Paper 54 Entered: February 23, 2018

APOTEX INC., APOTEX CORP.,
ARGENTUM PHARMACEUTICALS LLC,
ACTAVIS ELIZABETH LLC, TEVA PHARMACEUTICALS USA, INC.,
SUN PHARMACEUTICAL INDUSTRIES, LTD.,
SUN PHARMACEUTICAL INDUSTRIES, INC., and
SUN PHARMA GLOBAL FZE,
Petitioners,

v.

NOVARTIS AG., Patent Owner.

Case IPR2017-00854¹ Patent US 9,187,405 B2

Before LORA M. GREEN, CHRISTOPHER M. KAISER, and ROBERT A. POLLOCK, *Administrative Patent Judges*.

POLLOCK, Administrative Patent Judge.

ORDER
Conduct of the Proceeding
37 C.F.R. § 42.5

¹ Cases IPR2017-01550, IPR2017-01946, and IPR2017-01929 have been joined with this proceeding.



A conference call in the above proceedings was held on February 21, 2018, among counsel for the respective Petitioners, Patent Owner, and Judges Pollock, Green, and Kaiser to discuss issues raised in Patent Owner's email dated February 20, 2018. Ex. 3004.

In short, Patent Owner seeks authorization to file a motion to strike Petitioner's Reply Brief or, in the alternative, for additional pages in its Reply to Petitioner's Opposition to Motion to Amend, in which to submit sur-reply arguments. This issue relates to Patent Owner's argument that "pharmacokinetic data evidenced by Webb, Kahan 2003, and Park would have indicated to those of ordinary skill in the art that 0.5mg/day of fingolimod would not result in sufficient lymphopenia to successfully treat RR-MS." *See* Paper 11, 19. In our Decision on Institution we informed the parties that "[w]e . . . look forward to further development of this issue at trial." *Id.* at 20. In addressing Patent Owner's pharmacokinetic argument, Petitioner filed the declaration of a new expert, Dr. Leslie Benet, with its Reply to the Patent Owner Response, which Patent Owner contends is prejudicial.

Also during the conference call, the parties indicated disagreement in scheduling Dr. Benet's deposition prior to Due Date 3, the due date for Patent Owner's Reply to Petitioner's Opposition to Motion to Amend. Petitioner took the position that there was no need to schedule Dr. Benet's deposition before Due Date 3 because Petitioner did not cite Dr. Benet's testimony in its Opposition to Patent Owner's Motion to Amend.

Patent Owner engaged a court reporter for the call. Patent Owner will submit a copy of the transcript as an exhibit, which will serve as the official record



ORDER

Having considered the parties' positions, it is:

ORDERED that Patent Owner's request to file a motion to strike is denied.

FURTHER ORDERED that Patent Owner's request for additional pages in its Reply to Petitioner's Opposition to Motion to Amend is denied.

FURTHER ORDERED that, on or before March 16, 2018, Patent Owner may file a sur-reply not to exceed 15 pages addressing Petitioner's response to Patent Owner's pharmacokinetic argument. Patent Owner's sur-reply may be supported by additional testimonial evidence.

FURTHER ORDERED that the parties will hold the deposition of Dr. Benet at least 10 days prior to DUE DATE 3. Dr. Benet may be cross-examined on any issue raised in his expert report.

FURTHER ORDERED that the parties will use best efforts to adjust DUE DATES 3 through 6 in order to effect the timely cross-examination of Dr. Benet, as well as any other person submitting testimonial evidence in connection with Patent Owner's sur-reply.

FURTHER ORDERED that in the unlikely event the parties cannot agree on a schedule in accordance with the above, they shall jointly submit proposed schedules for the efficient conduct of this case, showing areas of agreement and disagreement, with a bullet point explanation for each area of disagreement.



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