NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S. LLC et al.,	:	
Plaintiffs,	:	Civil Action No. 17-9105 (SRC)
v.	:	
MYLAN GMBH et al.,	:	**OPINION**
Defendants.	:	

CHESLER, U.S.D.J.

INTRODUCTION

Plaintiffs Sanofi-Aventis U.S. LLC, Sanofi- Aventis Deutschland GmbH, and Sanofi Winthrop Industrie (collectively, "Sanofi") bring this action for patent infringement against Defendants Mylan GmbH, Biocon Ltd., Biocon Research Ltd., Biocon Sdn. Bhd., and Biocon S.A. (collectively, "Mylan.") Plaintiffs own U.S. Patent No. 9,526,844 ("the '844 patent"), which is listed in the Orange Book as protecting Plaintiffs' Lantus® SoloSTAR® insulin pen product. Mylan GmbH has filed New Drug Application ("NDA") No. 210605 seeking approval to market an insulin pen product. Plaintiffs complain that, by filing this NDA with the United States Food and Drug Administration, Defendants have infringed claims 21, 22, 25, and 30 of the '844 patent. Mylan contends that the asserted patent claims are invalid, pursuant to 35 U.S.C. § 112 ¶ 1 and 35 U.S.C. § 103. A bench trial on patent infringement and patent validity was held for 5 days, beginning on December 2, 2019, and ending on December 6, 2019. Upon hearing

the evidence presented at trial, this Court finds that Sanofi has failed to prove that claims 21, 22, 25, and 30 are infringed by Mylan's NDA product, and Mylan has proven that the asserted claims are invalid for failure to satisfy the written description requirement stated in 35 U.S.C. § 112 ¶ 1.

STIPULATED FACTS

The parties stipulated to the following facts in the Final Pretrial Order ("FPO"):

72. The following documents are prior art to the Device Patents under 35 U.S.C. § 102:

a. U.S. Patent No. 4,865,591 ("Sams")

b. U.S. Patent No. 6,235,004 ("Steenfeldt-Jensen")

c. U.S. Patent No. 5,674,204 ("Chanoch")

d. U.S. Patent No. 6,221,046 ("Burroughs")

e. U.S. Patent No. 7,241,278 ("Møller")

f. U.S. Patent No. 6,248,095 ("Giambattista '095")

g. U.S. Patent No. 6,582,404

h. U.S. Patent App. Pub. No. 2002/0052578

i. EU Patent Specification EP 0 608 343

j. Erdman Arthur G & Sandor, George N., Mechanism Design: Analysis and Synthesis, 110-20 (Prentice Hall 1984)

k. Sclater, Neil & Chironis, Nicholas P., Mechanisms & Mechanical Devices Sourcebook, 191-95 (McGraw Hill, 3d ed. 2001)

l. European Standard EN ISO 11608-1 (Dec. 2000)

THE ISSUES FOR TRIAL

1. Have Plaintiffs proven, by a preponderance of the evidence, that Defendants' NDA product infringes claims 21, 22, 25, or 30 of the '844 patent?

2. Have Defendants proven, by clear and convincing evidence, that claims 21, 22, 25, and 30 of the '844 patent are invalid as obvious, pursuant to 35 U.S.C. § 103?

3. Have Defendants proven, by clear and convincing evidence, that claims 21, 22, 25, and 30 of the '844 patent are invalid for lack of adequate written description, pursuant to 35 U.S.C. § 112 ¶ 1?

4. Have Defendants proven, by clear and convincing evidence, that claims 21, 22, 25, and 30 of the '844 patent are invalid for lack of enablement, pursuant to 35 U.S.C. § 112 ¶ 1?

THE EVIDENCE AT TRIAL

What follows are selected summaries of the testimony of the witnesses appearing in Court at trial:

A. Testimony of Robert Veasey

What follows is a summary of the witness's testimony. Mr. Veasey is a co-inventor, with Robert Perkins and David Plumptre, on the '844 patent. (Tr. 33:25-34:2.) The SoloSTAR® pen injector is a commercial product that came from this project. (Tr. 36:19-21.) The project to develop SoloSTAR® was named "Alpha." (Tr. 38:8-10.) When he began work on the Alpha project, three disposable injector pens were available to consumers, Opti Set, Humalog, and Novo's FlexPen, which was considered better than the others. (Tr. 38:11-22.) The Alpha team studied the FlexPen and measured aspects of it, including the coefficient of

friction. (Tr. 39:2-8.) The coefficient of friction is a measure of the resistance to sliding of two components in contact with each other. (Tr. 40:10-13.) The team derived a coefficient of friction of .15 for the FlexPen, based on the measured value of the most critical friction interface in the device, which was between the dial, the dose dial and the body. (Tr. 40:15-20.) Mr. Veasey told Dr. Slocum that .1 was the lowest realistic value that one could achieve for the coefficient of friction in a high-volume product like SoloSTAR® or FlexPen, if one used tribological grades of polymers, which have additives in them that make them slip particularly well. (Tr. 41:1-10.)

The team studied the FlexPen and found shortcomings, and designed the SoloSTAR® to improve on them. (Tr. 42:4-20.) In the real world, the coefficient of friction affects the amount of force a user must use to depress the pen button. (Tr. 44:4-16.) One goal for the design project was a pen with low injection force, because the elderly diabetes population has lower hand strength. (Tr. 46:15-47:15.) Another goal was a pen that had a maximum insulin dose of 80 units or more. (48:10-16.) SoloSTAR® is about 40 percent lower injection force than FlexPen. (Tr. 50:20-21.) The ’844 patent embodies the team’s design concept 12. (Tr. 56:25-57:1.) A patent application for the SoloSTAR® design was filed in Great Britain in March of 2003, and it has essentially the same specification as the ’844 patent has. (Tr. 57:9-23.)

The OptiClik was a reusable pen injector from Sanofi with a very different mechanism from SoloSTAR®. (Tr. 58:7-13.) To date, about 3 billion SoloSTAR® pens have been sold. (Tr. 61:4-5.) The SoloSTAR® has been awarded a number of industry awards. (Tr. 61:6-23.)

On cross-examination, Mr. Veasey said that he held an actual FlexPen at the end of 2001. (Tr. 64:1-11.)

B. Testimony of Charles Reinholtz

What follows is a summary of the witness's testimony. Dr. Reinholtz was qualified as an expert in mechanical engineering mechanisms as it relates to the issues of infringement in this case. (Tr. 89:15-20.) Dr. Reinholtz identified exhibit PTX-894 as the assembled Semglee[1] pen. (Tr. 92:12-14.) Becton Dickinson is the company that designed the Semglee pen. (Tr. 93:16-20.) As to '844 claim 21, the parties have agreed that only three elements are disputed as to infringement; the first is 21e. (Tr. 97:4-25.)

Limitation 21e states: "A sleeve that is disposed between the dose indicator and the driving member and releasably connected to the dose indicator." (Tr. 97:25-98:2.) The parties' dispute over 21e concerns the "releasably connected" limitation. (Tr. 98:3-6.) Defendants have taken the position that this means connected when the device is in a resting state, but Dr. Reinholtz disagreed with this. (Tr. 98:7-13.) He disagreed because the claim limitation does not require it to be connected in any particular state. (Tr. 98:15-16.)

The language of limitation 21e does not require that the sleeve is connected to the dose indicator during dose setting or injection. (Tr. 98:17-23.) The sleeve in the patent claims is called the setback in the Semglee, and the dose indicator is called the dose set knob in the Semglee. (Tr. 99:4-16.) In the Semglee, the setback is releasably connected, in rotation, to the dose set knob. (Tr. 99:17-23.) The NDA for the Semglee says that, when the user dials up a dose, there is no pressure on the button to lock the DSK and setback together so that the DSK can rotate freely whilst the setback remains rotationally static. (Tr. 100:17-24.) Then, to

[1] "Semglee" is one of the names used to refer to Mylan's accused pen, which is also called "Vystra." "Vystra" is the name that this Opinion will generally use for Mylan's accused device.

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