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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 IPR2018-01676
Patent 8,603,044 B2

Before HYUN J. JUNG, BART A. GERSTENBLITH, and JAMES J. MAYBERRY, *Administrative Patent Judges*.

GERSTENBLITH, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

A. Background

Mylan Pharmaceuticals Inc. ("Petitioner") filed a Petition (Paper 2, "Pet.") requesting institution of an *inter partes* review of claims 11, 14, 15, 18, and 19 of U.S. Patent No. 8,603,044 B2 (Ex. 1002, "the '044 patent"). Sanofi-Aventis Deutschland GmbH ("Patent Owner") filed a Preliminary Response (Paper 10). With prior authorization, Petitioner filed a Reply to Patent Owner's Preliminary Response (Paper 13; "PR Reply") limited to addressing whether we should exercise our discretion under 35 U.S.C. § 314(a) to deny the Petition, and Patent Owner filed a Sur-Reply in response (Paper 15, "PR Sur-Reply"). Pursuant to 35 U.S.C. § 314, an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition."

Upon consideration of the present record and for the reasons explained below, we determine that Petitioner has shown a reasonable likelihood that it would prevail with respect to at least one of the challenged claims. Accordingly, we institute an *inter partes* review of claims 11, 14, 15, 18, and 19 on all grounds raised in the Petition.

B. Related Proceedings

The parties indicate that the '044 patent has been asserted in *Sanofi-Aventis U.S. LLC v. Mylan GmbH*, No. 2:17-cv-09105 (D.N.J.); *Sanofi-Aventis U.S. LLC v. Merck Sharp & Dohme Corp.*, No. 1:16-cv-00812 (D. Del.); and *Sanofi-Aventis U.S. LLC v. Eli Lilly and Co.*, No. 1:14-cv-00113 (D. Del.). Paper 8, 2; Paper 9, 1–2.

The parties state that the '044 patent also is challenged in Case IPR2018-01675. Paper 8, 2; Paper 9, 2. The parties also state that patents related to the '044 patent are challenged in Cases IPR2018-01670, IPR2018-01677, IPR2018-01678, IPR2018-01679, IPR2018-01680, IPR2018-01682, IPR2018-01684, IPR2018-01696, and IPR2019-00122. Paper 8, 2–3; Paper 9, 1–2.

C. Real Parties in Interest

Petitioner identifies Mylan Pharmaceuticals Inc., Mylan Inc., Mylan GmbH, Biocon Research Ltd., Biocon Ltd., and Becton, Dickinson and Company as real parties in interest. Paper 8, 2. Patent Owner identifies Sanofi-Aventis Deutschland GmbH, Sanofi-Aventis U.S. LLC, and Sanofi Winthrop Industrie as real parties in interest. Paper 9, 1.

D. The Asserted Grounds of Unpatentability

Petitioner asserts claims 11, 14, 15, 18, and 19 of the '044 patent are unpatentable under 35 U.S.C. § 103(a) as obvious over (1) Steenfeldt-Jensen et al.[1] (Ex. 1014, "Steenfeldt-Jensen") and (2) Moller[2] (Ex. 1015) in combination with Steenfeldt-Jensen. Petitioner supports its challenge with a declaration by Karl R. Leinsing, dated September 9, 2018 (Ex. 1011, "the Leinsing Declaration").

E. The '044 Patent

The '044 patent "relates to pen-type injectors . . . where a user may set the dose." Ex, 1002, 1:20–24. Figures 1 and 2 of the '044 patent are reproduced below.

[1] U.S. Patent No. 6,235,004 B1, iss. May 22, 2001.

[2] U.S. Patent Application Pub. No. 2002/0052578 A1.

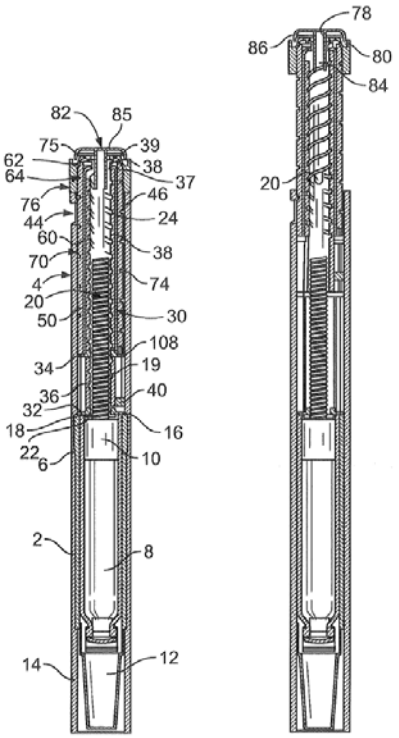

FIG. 1 FIG. 2

Figure 1 "shows a sectional view of a pen-type injector . . . in a first, cartridge full, position," and Figure 2 "shows a sectional view of the pen-type injector of FIG. 1 in a second, maximum first dose dialed, position." *Id.* at 2:53–57. The pen-type injector includes first cartridge retaining part 2 and second main housing part 4.[3] *Id.* at 3:27–28. Insert 16 is at a first end of housing part 4 and is fixed rotationally and axially to main housing 4. *Id.* at 3:49–51. Insert 16 includes threaded circular opening 18, through which piston rod 20 extends. *Id.* at 3:51–53, 3:57–59. Piston rod 20 includes first thread 19 that engages threaded circular opening 18. *Id.* at 3:56.

[3] The '044 patent refers to "second main housing part 4" and "main housing 4" interchangeably. *Compare* Ex. 1002, 3:28 ("second main housing part 4") *with id.* at 3:30 ("main housing 4").

Piston rod 20 also includes pressure foot 22 that abuts piston 10 of cartridge 8. *Id.* at 3:36–37, 3:59–60. Drive sleeve 30 extends about piston rod 20, and second thread 24 of piston rod 20 engages internal helical groove 38 of drive sleeve 30. *Id.* at 3:61–62, 4:4, 4:13–14.

Clutch or clutch means 60 is disposed about drive sleeve 30 adjacent its second end. *Id.* at 4:33–35, 4:49–50. Clutch 60 is keyed to drive sleeve 30 by splines to prevent relative rotation between clutch 60 and drive sleeve 30. *Id.* at 4:60–62. Clutch 60 also has teeth 66 that engage dose-dial sleeve 70. *Id.* at 4:50–52.

Dose dial sleeve 70 is outside of clutch 60 but within main housing 4. *Id.* at 5:3–5. Dose dial sleeve 70 has helical groove 74 on its outer surface, and helical rib 46 of housing 4 is seated in helical groove 70. *Id.* at 5:5–6, 5:9–11. Dose dial grip 76 is disposed about and secured to the second end of dose dial sleeve 70. *Id.* at 5:24–25, 5:27–28.

A user rotates dose dial grip 76 to set a dose and cause dose-dial sleeve 70, clutch 60, and drive sleeve 30 to rotate together out of main housing 4. *Id.* at 5:50–53, 5:61–65, Fig. 9. The dose can be reduced by turning dose dial grip 76 in the opposite direction. *Id.* at 6:19–20, Fig. 10. The user then presses button 82, which causes clutch 60 to disengage from dose dial sleeve 70 so that clutch 60 moves axially and dose dial sleeve 70 rotates back into main housing 4. *Id.* at 6:28–35, 6:38–40, Fig. 11. Drive sleeve 30 also moves axially and causes piston rod 20 to rotate through threaded opening 18 to dispense medicine from cartridge 8. *Id.* at 6:45–47.

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