

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 IPR2018-01675
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 12). With prior authorization, Petitioner filed a Reply to Patent Owner’s Preliminary Response (Paper 16; “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 19, “PR Sur-Reply”). Also with prior authorization, Petitioner filed a Motion to Correct the Petition (Paper 15) and Patent Owner filed an Opposition to the Motion (Paper 18). We granted Petitioner’s Motion to Correct (Paper 21), resulting in a citation change on page 25 of the Petition, which is shown in Exhibit 1037.¹ We also granted Patent Owner’s request to file an Amended Preliminary Response, which Patent Owner filed as Paper 23 (“Prelim. Resp.”), to respond to the corrected citation in the Petition. Paper 21, 4. Pursuant to 35 U.S.C. § 314, an *inter partes* review may not be instituted “unless . . . there is a reasonable

¹ Because it was a very minor change, we did not require Petitioner to file a “corrected petition”; rather, we agreed that we would treat the originally filed Petition as though the correction had been made. *See* Ex. 1039, 14:17–16:4. The citation on page 25 to Exhibit 1002 was thus changed from “*cf.* EX1002, 3:42–44” to “*cf.* EX1002, 3:62–64.” Ex. 1037.

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 10, 2; Paper 11, 2–3.

The parties state that the '044 patent also is challenged in Case IPR2018-01676. Paper 10, 2; Paper 11, 3. 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 10, 2–3; Paper 11, 2–3.

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 10, 2. Patent Owner identifies Sanofi-Aventis Deutschland GmbH, Sanofi-Aventis U.S. LLC, and Sanofi Winthrop Industrie as real parties in interest. Paper 11, 2.

D. The Asserted Ground 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 Burroughs et al.² (Ex. 1013, "Burroughs"). Petitioner supports its challenge with a declaration by Karl R. Leinsing, dated September 8, 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.

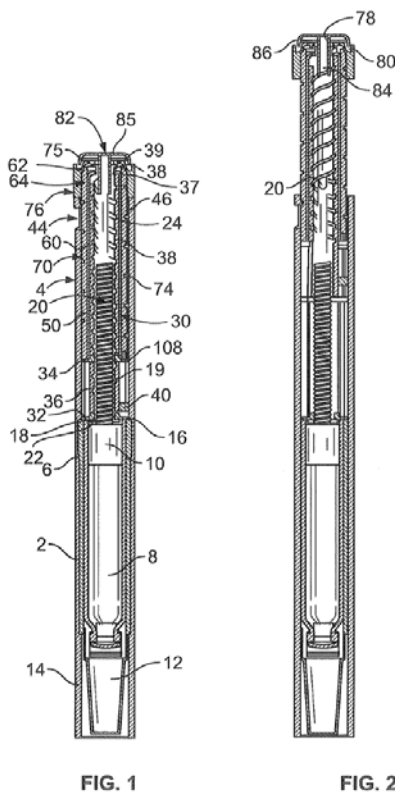


Figure 1 "shows a sectional view of a pen-type injector . . . in a first, cartridge full, position," and Figure 2 "shows a sectional view of the pen-

² US 6,221,046 B1, iss. Apr. 24, 2001.

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.

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

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”).

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