

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
and PFIZER INC.,

Petitioners,

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,
Patent Owner.

Case IPR2018-01676
Patent No. 8,603,044

PETITIONERS' REPLY TO PATENT OWNER RESPONSE

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I. INTRODUCTION

In its response, the patent owner (Sanofi) takes an excessively narrow reading of what the references would mean to a person of ordinary skill in the art (POSA), provides a flawed and biased analysis of the proposed modification using bases deliberately shielded from review, and argues against the combination for reasons that are internally inconsistent and at odds with real-world developments already in the record. Claims 11, 14, 15, 18 and 19 should be held unpatentable for the reasons provided in the petition and further developed below.

II. GROUND 1: STEENFELDT-JENSEN SUGGESTS MODIFICATION

Sanofi presents three arguments against modifying Steinfeldt-Jensen:

(1) Steinfeldt-Jensen's suggested alternate embodiments "where the piston rod guide is provided in the wall 4 and a nut element is rotated by the driver" do not suggest a threaded driver. POR 21-23.

(2) Any suggestion is for the first embodiment only. *Id.*, 24-26.

(3) A POSA would not have followed Steinfeldt-Jensen's suggestion because modification would increase friction losses in the drive mechanism. *Id.*, 26-39.

Each argument fails.

A. Steinfeldt-Jensen Teaches an Internally-Threaded Driver Tube

Sanofi sows confusion attempting to distinguish between a “nut member” (also referred to as a “nut element”) rotated by the driver tube and the driver tube itself having internal threading. POR, 21; EX2107, ¶¶215-22. The relevant disclosures in context makes clear that a driver with a nut member *is* an internally-threaded driver.

A POSA would have understood Steinfeldt-Jensen as describing an internally-threaded driver tube when it refers to a driver rotating a nut member. EX1095, ¶¶63-64. Steinfeldt-Jensen describes two ways to configure the driver: a driver can rotate a “piston rod guide” or a “nut member” (also referred to as a “nut element”). Pet., 53-56; EX1014, 3:41-47. These alternative drivers correspond to the well-known screw/nut principles that Dr. Slocum himself described in his background section. EX2107, ¶30 (“Many pen injector designs...operate using screw and nut mechanisms.... [A]xial motion can occur by causing the screw or the nut to rotate while the other is prevented from rotating....”).

The depicted embodiments with the driver rotating a piston-rod guide show the guide is not a separate component but simply the driver’s rectangular bore, which prevents relative rotation. EX1095, ¶65; EX1014, 6:35-36 (driver tube 26 is “integral with the piston rod guide”), 11:15-19 (piston rod’s not round cross-section “fits through the driver tube bore which has a corresponding not round cross-section”, transmitting rotation while allowing relative axial movement). Just as no meaningful

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