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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte LIEVEN ELVIRE COLETTE BAERT,
IKSOO CHUN, GUENTER KRAUS,
DEBORAH M. SCHACHTER, and QIANG ZHANG

Appeal 2018-002233
Application 14/300,607[1]
Technology Center 1600

Before JEFFREY N. FREDMAN, JOHN E. SCHNEIDER, and DAVID COTTA, *Administrative Patent Judges*.

COTTA, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a degradable, removable, pharmaceutical subcutaneous implant for the sustained release of one or more drugs. The Examiner rejected the claims on appeal as obvious under 35 U.S.C. § 103(a). We reverse.

[1] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42. According to Appellant, the real party in interest is Janssen Sciences Ireland UC, an affiliate of Johnson & Johnson. Appeal Br. 1.

STATEMENT OF THE CASE

The Specification states that "[i]mplantable drug delivery devices have been known in the art." Spec. 1. "In the art-known implantable drug delivery systems the active ingredient is embedded in a matrix material that is shaped in a cylindrical form of sufficient small size to allow subcutaneous implantation via a hollow needle." *Id.* This delivery form has the disadvantage that "there is a lag time between implantation and delivery of the drug because the bodily fluids have to penetrate the implant and start decomposing the polymeric matrix" leading to "irregularities in the release pattern." *Id.* In addition, the Specification asserts that no such delivery system has been designed to simultaneously deliver two or more drugs. *Id.*

According to the Specification "[t]he present invention relates to an implantable depot polymeric device that is easily introduced into the subcutaneous space, removed if the necessity arises, and degrades when drug delivery function is complete." *Id.* The implant is "composed of a tube . . . made of a degradable polymer . . . [having] a plurality of openings." Within the tube are "micro-particles contain[ing] an active agent or a combination of two or more active agents . . . size[d] . . . such that the majority of the microparticles cannot pass through the openings." *Id.* at 3–4.

Claims 1, 2, 8, 9, and 13–15 are on appeal. Claim 1 is representative and reads as follows:

> 1. A degradable, removable, pharmaceutical subcutaneous implant for the sustained release of one or more drugs in a subject, comprising
>
> a tube that is defined by an outer wall,
>
> wherein the outer wall is fabricated from poly(dioxanone); has a plurality of openings on its surface; and completely surrounds a cavity,
>
> and wherein the cavity contains one or more sets of

> microparticles embedded in a hydrogel, wherein at least one set of the microparticles comprises rilpivirine and a copolymer of lactide and glycolide, and
>
> wherein the size of the microparticles is selected such that the majority of the microparticles cannot pass through the openings.

Appeal Br. 7.

The Examiner rejected claims 1, 2, 8, 9, and 13–15 as obvious over the combination of Priewe,[2] Harbeson,[3] and Porjazoska.[4]

ANALYSIS

Each of the rejected claims requires a "tube" having an outer wall that "completely surrounds a cavity" and "has a plurality of openings on its surface." Appeal Br. 7. In finding the claimed subcutaneous implant obvious, the Examiner relies on Priewe as disclosing the claimed tube. Ans. 3–4. Appellant argues that Priewe does not disclose this limitation. Appeal Br. 4–5; Reply Br. 3. We find that Appellant has the better position.

We begin by construing the claims. We understand the term "tube," as used in claim 1, to mean a hollow, cylindrical body. This is consistent with the way the term "tube" is used in the Specification. Spec. 3 (describing the tube as having an "internal diameter" and an "inner diameter"); *id.* at 4 (describing the tube as having an "outer wall . . . completely surrounding a cavity"); *id.* at 5 (describing the tube as having openings through which fluid may penetrate); *id.* at 6 (describing the tube as

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[2] Priewe et al., WO 02/30482 A1, published Apr. 18, 2002 ("Priewe").
[3] Harbeson et al., US 2009/0036357 A1, published Feb. 5, 2009 ("Harbeson").
[4] Porjazoska et al., *Poly(lactide-co-glycolide) Microparticles as Systems for Controlled Release of Proteins – Preparation and Characterization*, 54 Acta Pharm. 215–229 (2004) ("Porjazoska").

"cylindrical"); *id.* at 8 (describing the tube as having an internal and an outer diameter); Fig. 2 (depicting a hollow cylindrical body). It is also consistent with the plain and ordinary meaning of the term "tube." *See* https://dictionary.cambridge.org/dictionary/english/tube (accessed 12/5/2019) (defining tube as "a long, hollow cylinder of plastic, metal, rubber, or glass, used for moving or containing liquids or gases").

The Examiner relies on Figure 5 of Priewe as disclosing this limitation. Ans. 3–4.[5] Figure 5 of Priewe is reproduced below.

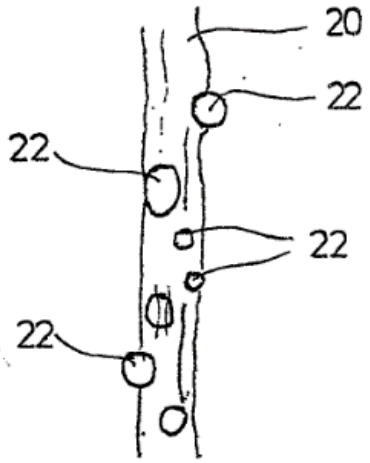

FIG. 5

Figure 5 is "a section from the filament prepared according to example 8, seen in side view." Priewe, 21. Example 8 describes the preparation of "[e]chogenic propylene filaments with pressure-sensitive glass hollow bodies." *Id.* at 25–26. According to Example 8, a mixture of polypropylene granules and glass hollow bodies (22) was melted, and a thread

[5] The Examiner also cites: Priewe's abstract; page 4, line 1 to page 8, line 30; page 14, lines 9–20; Example 8; and page 26, lines 9–12. However, the Examiner does not specifically identify anything in the cited material other than Figure 5 as disclosing structure corresponding to the claimed tube. Nor do we find anything in the cited material corresponding to the claimed tube. Accordingly, we focus our discussion on Priewe's Figure 5.

approximately 1 meter long was pulled out with a glass rod. *Id.* The glass hollow bodies (22) remained "intact" and could be seen under a microscope. In Figure 5, the glass hollow bodies (22) are shown "partially surrounded by [the] polypropylene" of the filament (20). *Id.*

We do not discern anything in Priewe to suggest that the filament in Figure 5 meets the requirement of claim 1 for a "tube." To the contrary, the method by which the filament (20) of Figure 5 was prepared — by pulling the filament out of a melted mixture of polypropylene with a glass rod — suggests that the filament is a solid structure. While the glass bodies (22) embedded within the filament are described as "hollow" (*id.* at 26), the Examiner does not direct us to any evidence to suggest that the filament (20) is hollow or would otherwise meet the definition of a "tube." Accordingly, we reverse the Examiner's rejection of claims 1, 2, 8, 9, and 13–15 as obvious over the combination of Priewe, Harbeson, and Porjazoska.

SUMMARY

In summary:

Claims Rejected	35 U.S.C. §	Basis	Affirmed	Reversed
1, 2, 8, 9, 13–15	103(a)	Priewe, Harbeson, Porjazoska		1, 2, 8, 9, 13–15

REVERSED