

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 IPR2019-01658
Patent No. RE47,614

**PETITIONER MYLAN PHARMACEUTICALS INC.'S
EXPLANATION OF MULTIPLE PETITIONS
CHALLENGING PATENT NO. RE47,614
AND RANKING OF PETITIONS**

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I. INTRODUCTION

Petitioner Mylan Pharmaceuticals Inc. (“Mylan”) seeks an *inter partes* review (“IPR”) of all claims of U.S. Patent RE47,614 (“Harms”; EX1001), which is assigned to Patent Owner (“Sanofi”), in this IPR and in IPR2019-01657. This paper explains why two petitions were filed and why both petitions warrant institution, pursuant to Trial Practice Guide Update (July 2019) (“Update”) at 27.

Each petition represents a single ground of unpatentability. The grounds themselves are parallel: in each case, the first two references together show the use of a spring washer to secure a drug cartridge within a drug-delivery device, while

the same third reference in each ground provides a spring washer with a specific structure. Due

IPR2019	Ground	Obviousness references
-01657	1	Burren, Venezia & De Gennes
-01658	2	Bitdinger, Schofield & De Gennes

to the number of claims (1-18), two petitions were required to comply with word-count constraints. Update at 26 (noting this justification for more than one petition). As it is, the background and description of the claimed invention are essentially the same. To further simplify joint consideration, the same expert declaration supports both grounds.

Because the petitions overlap to a significant degree and the grounds take complementary approaches to demonstrating obviousness, the marginal burden of

instituting both is much less than the burden of considering two completely independent petitions. IPR fees are now set to recover the cost of typical proceedings (Final Rule, *Setting and Adjusting Patent Fees During Fiscal Year 2017*, 82 Fed. Reg. 52780, 52790 (2017)), so Board resources would not be adversely affected.

Any additional burden on Sanofi should also be much less than usual because a single deposition will suffice for both trials and many of Sanofi's arguments and proofs should be the same. Moreover, Sanofi has moved to amend claims in other injector-pen IPRs. See IPR2018-01679, -01680 and -01682. In the event of an amendment for these claims, the parties, the Board and the public are all best served if likely prior art is already of record and under consideration to focus the scope of the amendment.

II. DIFFERENCES IN THE PETITIONS; RANKING

The patent claims a drug-delivery device having a spring washer with fixing elements. To address the apparent means-plus-function nature of the fixing limitation, both grounds use the same reference (De Gennes) to show a specific spring-washer structure. Each ground takes a different route to providing the basic drug-delivery device having a spring washer.

The first ground starts with Burren, an injector pen disclosing a coil-like spring to secure the drug cartridge. Burren teaches that the spring may have a

variety of shapes and may include legs. Venezia discloses the use of a spring washer to mediate the coupling of two portions of a syringe. Venezia's washer has a tongue that aligns and holds the washer in position in the barrel of the syringe. The references and accompanying exhibits and analysis show why one skilled in the art would modify Burren to use a washer-like spring in place of a coil-like spring. Burren is cited in the challenged patent's disclosure, but was not applied during examination. Venezia was not before the examiner.

The second ground starts with the Bitdinger reference, which teaches a reusable drug-delivery pen. Bitdinger relies on a stop to secure the drug cartridge within the pen. Schofield teaches the use of a resilient cushion or spring-loaded metallic washer for the same purpose in a syringe. The references and accompanying exhibits and analysis show why one skilled in the art would modify Bitdinger's drug-delivery device to use a spring washer in place of the stop. Bitdinger was not before the examiner. Schofield was cited but not applied during examination.

Ranking the petitions is difficult because they both provide strong, complementary approaches to demonstrating obviousness. The Burren reference has been widely used in foreign proceedings, even to show lack of novelty, but the claims and laws in those proceedings are materially different. Hence, at most, global uniformity might provide a modest justification to rank ground 1 before

ground 2. Claim construction is also a factor because the claims have limitations that could be read as means-plus-function limitations. If the Board should adopt a means-plus-function construction, then the Bitdinger reference of ground 2 provides a more direct equivalence to Sanofi's corresponding structure. The best course, however, would be to institute both grounds.

III. CONCLUSION

The challenged claims are unpatentable. Mylan respectfully requests institution of both grounds.

Dated: 7 October 2019

/Richard Torczon/
Richard Torczon, Reg. No. 34,448
Counsel for Mylan

CERTIFICATE OF SERVICE

I certify that today this EXPLANATION OF MULTIPLE PETITIONS CHALLENGING PATENT NO. RE47,614 AND RANKING OF PETITIONS was served by Priority Mail Express Delivery on the Patent Owner's correspondence address of record for this patent as follows:

FISH & RICHARDSON P.C.
P.O. Box 1022
Minneapolis, MN 55440-1022

Respectfully submitted,

Dated: 7 October 2019

/Richard Torczon/
Reg. No. 34,448