

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 IPR2017-01526¹ (Patent 7,476,652 B2)
Case IPR2017-01528 (Patent 7,713,930 B2)

Before ERICA A. FRANKLIN, ROBERT A. POLLOCK, and
MICHELLE N. ANKENBRAND, *Administrative Patent Judges*.

ANKENBRAND, *Administrative Patent Judge*.

ORDER
Conduct of the Proceeding
Authorizing Sur-reply and Sur-sur-reply
37 C.F.R § 42.5

¹ We exercise our discretion to issue one order to be entered in both cases. The parties are not authorized to use this style heading for subsequent papers without prior Board approval.

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On September 24, 2018, the Board held a conference call between counsel for the parties and Judges Ankenbrand and Pollock. We scheduled the conference call to notify the parties that we were considering authorizing additional briefing regarding Petitioner’s argument, made in the Reply, that Lantus Label’s² teaching of different in-use storage requirements would have indicated an aggregation problem that would have led a person of ordinary skill in the art to modify the Lantus formulation (the “in-use storage requirement argument”). Petitioner arranged for a court reporter to transcribe the conference call, and has filed a rough transcript as an exhibit in each proceeding (Ex. 1186, “Tr.”). Petitioner will file the final version of the transcript when it becomes available.

BACKGROUND

Previously, we authorized Patent Owner to file a motion to strike certain arguments Petitioner made in the Reply. *See* Ex. 2055, 43:3–20 (Transcript of July 17, 2018 Teleconference).³ We also authorized Patent Owner to file a sur-reply, but not as to the in-use storage requirement argument. *See id.* at 42:13–43:2. In its motion, Patent Owner requested to strike, *inter alia*, Petitioner’s argument that “a [person of ordinary skill in the art] ‘would have understood the different storage requirements as suggesting a propensity for insulin glargine to aggregate.’” Paper 47, 2.

During the oral hearing in these proceedings, Patent Owner argued that the way that Petitioner presented its case created a due process issue that

² Physicians’ Desk Reference, Lantus entry 709–713 (55th ed. 2001) (Ex. 1004).

³ Unless otherwise noted, citations are to the papers and exhibits filed in IPR2016-01526.

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the sur-reply and oral hearing could not remedy. Specifically, Patent Owner argued that it was unable to respond with its own evidence as to the issues it raised in the motion to strike, including Petitioner's in-use storage requirement argument. After having considered Patent Owner's due process assertion further, we were persuaded that additional briefing regarding the in-use storage requirement argument might be helpful in resolving the disputed issues in these proceedings.

DISCUSSION

During the conference, we explained that the panel contemplated authorizing further briefing according to the following parameters. Within one week, Patent Owner would file a six-page sur-reply limited to whether one of ordinary skill in the art would have understood the different storage requirements in the Lantus Label to suggest a propensity for insulin glargine to aggregate. *See* Tr. 3:3–4:14, 22:2–6. In support of its sur-reply, Patent Owner could file testimonial evidence from its declarant, Dr. Trout, but no other testimonial or documentary evidence. *Id.* at 4:14–17. Petitioner would respond one week later with a four-page sur-sur-reply. *Id.* at 4:23–25. We would not authorize additional evidence from Petitioner, but would allow Petitioner to reference Dr. Trout's cross-examination testimony in the sur-sur-reply. *Id.* at 5:1–5.

Although Patent Owner initially appeared inclined to reject the opportunity for further briefing unless the Board specifically was going to require it (Tr. 14:15–18:16), both parties were ultimately amenable to further briefing. *See generally* Tr. Patent Owner objected to limiting its supporting evidence to testimony from Dr. Trout and requested additional evidence including documents and potential testimony from fact witnesses related to

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confidential documents. *Id.* at 5:12–24, 7:10–15, 9:6–11:5. Petitioner sought leave to introduce additional evidence, if necessary, to rebut Patent Owner’s evidence. *Id.* at 11:8–12:15. Both parties objected to the time limits suggested by the panel. *Id.* at 22:7–18.

After considering the parties’ arguments, we concluded that we would authorize a six-page sur-reply for Patent Owner and a four-page sur-sur-reply for Petitioner. *Id.* at 20:14–21:3. We reconsidered the initial limitation on evidence that Patent Owner could submit (if it so desired) to support its sur-reply and determined that we would not limit such evidence to testimony from Dr. Trout. *Id.* at 21:4–11. We did not authorize Petitioner to file additional evidence supporting its sur-sur-reply, but invited Petitioner to renew its request at the appropriate time should such a request become necessary. *Id.* at 21:18–25.

We took under advisement the timing of the parties’ briefing. *Id.* at 22:25–23:6. Patent Owner requested two weeks to file its sur-reply and supporting evidence. Petitioner did not object and requested two weeks to file its sur-sur-reply. *Id.* at 22:7–18. The parties agreed that they would work together with respect to scheduling and completing depositions in a timely manner in order to fit within the timeline they proposed. Having further considered the requests, we determine that the four-week timeline that the parties proposed for completing the briefing is appropriate. Patent Owner’s sur-reply will be due by close of business on Tuesday, October 9, 2018, and Petitioner’s sur-sur-reply will be due by close of business on Tuesday, October 23, 2018.

It is

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ORDERED that Patent Owner is authorized to file a six-page sur-reply and any supporting evidence, limited to addressing Petitioner's in-use storage requirement argument, on or before close of business on Tuesday, October 9, 2018;

FURTHER ORDERED that Petitioner is authorized to file a four-page sur-sur-reply, limited to addressing the in-use storage requirement argument, on or before close of business on Tuesday, October 23, 2018; and

FURTHER ORDERED that Petitioner is not authorized at this time to file supporting evidence with its sur-sur-reply.

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