

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAMSUNG BIOEPIS CO., LTD.,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

Case IPR2023-00884

U.S. Patent No. 11,253,572

JOINT SUMMARY OF RELATED PROCEEDINGS

Pursuant to the Board’s April 18, 2024 email (Ex. 3002), the parties have prepared the following summary to update the Board on the related district court litigation, *Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc.*, No. 1:22-cv-00061 (ND WV) (the “Mylan Litigation”).

Joint Summary

On December 27, 2023, the District Court in the Mylan Litigation issued a decision concerning the patentability of U.S. Patent No. 11,253,572 (the “’572 patent”). Ex. 2093 (“Memorandum Opinion and Order”). In the Memorandum Opinion and Order, the District Court found “claim 6 of the ’572 patent is rendered obvious by the combination of Dixon and Hecht.” *Id.* at 236. The District Court also found “claim 25 of the ’572 patent [is] invalid as obvious in view of both the [U.S. Patent No. 7,303,747] alone, and the 9-14-2009 Press Release alone.”¹ *Id.* at 274.²

¹ “The Court also [found] that . . . claim 25 of the ’572 patent [is] invalid as obvious in view of both the ’747 patent, and the 9-14-2009 Press Release, either one in combination with Do 2009 and Lalwani 2009b.” *Id.* at 274.

² The Dixon, Hecht, and 9-14-2009 Press Release are also at issue in this proceeding. See Ex. 1009 (Dixon); Ex. 1016 (Hecht); Ex. 1005 (2009 Press Release).

On January 26, 2024, the parties to the Mylan Litigation appealed the Memorandum Opinion and Order, including the decision regarding the invalidity of the '572 patent, to the Federal Circuit. *See* Federal Circuit Appeal Nos. 2024-1402, 2024-1405. Before substantive briefing occurred, on April 12, 2024, both appeals were dismissed based on the parties' agreement that the Federal Circuit lacked subject matter jurisdiction given that the District Court's Memorandum Opinion and Order resolved fewer than all claims at issue. *Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc and Biocon Biologics Inc.*, Appeal No. 24-1402, Dkt. No. 26 (Fed. Cir., Apr. 12, 2024). Consequently, at the moment, there are currently no pending appeals of the District Court's Memorandum Opinion and Order. Currently pending before the District Court is Regeneron's motion for permanent injunction, which does not involve the '572 patent, or any member of the '572 patent family. *See Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc and Biocon Biologics Inc.*, Case No. 22-cv-61, Dkt. No. 708 (N.D.W. Va., Feb. 22, 2024). Both the District Court's decision regarding the invalidity of the '572 patent and the District Court's April 19, 2023 Order construing certain claim terms in the '572 patent will be subject to appeal upon entry of a final judgment from the District Court.

DATED: April 29, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies that a copy of the Joint Summary of Related Proceedings was served on April 29, 2024, to Counsel for Patent Owner Regeneron via email to Regeneron-MoFo-IPR@mofo.com; Counsel for Biocon Biologics, Inc. at MYL_REG_IPR@rmmslegal.com; and Counsel for Celltrion, Inc. at lgreen@geminilaw.com, fchu@geminilaw.com, rcerwinski@geminilaw.com, azalcenstein@geminilaw.com, and bmorris@geminilaw.com.

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