

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 No. 8,603,044

**MYLAN PHARMACEUTICALS INC.
OBJECTIONS TO EVIDENCE SUBMITTED WITH
PATENT OWNER RESPONSE
37 CFR §42.64(b)(1)**

I. OBJECTIONS

Petitioner (“Mylan”) submits the following objections:

1. **Declarations of Dr. Alexander Slocum, Dr. Robin S. Goland (Exhibits 2107, 2108, 2111, 2112)**

Grounds for objection: FRE 801-804.

To the extent that the declarants have not yet been made available for deposition, the declarations constitute hearsay.

Grounds for objection: FRE 702, 703, 705.

The declarations of Dr. Slocum and Dr. Goland do not provide sufficient facts or data, are not the product of reliable principles and methods, and have not applied the proper principles to the facts of this proceeding. In addition, the declarations do not disclose the underlying facts and data, and do not set forth the bases of their opinions.

For example, Appendices A through F of Dr. Slocum’s Declaration (EX2107) do not set forth the principles used nor do they demonstrate the calculations used in generating the spreadsheets.

Grounds for objection: FRE 402-403.

The declarations of Dr. Slocum and Dr. Goland do not apply a proper obviousness standard, and are thus irrelevant to the grounds of challenge. In addition, to the extent the declarants are alleging secondary considerations, they do

not establish a nexus between those considerations and the claims, and are again irrelevant. The declarations are also prejudicial and confuse the issues as a result.

To the extent the exhibits are admitted, their scope should be restricted to the purpose for which it was originally submitted. FRE 105.

2. Animations (Exhibits 2117, 2147-2152, 2162, 2167, 2168, 2206, 2207, 2211, 2215-2218)

Grounds for objection: FRE 801-804, 901.

The animations are offered, without sufficient foundation, purportedly to show animated operations of prior art and non-prior art injection pens. The animations are hearsay because they are offered for the truth of its content without satisfying any of the hearsay exceptions. In addition, the animations lack sufficient support to show that it is what Sanofi purports it to be.

Grounds for Objection: 401-402.

The animations are irrelevant to the extent they rely on an improper standard of obviousness.

To the extent the exhibits are admitted, their scope should be restricted to the purpose for which they were originally submitted. FRE 105.

3. Exhibits not discussed in Patent Owner Response (Exhibits 2100-2106, 2111-2116, 2118-2135, 2138-2146, 2151, 2158-2161, 2166-2174, 2176-2201, 2203-2205, 2208-2210, 2212, 2214)

Grounds for objection: FRE 402-403.

The exhibits are irrelevant as they are not discussed in the Patent Owner Response. These exhibits are also prejudicial and confuse the issues as a result.

To the extent the exhibits are admitted, their scope should be restricted to the purpose for which they were originally submitted. FRE 105.

4. Exhibits related to commercial pens (Exhibits 2136, 2137, 2175)

Grounds for objection: FRE 402-403.

The exhibits, which relate to commercial pens and their properties, such as injection force, are irrelevant to the extent they rely on an improper standard of obviousness. These exhibits are also prejudicial and confuse the issues as a result.

To the extent the exhibits are admitted, their scope should be restricted to the purpose for which they were originally submitted. FRE 105.

Respectfully submitted,

Dated: 2 July 2019

/ Richard Torczon /
Richard Torczon, Reg. No. 34,448

CERTIFICATE OF SERVICE

I certify that today I caused a true and correct copy of **Mylan Pharmaceuticals Inc. Objections to Evidence Submitted with Patent Owner Response**, on the Patent Owner at the email correspondence addresses of the Patent Owner as follows:

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Respectfully submitted,

Dated: 2 July 2019

/ Richard Torczon /
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