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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte LEROY E. HOOD, MURIEL Y. ISHIKAWA,
EDWARD K.Y. JUNG, ROBERT LANGER,
CLARENCE T. TEGREENE, LOWELL L. WOOD JR.,
and VICTORIA Y.H. WOOD

Appeal 2011-002608
Application 11/450,159
Technology Center 3700

Before DEMETRA J. MILLS, JEFFREY N. FREDMAN, and
ULRIKE W. JENKS, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to remote controlled fluid delivery devices. 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

"[T]he present application relates to remotely controlled delivery devices in which the concentration of a material in a fluid to be delivered may be varied. Control signals may be carried between a remote controller and a delivery device in an environment by electrical, magnetic, or electromagnetic fields or radiation." (Spec. 7.)

The Claims

Claims 125-154 are on appeal. Claim 125 is representative and reads as follows:

> 125. A delivery device comprising:
>
> a delivery reservoir configured to contain a delivery fluid, the delivery reservoir having at least one outlet through which the delivery fluid may exit the delivery reservoir;
>
> a delivery fluid contained within the delivery reservoir;
>
> a primary material contained within the delivery reservoir and having a controllable effective concentration in the delivery fluid; and
>
> at least one acoustically responsive control element adapted for modifying the distribution of the primary material between a first active form carried in the delivery fluid and a second form carried in the delivery fluid in response to an acoustic control signal, the effective concentration being the concentration of the first active form in the delivery fluid; wherein the second form is an inactive form of the primary material.

The issues

A. The Examiner rejected claims 125 and 126 under 35 U.S.C. § 102(b) as anticipated by Penner[1] (Ans. 4-5)

B. The Examiner rejected claims 125-128, 141-144, and 146-153 under 35 U.S.C. § 102(e) as anticipated by Williams[2] (Ans. 5-6).

C. The Examiner rejected claims 127 and 128 under 35 U.S.C. § 103(a) as obvious over Penner and Unger[3] (Ans. 7).

D. The Examiner rejected claims 129-132 under 35 U.S.C. § 103(a) as obvious over Penner and Kozak[4] (Ans. 7-8).

E. The Examiner rejected claims 129-132 under 35 U.S.C. § 103(a) as obvious over Williams and Acton[5] (Ans. 8).

F. The Examiner rejected claims 133-140 under 35 U.S.C. § 103(a) as obvious over Penner, Coppeta,[6] and Shaoulian[7] (Ans. 8-10).

G. The Examiner rejected claim 145 under 35 U.S.C. § 103(a) as obvious over Williams (Ans. 10).

H. The Examiner rejected claim 154 under 35 U.S.C. § 103(a) as obvious over Williams and Lent[8] (Ans. 11).

I. The Examiner rejected claims 141-143, 147, and 148 under 35 U.S.C. § 103(a) as obvious over Penner and Coppeta (Ans. 11-12).

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[1] Penner et al., US 2004/0032187 A1, published Feb. 19, 2004.
[2] Williams et al., US 2005/0234431 A1, published Oct. 20, 2005.
[3] Unger et al., US 5,770,222, issued Jun. 23, 1998.
[4] Kozak, A., US 6,077,837, issued Jun. 20, 2000.
[5] Acton, III, et al., US 5,719,296, issued Feb. 17, 1998.
[6] Coppeta et al., US 2005/0055014 A1, published Mar. 10, 2005.
[7] Shaoulian et al., US 2006/0241747 A1, published Oct. 26, 2006.
[8] Lent et al., US 6,458,118 B1, issued Oct. 1, 2002.

J. The Examiner rejected claims 144-146 under 35 U.S.C. § 103(a) as obvious over Penner, Coppeta, and Williams (Ans. 12).

A. 35 U.S.C. § 102(b) over Penner

The Examiner finds that Penner teaches:

> delivery device comprising: a delivery reservoir . . . having at least one outlet through which the delivery fluid may exit the delivery reservoir . . . a delivery fluid contained within the delivery reservoir [([0034])]; a primary material contained within the delivery reservoir and having a controllable effective concentration in the delivery fluid [([0034] prodrug)]; and at least one acoustically responsive control element . . . adapted for modifying the distribution of the primary material between a first active form carried in the delivery fluid and a second form carried in the delivery fluid in response to an acoustic control signal, the effective concentration being the concentration of the first active form in the delivery fluid; wherein the second form is an inactive form of the primary material . . . [([0034] the acoustic signal transforms the prodrug to the drug thereby transforming it between] a second inactive form to a first active form).

(Ans. 5.)

The issue with respect to this rejection is: Does the evidence of record support the Examiner's conclusion that Penner anticipates claims 125 and 126?

Findings of Fact

The following findings of fact ("FF") are supported by a preponderance of the evidence of record.

1. The Specification teaches that the "while in some embodiments an outlet may be a simple opening, in others the outlet may include a permeable or semipermeable membrane, filter or other some structure which

permits the exit of delivery fluid (or components of thereof) from the delivery reservoir" (Spec. 12).

2. The Specification teaches that the "delivery reservoir may include an outlet through which the delivery fluid moves into an environment, for example by pumping or diffusion" (Spec. 43).

3. The Specification teaches that the "term 'delivery fluid' as used herein, is intended to cover materials having any form that exhibits fluid or fluid-like behavior, including liquids, gases, powders or other solid particles in a liquid or gas carrier. The delivery fluid may be a solution, suspension, or emulsion" (Spec. 19).

4. Penner teaches "a device, system and method which can be used for localized intrabody delivery of molecules. Specifically, the present invention can be used to release molecules such as drugs within a specific body region using an acoustic activation signal provided from outside the body" (Penner 3 ¶ 0052).

5. Penner teaches that "[r]eservoirs **14** can be formed within a surface of device body **12** or within an interior volume thereof, provided molecules released therefrom can disperse into a medium surrounding device **10**" (Penner 4 ¶ 0058).

6. Penner teaches that

> the molecules contained within reservoir **14** can be provided as large aggregates which are unable to traverse barrier **16** which can be, in this case, a size selective membrane. Upon provision of the electrical potential the molecules disaggregate into smaller active units which are able to diffuse out of reservoir **14** through barrier **16**.

(Penner 4 ¶ 0070.)

7. Penner teaches "reservoirs **14** . . . each being configured for containing therapeutic molecules such as drugs and/or diagnostic molecules such as dyes preferably in a solution or as a suspension" (Penner 3 ¶ 0057).

8. Penner teaches

> (a) an intrabody implantable device including: (i) a device body including at least one reservoir being for containing a prodrug form of a drug, the at least one reservoir being formed with a barrier impermeable to the prodrug thereby preventing release thereof from the at least one reservoir; and (ii) at least one acoustic transducer being attached to, or forming a part of the device body, the at least one acoustic transducer being for converting an acoustic signal received thereby into an electrical signal, the electrical signal leading to a conversion of the prodrug into the drug, the drug being capable of traversing the barrier thereby releasing from the at least one reservoir; and (b) an extracorporeal unit for generating the acoustic signal.

(Penner 2 ¶ 0034.)

9. Penner teaches that "the electrical potential generated by electrodes **21** can cause the partial or full disintegration of barrier **16** and as such the release of the molecules from reservoir **14**" (Penner 4 ¶ 0072).

Principles of Law

"A single prior art reference that discloses, either expressly or inherently, each limitation of a claim invalidates that claim by anticipation." *Perricone v. Medicis Pharmaceutical Corp*., 432 F.3d 1368, 1375 (Fed. Cir. 2005).

Analysis

Claim interpretation is at the heart of patent examination because before a claim is properly interpreted, its scope cannot be compared to the

prior art. In this case, Appellants contend that "[n]owhere has the Examiner shown evidence of an outlet through which a delivery fluid may exit the reservoir" (App. Br. 26). Appellants contend that the "Examiner failed to demonstrate evidence . . . that a delivery fluid also exits the barrier" (*id.*). Appellants also contend that the "Examiner failed to show any evidence in Penner of a delivery fluid contained within a delivery reservoir" (*id.* at 28).

During prosecution, claim terms are given their broadest reasonable interpretation as they would be understood by persons of ordinary skill in the art in the light of the Specification. Therefore, we first turn to the Specification to interpret the terms "outlet" and "delivery fluid."

"outlet"

The Specification teaches that the "while in some embodiments an outlet may be a simple opening, in others the outlet may include a permeable or semipermeable membrane, filter or other some structure which permits the exit of delivery fluid (or components of thereof) from the delivery reservoir" (Spec. 12; FF 1).

We therefore find that the term "outlet" may reasonably be interpreted to encompass any opening, and that the opening may reasonably encompass a selective membrane or filter. Penner teaches that

> the molecules contained within reservoir **14** can be provided as large aggregates which are unable to traverse barrier **16** which can be, in this case, a size selective membrane. Upon provision of the electrical potential the molecules disaggregate into smaller active units which are able to diffuse out of reservoir **14** through barrier **16**.

(Penner 4 ¶ 0070; FF 6.)

We agree with the Examiner that Penner's barrier 16 is reasonably interpreted as an outlet consistent with the Specification, since the barrier 16 is a semipermeable membrane selectively releases molecules, where a "semipermeable membrane" is expressly disclosed as fulfilling the requirements for an outlet in the Specification (FF 1, 6).

"delivery fluid"

The Specification teaches that the "delivery reservoir may include an outlet through which the delivery fluid moves into an environment, for example by pumping or diffusion" (Spec. 43; FF 2). The Specification teaches that the "term 'delivery fluid' as used herein, is intended to cover materials having any form that exhibits fluid or fluid-like behavior, including liquids, gases, powders or other solid particles in a liquid or gas carrier. The delivery fluid may be a solution, suspension, or emulsion" (Spec. 19; FF 3).

We therefore find that a "solution" is reasonably interpreted as a delivery fluid which may move into an environment by diffusion, consistent with the Specification (FF 2-3). Penner teaches "reservoirs **14** . . . each being configured for containing therapeutic molecules such as drugs and/or diagnostic molecules such as dyes preferably in a solution or as a suspension" (Penner 3 ¶ 0057; FF 7).

We conclude that Penner's teaching of drugs in a solution (FF 7) where the drugs can diffuse from the reservoir 14 through barrier 16 (FF 6), satisfies the requirement in claim 125 for the release of the active form in the delivery fluid. We find that if the disaggregated drug molecules can pass through the size selective membrane (FF 6), the solvent in which the

molecules are dissolved will, by definition, be capable of diffusing through the membrane as well. Indeed, one definition of a solution is "a liquid preparation of one or more soluble chemical substances usually dissolved in water."[9]

Appellants contend that the "Examiner-cited portion of Penner fails to provide any specific examples of prodrug-to-drug conversions utilizing an electrical potential" (App. Br. 30).

We are not persuaded. Penner teaches that

> the molecules contained within reservoir **14** can be provided as large aggregates which are unable to traverse barrier **16** which can be, in this case, a size selective membrane. Upon provision of the electrical potential the molecules disaggregate into smaller active units which are able to diffuse out of reservoir **14** through barrier **16**.

(Penner 4 ¶ 0070; FF 6.) To the extent that Appellants are contending that Penner is not enabled, a reference is presumed to be enabled for the purpose of an anticipation rejection. *See In re Antor Media Corp*., 689 F.3d 1282, 1289 (Fed. Cir. 2012) ("[W]e therefore hold that, during patent prosecution, an examiner is entitled to reject claims as anticipated by a prior art publication or patent without conducting an inquiry into whether or not that prior art reference is enabling. As long as an examiner makes a proper prima facie case of anticipation by giving adequate notice under § 132, the burden shifts to the applicant to submit rebuttal evidence of nonenablement.")

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[9] http://medical-dictionary.thefreedictionary.com/ Solution+(chemistry) (accessed Feb. 5, 2013).

Appellants have provided no such rebuttal evidence that Penner is not enabled.

Claim 126

Appellants contend that there "is no teaching, and the Examiner has pointed to none, in paragraph [0034] of Penner of 'a chemically inactive form.'" (App. Br. 32.)

We begin by looking to the Specification to interpret the term "chemically inactive." The only use of the phrase appears to be the teaching that in some "embodiments, the second form may be a chemically inactive form. This case is depicted in FIG. 6A, in which the first active form is indicated by reference number 150, and the second (chemically inactive) form is indicated by reference number 152" (Spec. 17).

Applying the broadest reasonable interpretation to this phrase, consistent with the Specification, we find that any form of a material to be delivered which cannot perform its ordinary activity is reasonably interpreted as "chemically inactive." Penner teaches the "conversion of the prodrug into the drug, the drug being capable of traversing the barrier thereby releasing from the at least one reservoir" (Penner 2 ¶ 0034). Consistent with our interpretation, Penner's prodrug cannot perform the ordinary activity of the drug and is reasonably interpreted as "chemically inactive." Upon conversion, the drug is in an active form and is reasonably interpreted as "chemically active."

Conclusion of Law

The evidence of record supports the Examiner's conclusion that Penner anticipates claims 125 and 126.

B. 35 U.S.C. § 102(e) over Williams

The Examiner finds that Williams teaches

> delivery device comprising: a delivery reservoir configured to contain a delivery fluid ([0024]), the delivery reservoir having at least one outlet through which the delivery fluid may exit the delivery reservoir (Fig. 1 port 40); a delivery fluid contained within the delivery reservoir ([0024]); a primary material contained within the delivery reservoir and having a controllable effective concentration in the delivery fluid ([0128] Col. 2 microspheres); and at least one acoustically responsive control element ([0128] the microspheres can be triggered by ultrasonic energy, further acoustic energy can be used to deliver drug [0027]) adapted for modifying the distribution of the primary material between a first active form carried in the delivery fluid and a second form carried in the delivery fluid in response to an acoustic control signal

(Ans. 5.)

The issue with respect to this rejection is: Does the evidence of record support the Examiner's finding that Williams anticipates claim 125?

Findings of Fact

10. Williams teaches systems

> for administering drugs including hormones, chemotherapeutic agents, antibiotics pharmaceuticals, synthetic, recombinant or natural biologics, and other agents within the body. Generally speaking, the systems include drug reservoirs and associated components that are anchored in the vasculature and that administer drugs into the bloodstream or into certain organs or tissues

(Williams 1 ¶ 0024).

11. Williams teaches that

> a pump is preferably used to pump agent into the bloodstream. One type of a pump particularly useful in the device **10** is a gear pump which propels fluid using a pair of rotating gears. . . . [T]he pump **28** and motor **26** are disposed within one of the housing segments **25***a* forming the device body. Pickup tube **18**, which extends through reservoir **12** . . . has an outlet **34** . . . positioned within the housing segment **25***a*. An exit tube **36** has an inlet port **38** within the segment **25***a* and extends to the exterior face of the housing segment wall to form a delivery port **40** through which drug is released from the device.

(Williams 5 ¶ 0084.)

12. Williams teaches that "it may be particularly useful to provide the agent in the form of microspheres (e.g. agent embedded in a polymer matrix), which once released onto the bloodstream would become lodged in capillaries, arterioles, or associated small blood vessels from which they would release the embedded agent over time" (Williams 9 ¶ 0127).

13. Williams teaches that "physical activation may be achieved by exposing the microspheres to energy generated by ultrasonic . . . sources" (Williams 9 ¶ 0128).

Analysis

We begin with claim interpretation. Claim 125 is drawn to a device with a reservoir, where the reservoir comprises a primary material which can be modified to a second, active form in response to an acoustic control signal. The claim reasonably requires that the primary material is located in the reservoir when the acoustic control signal is applied, in order to satisfy the requirement for a "controllable effective concentration."

Appellants contend that there "is no teaching, and the Examiner has not pointed to any, in paragraphs [0127] or [0128] of Williams of 'a primary material contained within the **delivery reservoir** and having a controllable effective concentration in the **delivery fluid**'" (App. Br. 37-38).

The Examiner finds that "Williams teaches a remote activator which uses acoustic control is used to initiate drug delivery ([0027]) then there would be an element which responds to the control signal otherwise the signal would be ineffectual" (Ans. 14).

We find that Appellants have the better position. While Williams clearly has a reservoir with the primary material for release of microspheres into the blood steam (FF 11-12), Williams only teaches acoustic release of the drug from the microspheres after the microspheres have exited the reservoir into the bloodstream (FF 13) (emphasis added). The Examiner does not identify, and we do not find, a teaching in Williams where the material being delivered has a "controllable effective concentration" in the delivery reservoir as required by claim 125.

Conclusion of Law

The evidence of record does not support the Examiner's finding that Williams anticipates claim 125.

C. 35 U.S.C. § 103(a) over Penner and Unger

The Examiner finds that "Penner et al. teach a delivery device substantially as claimed. Penner et al. does not teach the form of the prodrug" (Ans. 7). The Examiner finds that Unger teaches that "prodrugs

are well known in the art and which can be activated using energy and the prodrug is contained in a microsphere" (*id.*).

The Examiner finds it obvious to "encapsulate the prodrug in a microsphere for delivery in the device of Penner et al. as Unger et al. teach such a mode of delivery for a prodrug is well know[n] in the art" (Ans. 7).

The issue with respect to this rejection is: Does the evidence of record support the Examiner's finding that Penner and Unger render claims 127 and 128 obvious?

Findings of Fact

14. Unger teaches that "[a]ny of a variety of therapeutics may be encapsulated in the microspheres. By therapeutic, as used herein, it is meant an agent having a beneficial effect on the patient. As used herein, the term therapeutic is synonymous with the term drug" (Unger, col. 9, ll. 30-34).

15. Unger teaches that "prodrugs can be activated . . . upon the application of ultrasound to the prodrug-containing microspheres with the resultant . . . release from the microspheres" (Unger, col. 11, ll. 53-56).

Principles of Law

The Supreme Court has emphasized that "the [obviousness] analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR Int'l v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

As noted by the Court in *KSR*, "[a] person of ordinary skill is also a person of ordinary creativity, not an automaton." *Id*. at 421. "The

combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *Id*. at 416.

Analysis

As discussed above, Penner teaches a delivery device comprising a delivery reservoir to contain a delivery fluid with a semi-permeable membrane as an outlet through which the delivery fluid may exit the reservoir (FF 4-6). Penner teaches a delivery fluid and prodrug within the reservoir (FF 7). Penner teaches that the effective concentration of the prodrug may be controlled by an acoustic signal which converts the inactive prodrug material to an active drug form (FF 8).

Unger teaches that "[a]ny of a variety of therapeutics may be encapsulated in the microspheres. By therapeutic, as used herein, it is meant an agent having a beneficial effect on the patient. As used herein, the term therapeutic is synonymous with the term drug" (Unger, col. 9, ll. 30-34; FF 14). Unger teaches that "prodrugs can be activated . . . upon the application of ultrasound to the prodrug-containing microspheres with the resultant . . . release from the microspheres" (Unger, col. 11, ll. 53-56; FF 15).

Applying the *KSR* standard of obviousness to the findings of fact, we agree with the Examiner that the ordinary artisan would have reasonably found it obvious to encapsulate either the active drugs or prodrugs of Penner into a microsphere as taught by Unger, since Unger teaches that ultrasound can be used to activate prodrug-containing microspheres (FF 15). Such a combination is merely a "predictable use of prior art elements according to their established functions." *KSR*, 550 U.S. at 417.

Appellants contend that the Examiner "failed to demonstrate where Penner or Unger, alone or in combination, discloses or suggests 'the second form is a chemically active form contained in a carrier structure'" (App. Br. 56).

We are not persuaded. Unger specifically teaches that "[a]ny of a variety of therapeutics may be encapsulated in the microspheres" (Unger, col. 9, ll. 30-31; FF 14). Unger then proceeds, from column 9, line 35 to column 11, line 33, to list a very wide and diverse range of active therapeutics which are reasonably in "chemically active form" when placed in the suggested microspheres. We conclude that the ordinary artisan, faced with Unger's extensive list of active compounds for inclusion into a microsphere, and Penner's teaching to use a reservoir to hold compounds until released by acoustic means, would have reasonably combined these teachings.

Conclusion of Law

The evidence of record supports the Examiner's finding that Penner and Unger render claims 127 and 128 obvious.

D. 35 U.S.C. § 103(a) over Penner and Kozak

Appellants contend that the "Examiner failed to provide any evidence in Penner or Kozak which establishes how it would have been obvious to combine 'a solution or suspension' of Penner with 'suspensions, emulsions, microemulsions, micellar dispersions, or the like' of Kozak" (App. Br. 59).

The Examiner finds that Kozak teaches

> Formulations of the compounds of the present invention into pharmaceutical compositions suitable for the chosen route of

> administration may include any physiologically acceptable solutions, suspensions, emulsions, microemulsions, micellar dispersions, or the like, with any pharmaceutically acceptable excipients, as are known in the art. In addition, formulations may include various encapsulations or depots designed to achieve sustained release of the prodrug

(Kozak, col. 6, ll. 30-38; Ans. 8).

We find that the Examiner has the better position. Appellants' arguments are flatly inaccurate. Penner already teaches "reservoirs **14** . . . each being configured for containing therapeutic molecules such as drugs and/or diagnostic molecules such as dyes preferably in a solution or as a suspension" (Penner 3 ¶ 0057; FF 7). So Penner already teaches the solution of claim 129 and the suspension of claim 130. Kozak expressly teaches placement of both pharmaceuticals and prodrugs, the "second form" of claim 125, into solutions, into suspensions, into emulsions and into dispersions and demonstrates that these are known equivalent forms for drug delivery (*see* Kozak, col. 6, ll. 30-38). An "[e]xpress suggestion to substitute one equivalent for another need not be present to render such substitution obvious." *In re Fout*, 675 F.2d 297, 301 (CCPA 1982). As noted by the Court in *KSR*, "[a] person of ordinary skill is also a person of ordinary creativity, not an automaton." 550 U.S. at 421.

E. 35 U.S.C. § 103(a) over Williams and Acton

This rejection relies upon the underlying anticipation rejection over claim 125 over Williams. Having reversed the rejection of claim 125 over Williams, we necessarily reverse this obviousness rejection further including Acton, since Acton does not cure the deficiencies of Williams.

F. 35 U.S.C. § 103(a) over Penner, Coppeta, and Shaoulian

The Examiner relies on Penner as discussed above and finds that "Coppeta et al. teach an equivalent reservoir delivery system which accelerates the release of the drug through the reservoir by using a shape memory material" (Ans. 9). The Examiner finds that "Shaoulian et al. teach that shape memory metals are equivalently responsive to exposure to various forms of energy including magnetic, electromagnetic, and acoustic" (*id.*).

The Examiner finds it obvious to "use an acoustic shape changing structure in the device of Penner et al. because Coppeta et al. teach such is effective for accelerating the release of the drug from the reservoir and Shaoulian et al. teach shape memory materials are effected by acoustic energy" (*id.*).

The issue with respect to this rejection is: Does the evidence of record support the Examiner's finding that Penner, Coppeta, and Shaoulian render claim 133 obvious?

Findings of Fact

16. Coppeta teaches a device to "accelerate the release of reservoir contents, particularly a drug formulation, out of a reservoir device, such as an implantable drug delivery device" (Coppeta 2 ¶ 0029).

17. Coppeta teaches that a "shape memory material, such as a shape memory alloy (SMA), a shape memory polymer, or a combination thereof, fashioned as a spring or lever is used to eject the contents from a reservoir upon thermal activation of the shape memory material" (Coppeta 3 ¶ 0037).

18. Coppeta teaches that "[r]upturing of the reservoir cap can occur due to the force of the spring on the drug formulation or other reservoir contents pushing against/through the reservoir cap" (Coppeta 3 ¶ 0041).

19. Shaoulian teaches that "shape memory material is responsive to energy, such as electromagnetic or acoustic energy, applied from an energy source" (Shaoulian, abstract).

20. The Specification teaches that "the shape-changing structure may be an expanding or contracting structure, wherein the change in at least one dimension includes an expansion or contraction in at least one dimension. Expansion or contraction of the expanding or contracting structure may modify the volume of a delivery reservoir" (Spec. 25).

Analysis

Claim 133

We begin with claim interpretation. Claim 133 requires "one acoustically responsive shape-changing structure capable of changing in at least one dimension in response to an acoustic control signal." Claim 133 requires that this change results in "modifying the distribution of the primary material between a first active form carried in the delivery fluid." Consistent with the Specification, one such change may be modifying the volume of the delivery reservoir (FF 20).

Penner teaches the device as discussed above. Penner teaches a modification of the delivery reservoir where "the electrical potential generated by electrodes **21** can cause the partial or full disintegration of barrier **16** and as such the release of the molecules from reservoir **14**" (Penner 4 ¶ 0072; FF 9). Coppeta also teaches modification of a delivery

reservoir where a "shape memory material, such as a shape memory alloy (SMA), a shape memory polymer, or a combination thereof, fashioned as a spring or lever is used to eject the contents from a reservoir upon thermal activation of the shape memory material" (Coppeta 3 ¶ 0037; FF 17). Shaoulian teaches that "shape memory material is responsive to energy, such as electromagnetic or acoustic energy, applied from an energy source" (Shaoulian, abstract; FF 19).

Applying the *KSR* standard of obviousness to the findings of fact, the ordinary artisan would have reasonably found it obvious to incorporate Coppeta's shape changing material into Penner's device in cause rupture of the outlet, barrier 16, and eject the contents of the reservoir 14, since this would fully disintegrate barrier 16 and permit rapid egress of the drug in the reservoir 14 as desired by Penner (FF 16-18). In addition, it would have been obvious to use acoustic energy since Shaoulian teaches that shape memory material is response to acoustic energy (FF 19). Such a combination is merely a "predictable use of prior art elements according to their established functions." *KSR*, 550 U.S. at 417.

Appellants contend that "the Examiner failed to provide any ***objectively-verifiable evidence*** of how the shape memory alloy of Coppeta is capable of **modifying the distribution** of the primary material between a first active form carried in the delivery fluid **and a second form**, as opposed to merely *ejecting contents* from a reservoir" (App. Br. 68).

We are not persuaded. When Coppeta ejects the contents from the reservoir, this necessarily results in a modification of the distribution of the material in the reservoir. As the Examiner finds, "[u]sing the shape changing

structure of Coppeta, which will be actuated by the acoustic control, modifies the distribution via the control signal as already taught by Penner and also through movement of material in the reservoir" (Ans. 16).

Appellants contend that by

> including a "shape memory alloy" or a 'shape memory polymer' of Coppeta, which is "<u>used to eject</u> the contents from a reservoir," (emphasis added) the acoustic transducer and the electrodes of Penner would be either be <u>rendered obsolete</u>, or substantial modification would be required to appropriately synchronize the permeabiliztion [sic] of the barrier with the ejection of contents from the reservoir

(App. Br. 70).

We are not persuaded. Penner teaches that one mode of release is to disintegrate the barrier (FF 9) and Coppeta and Shaoulian teach that this rupture can be accomplished using an acoustic transducer and a "shape memory polymer" (FF 16-19). In addition, it would have been routine for the ordinary artisan to synchronize the release with the permeabilization of the barrier in order to accelerate the release when desired as discussed by the Examiner (*see* Ans. 16).

Claim 137

Appellants contend that the

> Examiner failed to provide <u>any</u> ***objectively verifiable evidence*** of where Penner, Coppeta, or Shaoulian, alone or in combination, discloses or suggests "wherein expansion or contraction of the expanding or contracting structure exposes molecular structures to the delivery fluid that modify the <u>solubility of the **primary material in the delivery fluid**</u>"

(App. Br. 72).

The Examiner finds that "as the drug is released from the reservoir the molecular structures of the target region are exposed to the delivery fluid which would necessarily modify the solubility" (Ans. 9).

We find that the Examiner has the better position. The Examiner contends that any change in the volume of the solution by contacting the drug with delivery fluid will necessarily modify the solubility. Since solubility is defined as "[t]he amount of a substance that can be dissolved in a given amount of solvent,"[10] it is inherently necessary that as the amount of solvent changes, the solubility changes as well. *See In re Best*, 562 F.2d 1252, 1255 (CCPA 1977) ("Where, as here, the claimed and prior art products are identical or substantially identical . . . the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product.") Appellants have provided no evidence to satisfy this burden.

Claims 139 and 140

Appellants contend that the

> Examiner also asserted on page 8 of the Final Action that "it would have been obvious to a person of ordinary skill in the art ... to modify the polarity of the fluid in order to ease the acceptance of the drug within the body." However, the Examiner failed to provide any evidence whatsoever to establish this unsupported assertion

[10] http://www.thefreedictionary.com/solubility (accessed Feb. 5, 2013).

(App. Br. 73-74). Appellants make a similar contention for claim 140 (*see* App. Br. 74).

We find that Appellants have the better position. "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). Here, we agree with Appellants that the Examiner did not provide evidence to support the obviousness of modifying the polarity, and thus did not satisfy the burden of establishing a prima facie case of obviousness. Similarly, the Examiner provided no evidence teaching that "primary material bound by the interaction sites is removed from the delivery fluid" as required by claim 140.

Conclusion of Law

The evidence of record supports the Examiner's finding that Penner, Coppeta, and Shaoulian render claims 133 and 137 obvious.

The evidence of record does not support the Examiner's finding that Penner, Coppeta, and Shaoulian render claims 139 and 140 obvious.

G. 35 U.S.C. § 103(a) over Williams

This rejection relies upon the underlying anticipation rejection over claim 125 over Williams. Having reversed the anticipation rejection of claim 125 over Williams, we necessarily reverse this obviousness rejection further since the further teachings of Williams do not cure the deficiencies of the anticipation rejection.

H. 35 U.S.C. § 103(a) over Williams and Lent

This rejection relies upon the underlying anticipation rejection over claim 125 over Williams. Having reversed the rejection of claim 125 over Williams, we necessarily reverse this obviousness rejection further including Lent, since Lent does not cure the deficiencies of Williams.

I. 35 U.S.C. § 103(a) over Penner and Coppeta

Claim 141

Appellants rely upon overcoming the anticipation rejection over Penner. Appellants also contend that the "Examiner failed to establish that it would have been obvious to one of ordinary skill in the art to have combined the disclosure of Penner with the disclosure of Coppeta" (App. Br. 79).

The Examiner finds that "Penner et al. does not teach a pump. However, Coppeta et al. teach an equivalent reservoir delivery system which can be used as part of an osmotic or mechanical drug pump ([0139])." (Ans. 12). The Examiner finds it obvious to "use a pump to deliver the fluid with the device if Penner et al. because Coppeta et al. teach that such drug reservoirs are beneficial for use with drug pumps" (*id.*).

We find that the Examiner has the better position. The Examiner has provided a specific reason to include a pump, which is that pumps assist in the delivery of drugs to the patient. "A person of ordinary skill is also a person of ordinary creativity, not an automaton." *KSR*, 550 U.S. at 421. We agree with the Examiner that the person of ordinary creativity would have reasonably incorporated a pump when necessary to achieve more rapid transfer of drug from the reservoir to the patient.

Claim 148

Appellants contend that the "Examiner failed to demonstrate how the unsupported assertion of 'the drugs are delivered to the environment of the patient' discloses or suggests 'the downstream location includes a downstream environmental interface'" (App. Br. 80).

We begin with claim interpretation, specifically with the phrase "downstream environmental interface" from claim 148. The Specification teaches that an "environmental interface may function to facilitate the distribution of a primary material into an environment" (Spec. 45). Neither the Specification nor claim 148 provide any specific structure for a "downstream environmental interface." Thus, the broadest reasonable interpretation of this component is the furthest downstream component which interacts with the environment in which the device is situated. In this case, Penner teaches that barrier 16 is downstream of the reservoir and is an environmental interface, which reasonably satisfies this limitation as broadly interpreted in light of the Specification.

J. 35 U.S.C. § 103(a) over Penner, Coppeta, and Williams

The Examiner finds it obvious to "use one of the various claimed pumps with the device of Penner et al. and Coppeta et al. because Williams et al. teach numerous pumps are equivalent and further to substitute a centrifugal pump as it would achieve the predictable result of providing pumping" (Ans. 12).

The Examiner provides sound fact-based reasoning for modifying Penner and Coppeta with Williams. We adopt the fact finding and analysis

of the Examiner as our own. Appellants' arguments are directed at the above affirmed obviousness rejection over Penner and Coppeta. Therefore, consistent with that rejection which we affirmed above, we affirm this rejection for the reasons stated by the Examiner.

SUMMARY

In summary, we affirm the rejection claims 125 and 126 under 35 U.S.C. § 102(b) as anticipated by Penner.

We affirm the rejection of claims 127 and 128 under 35 U.S.C. § 103(a) as obvious over Penner and Unger.

We affirm the rejection of claims 129-132 under 35 U.S.C. § 103(a) as obvious over Penner and Kozak.

We affirm the rejection of claims 133-138 under 35 U.S.C. § 103(a) as obvious over Penner, Coppeta, and Shaoulian.

We affirm the rejection of claims 141-143, 147, and 148 under 35 U.S.C. § 103(a) as obvious over Penner and Coppeta.

We affirm the rejection of claims 144-146 under 35 U.S.C. § 103(a) as obvious over Penner, Coppeta, and Williams.

We reverse the rejection of claims 125-128, 141-144, and 146-153 under 35 U.S.C. § 102(e) as anticipated by Williams.

We reverse the rejection of claims 129-132 under 35 U.S.C. § 103(a) as obvious over Williams and Acton.

We reverse the rejection of claim 145 under 35 U.S.C. § 103(a) as obvious over Williams.

We reverse the rejection of claim 154 under 35 U.S.C. § 103(a) as obvious over Williams and Lent.

We reverse the rejection of claims 139 and 140 under 35 U.S.C. § 103(a) as obvious over Penner, Coppeta, and Shaoulian.

Claims 139, 140, and 149-154 are not currently subject to an affirmed rejection.

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