

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INC.  
and PFIZER INC.,  
Petitioners,

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,  
Patent Owner.

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Case IPR2018-01675  
Patent No. 8,603,044

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**PETITIONERS' REPLY TO PATENT OWNER RESPONSE**  
37 CFR §42.23

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## I. INTRODUCTION

The patent owner (Sanofi) reads Burroughs (EX1013), not as a whole, but as disjoint teachings in a manner inconsistent with precedent and the understanding of a person of ordinary skill in the art (POSA). The preponderance of evidence of record—including testimony from pen designer Karl Leinsing (EX1011, EX1095) and cross examination testimony from Sanofi’s Professor Slocum (EX1053, EX1054)—contradicts Sanofi’s arguments.

Claims not argued separately stand or fall together. *In re Dillon*, 919 F.2d 688, 692 (Fed. Cir. 1990) (en banc). Sanofi only separately argues claim 11,<sup>1</sup> leaving the remaining claims to stand or fall with claim 11 from which they depend. For the reasons given in the petition alone and in light of the arguments below, all challenged claims are unpatentable.

## II. LEVEL OF SKILL

Sanofi disputes the level of skill in the art and whether it requires any years of experience but concedes that any differences between the parties do not affect

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<sup>1</sup> Sanofi only discusses claim 14 to deny a means-plus-function reading for *clicker*. POR 13.

this trial. POR 8-9. Petitioners agree with the Board that the art of record amply reflects the level of skill. Paper 28, 12-13.

### III. CLAIM CONSTRUCTION

Claims have their ordinary and customary meaning, consistent with the specification. 37 CFR §42.100(b); *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc). If it would make a difference, the Board will adopt the broadest reasonable interpretation in this trial. Paper 28, 13.

Sanofi asserts that Petitioners have not settled on a meaning for *tubular clutch* and *clicker*, which the petition explained could be subject to a means-plus-function interpretation. POR 9. Claim construction is a question of law, and the tribunals regularly arrive at a final construction in their final decisions. *Jack Guttman, Inc. v. Kopykake Enter., Inc.*, 302 F.3d 1352, 1361 (Fed. Cir. 2002) ("District courts may engage in a rolling claim construction, in which the court revisits and alters its interpretation of the claim terms as its understanding of the technology evolves."). In fact, the Board will deny petitions for failing to address a foreseeable alternate construction. *Ethicon Endo-Surgery, Inc. v. Covidien AG*, IPR2016-00944, Paper 8, 5-6 (denying follow-on institution for claim construction not addressed in earlier petition). The Board was not confused when instituting this trial. Paper 28, 15-16.

In any case, Sanofi rejects means-plus-function constructions for these terms. POR 10. Similarly, the institution decision provisionally adopted Sanofi’s broader constructions. Sanofi has waived any argument resting on a means-plus-function construction, including any separate argument that the art would not teach the invention with a means-plus-function construction. Accordingly, Petitioners will proceed with the broader plain and ordinary meaning for these terms.

Other than contending *clicker* is not a means-plus-function limitation, Sanofi’s response only addresses the construction of *tubular clutch*, which Sanofi would construe as “a component that can operate to reversibly lock two components in rotation.” POR 10-12. While Sanofi challenges Petitioners’ means-plus-function construction for its use of the phrase “during dose setting”, Sanofi does not address the plain-meaning construction that the petition offered. The petition—relying on Sanofi’s own representations to the district court in the collateral proceeding—proposed the following construction: “A tubular structure that couples and decouples a moveable component from another component” Pet. 16, citing EX1019, 23. This construction does not restrict the claims to dose setting, rendering Sanofi’s argument moot.

In an earlier proceeding, Sanofi proffered a similar construction of the term (“A first component that couples and decouples at least a second component to a third component.”), which the court construed as “[a] structure that couples and

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