Filed: July 23, 2018

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 IPR2017-01528
Patent Number: 7,713,930

PATENT OWNER SURREPLY

Sanofi's Patent Owner Response demonstrated that Mylan failed to produce evidence that a POSITA would have known or expected that the original, FDA-approved LANTUS formulation was prone to aggregation under normal storage and use conditions. Faced with a Petition that failed to prove obviousness, Mylan hired a new expert (at $2,000/hour) to improperly espouse new theories that likewise fail on the merits. Mylan now argues that confidential documents of customer complaints of turbid Lantus vials show that "the public knew insulin glargine had an aggregation problem." Reply at 4. None of these documents are prior art, and none demonstrate that a POSITA would have known about a glargine aggregation problem. These documents cannot fill the void in Petition nor do they create a motivation for a POSITA to modify the original Lantus formulation. Moreover, confidential documents, which are not prior art and reflect the knowledge of the inventors ***after*** they had already experienced the problem, conducted an extensive internal investigation, and achieved success solving the problem, cannot be used to show what a POSITA would have known or expected.

Mylan has failed to establish that Sanofi's confidential documents (Exs. 1144, 1148, 1152, 1154-55, 1158, and 1160) or the "MedWatch" reports (Exs. 1057, 1058) show that a POSITA would have known that glargine had an aggregation problem. As an initial matter, Mylan fails to establish they are prior

art.[1] *Astra v. Andrx.*, 222 F. Supp. 2d 423, 591 (S.D.N.Y. 2002), *aff'd,* 84 F. App'x 76 (Fed. Cir. 2003) ("Astra's confidential internal work is not in the public domain and is not available as prior art."). Moreover, even assuming for the sake of argument that the documents were available as prior art, nothing correlates the turbidity of the vials with an aggregation problem under normal storage and use conditions.[2] Indeed, during the recent Merck trial, Judge Andrews confirmed that Lantus turbidity and aggregation were "low probability events" not reflected in the prior art, and that the alleged customer complaints are "irrelevant." Ex. 2051 at 7.

Mylan's cited case law does not support its argument that knowledge of a problem can be imputed to a POSITA based on patients' confidential complaints. *Intercont. Great Brands* involved a problem that was admittedly well-known to a POSITA. 118 F. Supp. 3d 1022, 1035 (N.D. Ill. 2015). *Nat'l Steel Cars* involved only a finding that the knowledge of a specific, identified individual with technical expertise may be relevant to whether a POSITA would have motivation to combine the references at issue. 357 F.3d 1319, 1339 (Fed. Cir. 2004).

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[1] Mylan also states that an FDA Field Alert (referenced in confidential Ex. 1160) "issued to the public," but cites no evidence to support that assertion.

[2] Mylan's new arguments regarding a Walgreens recall due to unrefrigerated shipping, and one Lantus vial left in a hot car confirm that turbidity is insufficient to motivate reformulation. Mishandling can cause turbidity, and Mylan cannot credibly argue that mishandling would have motivated a POSITA to reformulate.

Mylan argues that the confidential documents "confirm public knowledge that insulin glargine is prone to aggregation." Reply at 11-14. Mylan, however, fails to differentiate between a POSITA's knowledge based on the prior art, and knowledge of the inventors. The former is relevant to obviousness, the latter is not. The confidential documents relied on by Mylan (Exs. 1144, 1146, 1148, 1151-1153, 1156, 1159, and 1161) reflect the inventors' knowledge ***after*** they had identified a problem with Lantus, conducted an extensive internal investigation, or successfully reformulated. These documents cannot be divorced from the unique knowledge of the Sanofi inventors. Indeed, both show that Sanofi ***did not*** expect an aggregation problem. The recent trial testimony of Dr. Norbert Lill, an inventor, and Angela Moskow, a prior Lantus Product Manager, confirmed that Sanofi was surprised by the turbidity complaints, having not had similar issues after launching in Europe, and embarked on an extensive investigation to identify the source of the problem. Ex. 2052 at 72:11-76:10; 78:15-79:1; 99:8-100:17; 100:18-106:18 (discussing Exs. 1151-52); 108:2-9. Dr. Goland, a Columbia endocrinologist, confirmed that she never heard of complaints from her patients about turbid vials. *Id*. at 161:6-162:3. The Lantus reformulation that resulted in the claimed invention was a "last resort," *id*. at 103:3-103:19, without any expectation of success given the unique properties of Lantus.

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Respectfully submitted,

/Elizabeth Stotland Weiswasser/
Elizabeth Stotland Weiswasser
Reg. No. 55,721
Lead Counsel for Patent Owner
Anish R. Desai
Reg. No. 73,760
Aaron L. J. Pereira
Reg. No. 71,839
Backup Counsel
Weil, Gotshal & Manges LLP
767 Fifth Avenue
New York, NY 10153
Phone: 212-310-8000

Attorneys for Patent Owner

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on July 23, 2018, the foregoing **PATENT OWNER'S MOTION TO STRIKE** was served via electronic mail, upon the following:

Jeffrey W. Guise
Lorelei Westin
Clark Lin
WILSON SONSINI GOODRICH & ROSATI
650 Page Mill Road
Palo Alto, CA 94304
jguise@wsgr.com
lwestin@wsgr.com
clin@wsgr.com

Richard Torczon
WILSON SONSINI GOODRICH & ROSATI
1700 K Street NW, 5th Floor
Washington, D.C. 20006
rtorczon@wsgr.com

Douglas H. Carsten
Alina Litoshyk
Elham F. Steiner
WILSON SONSINI GOODRICH & ROSATI
12235 El Camino Real, Suite 200
San Diego, CA 92130
dcarsten@wsgr.com
alitoshyk@wsgr.com
esteiner@wsgr.com

/Timothy J. Andersen/
Timothy J. Andersen
Case Manager
Weil, Gotshal & Manges LLP
2001 M Street, NW, Suite 600
Washington, DC 20036
timothy.andersen@weil.com