel teaches that "[p]ulse modes with frequencies near the kilohertz range and pulse durations from some microseconds to some milliseconds have been successfully used" (Hänsel, col. 7, ll. 16-18).

8. The Specification teaches a "laser pulse frequency from 1 MHz to 10 GHz" (Spec. 8 ¶ 0045).

9. The Specification teaches that "one can likely operate within a range from 5 fs to 1 ps" (Spec. 9 ¶ 0048).

10. Hänsel teaches that "[s]patial modulation can be performed with electro-optical converters in transmission or reflection mode, or using a scanner" (Hänsel, col. 6, ll. 16-18).

11. Hänsel teaches that the prior art ablation techniques used "energies from 10 μJ to 10 mJ" (Hänsel, col. 2, l. 22).

Principles of Law

"In patent prosecution the examiner is entitled to reject application claims as anticipated by a prior art patent without conducting an inquiry into whether or not that patent is enabled or whether or not it is the claimed material (as opposed to the unclaimed disclosures) in that patent that are at issue." *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1355 (Fed. Cir. 2003). "The applicant, however, can then overcome that rejection by proving that the relevant disclosures of the prior art patent are not enabled." *Id.*

Analysis

The *Amgen* reasoning was recently reaffirmed in *Antor*, where the Federal Circuit explained that "[e]nablement of prior art requires that the reference teach a skilled artisan to make or carry out what it discloses in relation to the claimed invention." *In re Antor Media Corp*., 689 F.3d 1282, 1290 (Fed. Cir. 2012). *Antor* further teaches that the Appellants must show "that undue experimentation would be required to perform the claimed invention based on the teaching" in the prior art. *Id*. at 1289.

Claim 13 is representative of the rejected claims. *See* 37 C.F.R. § 41.37(c)(1)(vii). Claim 13 recites a method for modifying the refractive index of ocular tissue by irradiating selected regions of the ocular tissue with a focused, visible or near-IR laser below the optical breakdown threshold of the tissue to provide refractive structures that exhibit a change in refractive index, but which exhibit little or no scattering loss. The selected regions are scanned with the laser such that ablation or removal of the tissue is not observed in the irradiated region.

As the Examiner found, Hänsel teaches laser wavelengths and spot sizes which fall within the ranges disclosed as functional in the Specification (FF 2-5). Hänsel also teaches that selection of pulse duration and repeat frequencies are results optimizable variables (FF 6). While Hänsel's values for pulse frequency and duration differ somewhat from those in the Specification (FF 7-9), Appellants have made no specific evidentiary showing demonstrating undue experimentation. Instead, Appellants simply criticize the disclosure (*see* App. Br. 8), and point out how the disclosures of the Specification and Hänsel both relate to the elements of representative

claim 13 (*see id.* at Evidence Appendix). However *Antor* and *Amgen* make it clear that evidence supporting a finding of undue experimentation, not simply attorney argument, is required to demonstrate that a reference, particularly a patent reference claiming similar subject matter, is not enabled. *Antor* at 1289, *Amgen* at 1355.

Conclusion of Law

Appellants have not advanced adequate evidence to undermine the Examiner's conclusion that Hänsel is an enabled reference which anticipates representative claim 13.

B. 35 U.S.C. § 103(a) over Hänsel

The Examiner finds that "[w]hile Hansel is silent with regards to the exact change in refractive index, it is the examiner's position that one of ordinary skill in the art would choose the desired change in refractive index to improve the patient's vision as much as possible as taught by Hansel" (Ans. 6-7). The Examiner finds that "[o]ne of ordinary skill in the art knows the ablation thresholds of ocular tissue and would choose energy levels below this threshold in order to prevent removal of tissue as ablation is not a desired result of the method taught by Hansel" (Ans. 7).

Appellants contend that "[b]ecause the range of change in refractive index is not expressly or implicitly described or suggested in Hansel the assertion of a *prima facie* case of obviousness as to claims 15, 31 and 36 is legal error" (App. Br. 17). Appellants also contend that "with respect to the asserted statement of knowledge in the art of 'ablation thresholds of ocular tissue', is the examiner relying upon judicial notice? The ablation thresholds are certainly nowhere to be found in Hansel" (*id.* at 18).

We find that Appellants have the better position. While Hänsel teaches changing the refractive index (FF 1), the Examiner does not identify, and we do not find, any teaching or suggestion in Hänsel which provides a specific numerical value change in the refractive index. The Examiner has produced no evidence in Hänsel or from any other source which teaches any reason to make a range of change in the refractive index of 0.001 to 0.03, as required by claim 15. There is also no evidence even suggesting that performing the method of Hänsel using the parameters taught by Hänsel would inherently result in the claimed range of the refractive index. Nor is there evidence that the refractive index changes represent a routinely optimizable variable.

The pulse energy range is a closer case, since Hänsel teaches that the prior art ablation techniques used "energies from 10 μJ to 10 mJ" (Hänsel, col. 2, l. 22; FF 11), suggesting that this is an optimizable variable. However, the broadest claimed range of energies in the instant claims, found in claim 14, is a range from 0.01 nJ to 10 nJ, which is 1000 fold lower in power than the only disclosed range in the prior art. While Hänsel would certainly suggest to the ordinary artisan that the range for non-ablative techniques must fall below 10 μJ, there is no evidence on record which supports the Examiner's position that the ordinary artisan would have recognized that the energy range should fall 1000 fold in order to avoid ablation, rather than 10 fold or 100 fold to ranges of 100 nJ or 1 μJ.

Indeed, there is no evidence that even 0.01 nJ would have necessarily been sufficiently low enough in energy to avoid ablation, and it might have been that still lower energies would be required to avoid ablation. "In

proceedings before the Patent and Trademark Office, the Examiner bears the burden of establishing a prima face case of obviousness based upon the prior art." *In re Fritch*, 972 F.2d 1260, 1265 (Fed. Cir. 1992). We appreciate that the burden may often be challenging in areas of scant prior art, where the implicit knowledge of the ordinary artisan may not be recorded in the literature. However, where there is no supporting evidence, and the claimed refractive index and pulse energy ranges differ so dramatically from any ranges disclosed in the prior art of record, we conclude that there is not a *prima facie* case of obviousness.

C. 35 U.S.C. § 103(a) over Hänsel and Seiler

The Examiner finds it obvious "to perform the method taught by Hansel after cataract surgery as taught by Seiler in order to correct vision problems created by the surgery or afterwards as taught by Seiler" (Ans. 8).

The Examiner provides sound fact-based reasoning for combining Hänsel and Seiler. We adopt the fact finding and analysis of the Examiner as our own. Appellants "concede the unpatentability of claims 18 and 29 over Hansel in view of Seiler under section 103(a)" (App. Br. 6), if the anticipation rejection over Hänsel is affirmed. Therefore, consistent with the anticipation rejection, which we affirmed above, we affirm this rejection for the reasons stated by the Examiner.

SUMMARY

In summary, we affirm the rejection of claim 13 under 35 U.S.C. § 102(b) as anticipated by Hänsel. Pursuant to 37 C.F.R. § 41.37(c)(1), we also affirm the rejection of claims 16, 17, and 30 as these claims were not argued separately.

We reverse the rejection of claims 14, 15, 19, 27, 28, 31, and 36-38 under 35 U.S.C. § 103(a) as obvious over Hänsel.

We affirm the rejection of claims 18 and 29 under 35 U.S.C. § 103(a) as obvious over Hänsel and Seiler.

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

AFFIRMED-IN-PART

cdc