Trials@uspto.gov
571-272-7822

Paper No. 87
Entered: December 12, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,
Patent Owner.

Case IPR2017-01528
Patent 7,713,930 B2

Before ERICA A. FRANKLIN, ROBERT A. POLLOCK, and MICHELLE N. ANKENBRAND, *Administrative Patent Judges.*

ANKENBRAND, *Administrative Patent Judge*.

FINAL WRITTEN DECISION

Finding Claims 1–20 Unpatentable
35 U.S.C. § 318(a); 37 C.F.R. § 42.73

Denying-in-part and Dismissing-in-part as Moot Patent Owner's Motion to Strike
37 C.F.R. §§ 42.5(a), 42.20(a)

Dismissing Petitioner's Motion to Exclude and Denying-in-part and Dismissing-in-part as Moot Patent Owner's Motion to Exclude
37 C.F.R. § 42.64(c)

Denying Petitioner's First Motion to Seal, Granting Petitioner's Second Motion to Seal, and Granting Patent Owner's Motions to Seal
37 C.F.R. § 42.54

I. INTRODUCTION

This is a Final Written Decision in an *inter partes* review challenging the patentability of claims 1–20 (collectively, the "challenged claims") of U.S. Patent No. 7,713,930 B2 (Ex. 1002, "the '930 patent"). We have jurisdiction under 35 U.S.C. § 6. For the reasons that follow, we determine that Petitioner demonstrates, by a preponderance of the evidence, that the challenged claims are unpatentable.

A. Procedural History

Mylan Pharmaceuticals, Inc. ("Petitioner") filed a Petition (Paper 2, "Pet.") requesting an *inter partes* review under 35 U.S.C. § 311. Petitioner supported its Petition with the testimony of Samuel H. Yalkowsky, Ph.D. (Ex. 1003). On December 13, 2017, we instituted trial to determine whether:

1. Claims 1–20 of the '930 patent are unpatentable under 35 U.S.C. § 103 as obvious over the combination of Lantus Label[1] and Lougheed[2];
2. Claims 1–18 and 20 of the '930 patent are unpatentable under 35 U.S.C. § 103 as obvious over the combination of Lantus Label and FASS[3];

[1] Physicians' Desk Reference, Lantus entry 709–713 (55th ed. 2001) (Ex. 1004). We refer in this decision to the corrected version of Exhibit 1004.

[2] W.D. Lougheed et al., *Physical Stability of Insulin Formulations*, 32 DIABETES 424–432 (1983) (Ex. 1006).

[3] Farmaceutiska Specialiteter I Sverige ("FASS"), Summary of Product Characteristics Entry for Insuman Infusat (2000) (certified English translation provided as Ex. 1007A; original Swedish version provided as Ex. 1007).

3. Claims 1–18 and 20 of the '930 patent are unpatentable under 35 U.S.C. § 103 as obvious over the combination of Lantus Label and Grau[4];
4. Claim 19 of the '930 patent is unpatentable over the combination of Lantus Label, FASS or Grau, and Lougheed;
5. Claims 1–20 of the '930 patent are unpatentable under 35 U.S.C. § 103 as obvious over the combination of Owens[5] and Lougheed;
6. Claims 1–18 and 20 of the '930 patent are unpatentable under 35 U.S.C. § 103 as obvious over the combination of Owens and FASS;
7. Claims 1–18 and 20 of the '930 patent are unpatentable under 35 U.S.C. § 103 as obvious over the combination of Owens and Grau; and
8. Claim 19 of the '930 patent is unpatentable over the combination of Owens, FASS or Grau, and Lougheed.

Paper 12 ("Institution Decision" or "Inst. Dec.").

Following institution, Sanofi-Aventis Deutschland GmbH ("Patent Owner") filed a Response (Paper 26, "Resp.") and supporting declarations from Bernhardt Trout, Ph.D. (Ex. 2006) and Laurence C. Baker, Ph.D. (Ex. 2039). Petitioner filed a Reply (Paper 41, "Reply") and supporting declarations from Dr. Yalkowsky (Ex. 1181), Robert S. Langer, Sc.D. (Ex. 1111), Deforest McDuff, Ph.D. (Ex. 1169), and William C. Biggs, M.D. (Ex. 1174).

During an interlocutory teleconference on July 17, 2018, we authorized Patent Owner to file a motion to strike certain arguments Petitioner made in the

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[4] Ulrich Grau & Christopher D. Saudek, *Stable Insulin Preparation for Implanted Insulin Pumps – Laboratory & Animal Trials*, 36 DIABETES 1453–59 (1987) (Ex. 1008).

[5] David R. Owens et al., *Pharmacokinetics of ^{125}I-Labeled Insulin Glargine (HOE 901) in Healthy Men – Comparison with NPH insulin and the influence of different subcutaneous injection sites*, 23 DIABETES CARE 813–819 (2000) (Ex. 1005).

Reply. *See* Ex. 2055, 43:3–20 (Transcript of July 17, 2018 teleconference). We also authorized Patent Owner to file a sur-reply as to certain, but not all, arguments in Petitioner's Reply. *Id.* at 42:13–43:2. Subsequently, Patent Owner filed a Sur-reply (Paper 44) and a Motion to Strike (Paper 45, "Mot. to Strike"). Petitioner filed an opposition to Patent Owner's Motion to Strike (Paper 50, "Mot. to Strike Opp.").

Petitioner and Patent Owner also filed several motions to seal certain briefs and exhibits. Paper 43 (Patent Owner's Supplemental Motion to Seal), Paper 76 (Patent Owner's Motion to Seal), Paper 84 (Petitioner's Motion to Seal), Paper 86 (Petitioner's Motion to Seal and for Entry of Proposed Protective Order). Both parties also filed motions to exclude, which have been fully briefed. *See* Papers 55, 62, 69 (briefing related to Petitioner's Motion to Exclude); Papers 59, 65, 68 (briefing related to Patent Owner's Motion to Exclude). Patent Owner also filed Observations on the Cross-Examination Testimony of Petitioner's Reply Declarants, and Petitioner responded. Papers 58, 66. The record further includes a transcript of the final oral hearing conducted on September 27, 2018. Paper 75 ("Tr.").

After the final oral hearing, we authorized Patent Owner to file a second sur-reply and additional evidence, and we authorized Petitioner to file a sur-sur-reply. Paper 75. Subsequently, Patent Owner filed the Sur-reply (Papers 77 (confidential version), 78 (public version)), and Petitioner filed the Sur-sur-reply (Papers 83 (confidential version), 85 (public version)).

B. Related Matters

The parties identify the following pending litigation involving the '930 patent: *Sanofi-Aventis U.S. LLC v. Merck Sharp & Dohme Corp.*, C.A. No. 1:16-cv-00812-RGA (D. Del.); *Sanofi-Aventis U.S. LLC v. Merck Sharp & Dohme*

Corp., C.A. No. 2:17-cv-05914 (D.N.J.); *Sanofi- Aventis U.S. LLC v. Mylan N.V.*, C.A. No. 2:17-cv-09105-SRC (D.N.J); and *Sanofi- Aventis U.S. LLC v. Mylan N.V.*, C.A. No. 1:17-cv-00181-IMK (D.W.V.). Paper 6, 2; Paper 13, 1–2. The parties also identify the following concluded litigation involving the '930 patent: *Sanofi-Aventis U.S. LLC v. Eli Lilly & Co.*, C.A. No. 1:14-cv-00113-RGA (D. Del.); *Sanofi-Aventis U.S. LLC v. Eli Lilly & Co.*, C.A. No. 1:14-cv-00884-RGA (D. Del.). Paper 6, 2; Paper 13, 1.

And the parties identify as related Case IPR2017-01526— an *inter partes* review involving U.S. Patent No. 7,476,652 (Ex. 1001), which issued from a parent application to the application that issued as the '930 patent. Paper 6, 2; Paper 13, 2. Concurrent with this decision, we issue a Final Written Decision in Case IPR2017-01526.

C. The '930 Patent (Ex. 1002)

The '930 patent, titled "Acidic Insulin Preparations Having Improved Stability," issued on May 11, 2010. Ex. 1002, (45), (54). The '930 patent relates to a pharmaceutical formulation comprising a modified insulin—insulin glargine (Gly(A21)-Arg(B31)-Arg(B32)-human insulin); at least one surfactant; at least one preservative; and optionally an isotonicizing agent, buffers or other excipients, wherein the formulation has a pH in the acidic range. *See, e.g.*, Ex. 1002, Abstract, 1:15–23, 11:49–56. The formulation is used to treat diabetes, and is "particularly suitable for preparations in which a high stability to thermal and/or physicomechanical stress is necessary." *Id.* at 1:19–22. According to the specification, insulin glargine was a known modified insulin with a prolonged duration of action injected once daily as an acidic, clear solution that "precipitates on account of its solution properties in the physiological pH range of the subcutaneous tissue as a stable hexamer associate." *Id.* at 2:56–61.

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