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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte GARY S. ROGERS

Appeal 2011-006661
Application 11/448,296
Technology Center 3700

Before ERIC GRIMES, FRANCISCO C. PRATS, and
SHERIDAN K. SNEDDEN, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims to methods of applying low irradiance photodynamic therapy to patients. The Examiner entered rejections for obviousness.

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

STATEMENT OF THE CASE

“Photodynamic therapy (PDT) is a ternary treatment for cancer It is also being used for treatment of psoriasis and acne, among other skin growths and is an approved treatment for wet macular degeneration” (Spec. 1). In photodynamic therapy, a patient receives either a photosensitizer or

its metabolic precursor (*id.*). Exposure to light raises the photosensitizer in the patient's body to an excited state that in turn produces an excited singlet state oxygen molecule which ultimately kills cells in the target tissue (*see id.*).

Appellant's invention is directed to providing "continuous low irradiance photodynamic therapy to a patient. . . . The method includes applying a photosensitizer to the patient; applying a conformable skin facing light applicator to the patient; and providing continuous low irradiance photodynamic therapy through the light applicator" (*id.* at 2). In one embodiment, the skin-conformable light applicator can "be integrated into a garment that is worn by the patient" (*id.* at 3).

Claims 1-3, 5-14, and 16-19 stand rejected and appealed (App. Br. 1). Claims 1 and 5 illustrate the appealed subject matter and read as follows:

1. A method for providing continuous low irradiance photodynamic therapy to a patient's cancer, comprising:
 - applying a photosensitizer to the patient;
 - applying a conformable skin facing light applicator to the patient; and
 - providing continuous low irradiance photodynamic therapy of less than or equal to about 5 mW/cm^2 through the light applicator to activate the photosensitizer and thereby treat the patient's cancer.

5. The method of claim 1, wherein the light applicator provides a light intensity to the patient of between about 0.25 and 3 mW/cm^2 .

The following rejections are before us for review:

(1) Claims 1-3, 5-8, 11-14, and 16-19, under 35 U.S.C. § 103(a) as obvious over Whitehurst¹ and Chen² (Ans. 3-4); and

(2) Claims 9 and 10, under 35 U.S.C. § 103(a) as obvious over Whitehurst, Chen, Rosen,³ and Zharov⁴ (Ans. 4).

DISCUSSION

In the rejection over Whitehurst and Chen, the Examiner cited Whitehurst as disclosing a fabric or garment that incorporated a light source suitable for providing PDT (*see* Ans. 3-4). The Examiner cited Chen as teaching “the desirability of providing very low level intensities of light (‘about 5 mW/cm²’ wherein 3 mW/cm² is considered ‘about 5’) in PDT for cancer, for a time period encompassing 2-24 hours (see paragraph [0028]) since this increases the depth of effect and provides less heating to tissue” (*id.* at 4).

Based on these teachings, the Examiner concluded that an ordinary artisan would have considered it obvious to use Whitehurst’s applicator in Chen’s methods “since this would allow intimate contact of the applicator with irregular surfaces, or alternatively to employ the intensity levels of Chen et al (‘434), since this is an appropriate fluence to activate the photosensitizer, thus producing a method such as claimed” (*id.*).

In traversing the rejection, Appellant states that the argument[s] in this section are directed to claim 5 and not to claim 1. No admission is intended with respect to claim 1,

¹ U.S. Patent App. Pub. No. 2002/0138120 A1 (published September 26, 2002).

² U.S. Patent App. Pub. No. 2003/0114434 A1 (published June 19, 2003).

³ U.S. Pat. No. 6,045,575 (issued April 4, 2000).

⁴ U.S. Pat. No. 6,443,978 B1 (issued September 3, 2002).

however, in order to expedite prosecution of this application, Applicant's arguments below are particularly addressed to the rejection of claim 5 (as they were in the un-entered after final amendment[]).

(App. Br. 5.)

In particular, Appellant argues that neither Chen nor Whitehurst suggests applying light in the intensity range required by claim 5 (*see id.* at 6-14; *see also* Reply Br. 4 (“Nothing in the art suggests successful treatment at between about 0.25 mW/cm² and 3 mW/cm² as claimed.”)).

As stated in *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992):

[T]he examiner bears the initial burden . . . of presenting a *prima facie* case of unpatentability. . . .

After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument.

Ultimately, “[i]n determining whether obviousness is established by combining the teachings of the prior art, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art.” *In re GPAC Inc.*, 57 F.3d 1573, 1581 (Fed. Cir. 1995) (internal quotations omitted).

Here, as discussed below, we agree with Appellant that a preponderance of the evidence does not support the Examiner's finding that Whitehurst and Chen would have suggested applying light at the intensity range recited in claim 5. As to claim 1, however, we find that a preponderance of the evidence supports the Examiner's conclusion of obviousness.

Appellant's claim 1 recites a PDT method whereby the practitioner administers a photosensitizer to the patient, applies a skin-conformable light applicator to the patient, and through the applicator applies continuous irradiance PDT to the patient at a light intensity of less than or equal to about 5 mW/cm^2 .

As the Examiner found, and Appellant does not dispute, Whitehurst discloses a skin-conformable garment suitable for applying PDT to a patient (*see, e.g.* Whitehurst [0044]).

As the Examiner also found, Chen discloses a PDT method whereby relatively low intensity light, but a relatively high overall dose, is applied to a patient:

At least a portion of the subject is irradiated with light at a wavelength or waveband within a characteristic absorption waveband of the photosensitizing agent. The light is administered at a relatively low fluence rate, but at an overall high total fluence dose, resulting in minimal collateral normal tissue damage. It is contemplated that an optimal total fluence for the light administered to a patient will be determined clinically, using a light dose escalation trial.

(Chen [0052].)

Chen also discloses that its preferred methods include transcutaneous application of the light (*see id.* at [0023], [0053]).

Chen further discloses:

The intensity of radiation used to treat the target cell or target tissue is preferably between about 5 mW/cm^2 and about 100 mW/cm^2 . More preferably, the intensity of radiation employed should be between about 10 mW/cm^2 and about 75 mW/cm^2 . Most preferably, the intensity of radiation is between about 15 mW/cm^2 and about 50 mW/cm^2 .

(*Id.* at [0077].)

We agree with the Examiner that an ordinary artisan, advised by Chen of the suitability of applying transcutaneous PDT at a preferred light intensity from about 5 mW/cm² to about 100 mW/cm², and further advised by Whitehurst of the suitability of using a skin-conforming garment to apply PDT, would have been prompted to use Whitehurst's garment to apply PDT at the light intensities described in Chen.

As Chen's light intensity range of about 5 mW/cm² to about 100 mW/cm² overlaps the light intensity range of Appellant's claim 1, we also agree with the Examiner that a prima facie case of obviousness exists as to claim 1. *See, e.g., In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003) (overlapping ranges show prima facie obviousness).

Appellant contends that Chen's preferred light intensity range of from about 5 mW/cm² to about 100 mW/cm² is "without support" or "unsupported" (*see, e.g.* Reply Br. 4-5), presumably due to the absence of working examples. It is well settled, however, that obviousness determinations are not limited to working examples, but include all relevant teachings, including unpreferred embodiments. *See In re Mills*, 470 F.2d 649, 651 (CCPA 1972) ("All the disclosures in a reference must be evaluated, including nonpreferred embodiments, and a reference is not limited to the disclosure of specific working examples." (Citations omitted.)).

As Appellant's arguments do not, therefore, persuade us that a preponderance of the evidence fails to support the Examiner's conclusion of obviousness as to claim 1, we affirm the Examiner's obviousness rejection

of that claim, and its dependent claims 2, 3, 6-8, 11-14, and 16-19, over Whitehurst and Chen.

As to claim 5, however, we agree with Appellant that a preponderance of the evidence does not support the Examiner's prima facie case.

As noted above, claim 5 limits the process of claim 1 to a light intensity of "between about 0.25 and 3 mW/cm²."

The lower limit of Chen's broadest explicitly described (and preferred) light intensity range is "*about* 5 mW/cm²" (Chen [0077], [0096] (emphasis added)). Thus, the upper limit of the range recited in claim 5 is about 40% lower than the broadest preferred range disclosed by Chen.

The Examiner has not, however, pointed to any clear or specific teaching in Chen, or elsewhere in the record, suggesting that person of skill in this art would have reasonably interpreted Chen's use of the term "about" to be sufficiently expansive so as to describe values 40% lower than the expressly stated lowest value of 5 mW/cm². We are therefore not persuaded that a preponderance of the evidence supports the Examiner's finding (Ans. 4), that claim 5's upper light intensity limit of 3 mW/cm² is expressly described or taught by the range in Chen that includes a lower limit of about 5 mW/cm².

Moreover, viewing the overall teachings in the cited references, in particular Chen, we are not persuaded that the references would have suggested administering, to a patient, light within the intensity range recited in claim 5.

We note, as the Examiner argues, that Chen broadly discloses transcutaneously irradiating a mammalian subject in which the "intensity of the light used for irradiating is substantially less than 500 mw/cm²" (Chen

[0020]. We also note, as does the Examiner (Ans. 9), that Chen describes using photosensitizers targeted to specific diseased tissues, thereby allowing application of a relatively low fluence rate, but high total dose of light (*see id.* at [0079]). We further note Chen's teaching that an optimal light dosage rate can be determined clinically (*see id.* at [0052]).

However, as to specific teachings regarding suitable light intensity ranges, the broadest preferred range described in Chen is between about 5 mW/cm² and about 100 mW/cm², with a more preferred intensity being between about 10 mW/cm² and about 75 mW/cm², and the most preferred intensity being between about 15 mW/cm² and about 50 mW/cm² (Chen [0077]). Moreover, as Appellant points out, Example 1 of Chen used a fluence rate of about 150-180 mW/cm², despite the fact that the light applicators were directly implanted into the target tumor (*see id.* at [0093]), as opposed to being applied through the skin by a device like the one described in Whitehurst.

Thus, it may be true that Chen uses the term "about" to describe the lower limits of its ranges. However, given the overall preference for a range of light intensities significantly higher than 3 mW/cm², and given the exemplified use of a still higher light intensity applied directly to the tumor, we agree with Appellant that Chen does not suggest that applying light at the intensity range of claim 5 would have produced a useful therapeutic result. We are therefore not persuaded that Chen, even when combined with Whitehurst, would have suggested applying light at the intensity required in claim 5 to a patient.

We note, as the Examiner argues (Ans. 8), that Chen also focuses largely on the total light dosage applied, with a lower range of 30 Joules

described as being suitable (*see* Chen [0052]). As Appellant points out, however (Reply Br. 4), that disclosure is not accompanied by any specific teaching or suggestion as to the size of the area of tissue to which that light dosage should be applied. We are therefore not persuaded that Chen's teachings regarding total light dosages suggest applying light at an intensity 40% lower than the lower limit of the broadest range Chen explicitly discloses.

The Examiner also argues that the light intensity range has not been shown by Appellant to be critical, nor has Appellant shown any unexpected result coming from the claimed light dosage (*see* Ans. 10-11). It may be true that Appellant has not presented data showing unexpected results (*see* Reply Br. 5). However, as we are not persuaded, for the reasons discussed above, that a preponderance of the evidence supports the Examiner's prima facie case of obviousness, we are not persuaded that the absence of evidence of unexpected results undermines Appellant's position here.

In sum, as we are not persuaded, for the reasons discussed, that the preponderance of the evidence supports the Examiner's conclusion of obviousness as to claim 5, we reverse the Examiner's rejection of that claim over Whitehurst and Chen.

The Examiner also rejected claims 9 and 10, both of which depend from claim 1, as being obvious over Whitehurst, Chen, Rosen, and Zharov (Ans. 4). The Examiner cited Rosen and Zharov as evidence that the effective areas of light treatment recited in those claims would have been considered obvious to an ordinary artisan practicing the method suggested by Whitehurst and Chen (*see id.*).

Appellant does not list this rejection as a rejection to be reviewed on appeal (*see* App. Br. 2-3), nor does Appellant direct substantive argument to this rejection (*see* App. Br., Reply Br., *generally*). Thus, as Appellant alleges no defect in the Examiner's prima facie case of obviousness as to claims 9 and 10, and as we detect none, we affirm this rejection as well.

SUMMARY

We affirm the Examiner's obviousness rejection of claims 1-3, 6-8, 11-14, and 16-19 over Whitehurst and Chen.

However, we reverse the Examiner's obviousness rejection of claim 5 over Whitehurst and Chen.

We also affirm the Examiner's obviousness rejection of claims 9 and 10 over Whitehurst, Chen, Rosen, and Zharov.

TIME PERIOD

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

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