UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte DAVID D. KONIECZYNSKI, ALAN J. DEXTRADEUR and WILLIAM L. ROHR

Appeal 2007-3902
Application 10/092,954
Technology Center 1600

Decided: December 3, 2007

Before TONI R. SCHEINER, ERIC GRIMES, and RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to an implantable drug delivery system. The Examiner has rejected the claims as anticipated. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

BACKGROUND

The Specification teaches that the "ability to implant a drug delivery system capable of selectively delivering multiple small doses of a drug, or doses of different drugs, has been realized … by the advent of microchip technology" and that a "microchip device may include a plurality of drug

reservoirs that are etched into … a biocompatible implantable substrate, and are filled with the intended drug(s)" (Specification 2). The Specification further teaches that "release of material from each reservoir is separately controlled, for example, by a barrier membrane or other controllable member that controllably effects release of the drug from the reservoir" (*id.*).

The Specification also teaches that "a limitation of current microchip drug delivery systems is that generally only small amounts of material enter the targeted organ, or permeate the targeted site within the organ" and that "[t]ypically, the drug is released from a reservoir housed within the microchip, and the drug travels into or over a target tissue region by a diffusion process, often competing against a clearance reaction having a rate which may be comparable to the release rate" (*id.* at 3). The Specification states that there "remains a need for an efficient implantable drug delivery system effective to selectively deliver one or more drugs to a target site" (*id.*) and discloses "an implantable drug delivery system, including an infusion pump assembly and a controlled release biomaterial delivery unit, such as a microchip delivery device" such that the "infusion pump assembly delivers a carrier fluid to a fluid outlet, and a fluid delivery pathway extends from the outlet past the controlled release material delivery unit to a distal ported outlet, which is implanted at a target tissue site" (*id.* at 3-4).

DISCUSSION

1. CLAIMS

Claims 1, 3, 7, 8, 10, 11, 14-17, 19, 20, 22, 25 and 28-40 are pending and on appeal. The claims have not been argued separately and therefore

stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii). We will focus on claim 1, the broadest claim on appeal, which reads as follows:

> 1. An implantable drug delivery system, comprising:
> an infusion pump including a fluid outlet;
> a fluid delivery line effective for extending from the fluid outlet to a discharge portion positionable at a target tissue site; and
> a controlled release drug assembly downstream from the infusion pump, said drug assembly being configured for controllably releasing drug material, and communicating with said fluid delivery line such that the drug material is released into said fluid delivery line,
> wherein the pump assembly is effective to deliver a carrier fluid to the fluid outlet such that the drug material released into the delivery line discharges at the discharge portion to treat the target tissue site.

2. ANTICIPATION

Claims 1, 3, 7, 8, 10, 11, 14-17, 19, 20, 22, 25 and 28-40 stand rejected under 35 U.S.C. § 102(e) as anticipated by Uhland[1] on the basis that Uhland discloses an implantable system in the section entitled "Microchip Device with Implantable Pump" (beginning para. 0107) and that Uhland discloses that the micropump can pump the carrier fluid across one or more surfaces of the microchip device (Answer 4). The Examiner further finds that the term "target tissue" is broad enough to include implanting the distal (outlet) end of the micropump in any area of the body (*id.* at 5).

We agree with the Examiner that Uhland discloses all of the limitations in claim 1. The implantable drug delivery system defined by claim 1 has three components: an infusion pump, a fluid delivery line, and a controlled release drug assembly.

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[1] Uhland, US Publication No. 2004/0034332 A1, Feb. 19, 2004.

Uhland discloses a "a microchip device [that] is incorporated into an implantable micropumping system for the delivery of drugs over extended periods of time" (Uhland, para. 0108). Thus, Uhland teaches an implantable drug delivery system comprising an infusion pump.

The microchips that Uhland teaches combining with known micropumping systems are made for controlled release of drugs (*id.* at para. 0108-0109: "The micropump pumps the carrier fluid across one or more surfaces of the microchip device. . . . As the fluid passes over or around the activated and opened reservoir, the solid drug dissolves in the carrier fluid."). Thus, Uhland's device comprises a controlled release drug assembly which is "communicating" with the fluid delivery line as recited in claim 1. Finally, Uhland teaches that the implantable micropumping system is "for delivery of drugs over extended periods of time" (*id.* at para. 0108). That is, "the solid drug dissolves in the carrier fluid, forming a solution that is pumped into the extra-cellular environment" (*id.* at para. 0109).

Uhland does not expressly teach that the system comprises a fluid delivery line extending from the fluid outlet of the micropump to a discharge portion. However, we agree with the Examiner that it is reasonable to conclude that such a fluid delivery line is inherent in the disclosed device. As the Examiner has pointed out (Answer 4), Uhland's Figure 8A shows a macro-scale example of a drug delivery system comprising Uhland's drug delivery microchips. Figure 8A shows that the carrier fluid 104 passes across the drug-containing microchip 112, passes to a mixing chamber 130, and is discharged via tube 116. While an implantable device would not require tube 116 – because the device would already be in the patient – it

would still reasonably appear to require a fluid delivery line to route the carrier fluid from a reservoir or inlet to the microchip and out of the implanted device.[2]

We find that Uhland's device comprises all of the elements defined by claim 1, arranged as recited in the claim.

Appellants argue that Uhland does not disclose all of the limitations of the claimed system (Appeal Br. 7-8; Reply Br. 2-3). Appellants argue that "Uhland does not teach or suggest that the fluid delivery line extends from the fluid outlet to a discharge portion positionable at a target tissue site" as recited in claim 1, that "there is no mention in Uhland of directing fluid to a target tissue site," but rather that Uhland teaches that "the fluid from the micropump is released at a position proximate to the micropump itself and diffused through the body" (Appeal Br. 7-8.). Appellants further argue that "Uhland … only teaches or suggests using a drug delivery pump for use with drugs, such as pain medication or insulin, that are delivered generally to a non-specific site in the body" and that these "drugs are not delivered to a target tissue *to treat* that target tissue, but rather are released into the body, often subcutaneously, and diffused through the body to effect treatment at a tissue site that is remote from the delivery site" (Reply Br. 2-3).

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[2] Appellants refer to Fig. 1 of Rosenberg (US 4,596,575, Jun 24, 1996), as cited in Uhland in para. 109, as showing an implantable drug infusion device with a "unit (4)" and liquid "pumped into the body through feed tube 7" (Appeal Br. 7). The feed tube (7) serves the same function as the "fluid delivery line" of instant claim 1. Thus, the finding that a fluid delivery line would be inherent in an implantable drug delivery system is consistent with and supported by Rosenberg's disclosure of an implantable drug delivery device.

We are not persuaded by these arguments. It is well settled that "claims in an application are to be given their broadest reasonable interpretation consistent with the specification and that claim language should be read in light of the specification as it would be interpreted by one of ordinary skill in the art." *In re Sneed*, 710 F.2d 1544, 1548 (Fed. Cir. 1983) (citation omitted).

In the instant case, the Specification does not define the terms "fluid delivery line" or "target tissue site." The broadest reasonable interpretation of a "fluid delivery line" is a line, of any size or length, that is capable of delivering fluids. The broadest reasonable interpretation of a "target tissue site" is any tissue site intended to be targeted by the drug released from the drug delivery system.

We agree with the Examiner that claim 1, under the broadest reasonable interpretation, reads on the "Microchip Device with Implantable Pump" disclosed in Uhland. An implantable micropump with a microchip would have a fluid outlet and the device may be implanted in an area of the body needing treatment such that the device would comprise a "fluid delivery line effective for extending from the fluid outlet to a discharge portion positionable at a target tissue site," as recited in instant claim 1.

"Absent claim language carrying a narrow meaning, the PTO should only limit the claim based on the specification or prosecution history when those sources expressly disclaim the broader definition." *In re Bigio*, 381 F.3d 1320, 1325 (Fed Cir. 2004). Thus, it would be improper to limit claim 1 only to devices wherein the discharge portion is substantially separate and remote from the micropump. Because we agree that the Examiner's

interpretation of claim 1 is reasonable, and because claim 1 does not have any language that distinguishes the claimed implantable drug delivery device from the implantable drug delivery devices disclosed in Uhland, we agree with the Examiner that claim 1 encompasses the implantable drug delivery device disclosed in Uhland.

Appellants also argue that "Uhland does not disclose a substantial teaching of how a micropumping system would function" (Appeal Br. 6-7). Appellants further argue that "Figure 8A of Uhland only illustrates an intravenous drug delivery system that exists outside of the body of a patient" and that "there is no teaching in Uhland that explains how the *external IV system* illustrated in Figure 8A could be altered or reconfigured to be used as an implantable device" (Reply Br. 3).

Appellants' argument, in essence, is that Uhland does not enable the disclosed "Microchip Device with Implantable Pump." This argument is not persuasive. "Anticipation does not require the actual creation or reduction to practice of the prior art subject matter; anticipation requires only an enabling disclosure." *Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1380 (Fed. Cir. 2003) (citing *In re Donohue*, 766 F.2d 531, 533 (Fed. Cir. 1985)). "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. . . . The applicant, however, can then overcome that rejection by proving that the relevant disclosures of the prior art patent are not enabled." *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1355 (Fed. Cir. 2003). Thus, "a presumption arises that both the claimed and unclaimed disclosures in a prior art patent are enabled" (*id.*)

The Uhland disclosure is presumed to be enabling. Appellants have provided no evidence to show that undue experimentation would have been required to practice Uhland's "Microchip Device with Implantable Pump" for drug delivery. Further, Uhland specifically teaches that "[m]icropump apparatus suitable for use in these devices are known in the art" (Uhland, para. 0108). On this record, Appellants have not met their burden of rebutting the presumption of enablement of the Uhland reference.

SUMMARY

We agree with the Examiner that Uhland discloses all of the limitations of claim 1. Uhland is presumed to be enabled, and the presumption of enablement has not been successfully rebutted. We therefore affirm the Examiner's anticipation rejection of claim 1. Claims 3, 7, 8, 10, 11, 14-17, 19, 20, 22, 25 and 28-40 fall with claim 1.

AFFIRMED

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