

Filed on behalf of Patent Owners Genentech, Inc. and City of Hope by:

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SANOFI-AVENTIS U.S. LLC,
REGENERON PHARMACEUTICALS, INC., AND,
GENZYME CORPORATION,
Petitioners,

v.

GENENTECH, INC. AND CITY OF HOPE,
Patent Owners.

Case IPR2015-01624¹
Patent 6,331,415

**PATENT OWNERS' NOTICE OF FILING OF SUPPLEMENTAL
EVIDENCE**

¹ Case IPR2016-00460 has been joined with this proceeding.

On May 20, 2016, Petitioners filed and served Petitioners' Objections to Evidence Pursuant To 37 C.F.R. § 42.64 in the instant IPR proceeding. *See* IPR2015-01624, Paper No. 29. In particular, Petitioners objected to Exhibit 2035 (File History of U.S. Patent No. 4,495,280), as well as paragraphs 161, 189, and 195 of the Expert Declaration of John Fiddes (Ex. 2019) (all of which pertain to the file history of Exhibit 2035), as lacking completeness under Federal Rule of Evidence 102. *See id.* at 1, 3, 9. Patent Owners disagreed with Petitioners' objections. Furthermore, Petitioners failed to identify any particular pages of the file history in Exhibit 2035 that are purportedly missing.

In order to obviate these objections, Patent Owners requested and obtained a copy of the file history of U.S. Patent No. 4,495,280 that has been certified by the United States Patent and Trademark Office ("USPTO"), and file said certified file history herewith as Exhibit 2141.

On June 6, 2016, Patent Owners filed a Notice Regarding Supplemental Evidence (Paper No. 32), in which Patent Owners notified the Board that the time required to obtain a certified file history from the USPTO can be longer than three weeks. Patent Owners diligently requested this certified file history upon receiving Petitioners' objections, but just recently received the certified file history.

Furthermore, Patent Owners have conferred with Petitioners' counsel and they do not object to Patent Owners' filing of this certified file history after the 10

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Patent Owners' Notice of Filing of Supplemental Evidence

business day deadline for filing of supplemental evidence.

Respectfully submitted,

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Dated: June 30, 2016

Patent Owners' Updated Exhibit List

<u>Patent Owners' Exhibit Number</u>	<u>Exhibit Name</u>
2001	Expert Report of John Fiddes, Ph.D., <i>Bristol-Myers Squibb Company v. Genentech, Inc.</i> , No. 2:13-cv-05400-MRP-JEM (C.D. Cal.) (Nov. 10, 2014) ("Fiddes Rep.")
2002	Declaration of Steven Lanier McKnight Under 37 C.F.R. § 1.132 in Reexaminations 90/007,542 and 90/007,859 (May 18, 2007) ("McKnight Decl.")
2003	Second Declaration of Steven Lanier McKnight Under 37 C.F.R. § 1.132 in Reexaminations 90/007,542 and 90/007,859 (June 3, 2008) ("McKnight Decl. II")
2004	Declaration of Dr. Timothy Roy Harris Under 37 C.F.R. § 1.132 in Reexaminations 90/007,542 and 90/007,859 (Nov. 23, 2005) ("Harris Decl.")
2005	Second Declaration of Dr. Timothy Roy Harris Under 37 C.F.R. § 1.132 in Reexaminations 90/007,542 and 90/007,859 (Oct. 26, 2006) ("Harris II Decl.")
2006	Declaration of Dr. Douglas A. Rice Under 37 C.F.R. § 1.132 in Reexaminations 90/007,542 and 90/007,859 (Oct. 26, 2006) ("Rice Decl.")
2007	Declaration of Michael Botchan Under 37 C.F.R. § 1.132 in Reexaminations 90/007,542 and 90/007,859 (May 20, 2007) ("Botchan Decl.")
2008	Gilbert, W. & Villa-Komaroff, L., <i>Useful Proteins from Recombinant Bacteria</i> , <i>Scientific American</i> , 242:74-94 (1980)
2009	Expert Report of Dr. E. Fintan Walton, <i>MedImmune, Inc. v. Genentech, Inc.</i> , No. 03-cv-2567 (C.D. Cal.) (Feb. 29, 2008) ("Walton Rep.")
2010	Transcript of Deposition of Dr. Jefferson Foote, <i>Bristol-Myers Squibb Company v. Genentech, Inc.</i> , No. 2:13-cv-05400-MRPJEM (Jan. 9, 2015) ("Foote Dep.")
2011	Goeddel, D.V., <i>et al.</i> , <i>Expression in Escherichia coli of chemically synthesized genes for human insulin</i> , <i>Proc. Nat'l Acad. Sci. (USA)</i> 76:106-110 (1979) ("Goeddel 1979")
2012	Frank, B.H., <i>et al.</i> , <i>Two Routes for Producing Human Insulin Utilizing Recombinant DNA Technology</i> , <i>Munch. Med. Wschr.</i> , 125, Suppl. 1:S14-S20 (1983) ("Frank 1983")

Patent Owners' Notice of Filing of Supplemental Evidence

<u>Patent Owners' Exhibit Number</u>	<u>Exhibit Name</u>
2013	Kohler, G. and Milstein, C., <i>Continuous Cultures of Fused Cells Secreting Antibody of Predefined Specificity</i> , Nature 256:495-497 (Aug. 7, 1975) ("Kohler and Milstein")
2014	90/007,542 Office Action Response filed 2/13/2009
2015	Christie, N.T., <i>et al.</i> , <i>Selective amplification of variants of complex repeating unit in DNA of a crustacean</i> , Proc. Nat'l Acad. Sci., 77(5):2786-2790 (1980) ("Christie 1980")
2016	Frommer, <i>et al.</i> , <i>Simple repeated sequences in human satellite DNA</i> , Nuc. Acids Res. 10(2):547-563 (1982) ("Fromer 1982")
2017	Israelewski, N., <i>Structure and function of an AT-rich, interspersed repetitive sequence from Chironomus thummi: solenoidal DNA, 142 bp palindrome-frame and homologes with the sequence for site-specific recombination of bacterial transposons</i> , Nuc. Acids Res. 11(20):6985-6996 (1983) ("Israelewski 1983")
2018	Declaration of Robert J. Gunther Jr. in Support of Motion for Admission Pro Hac Vice
2019	Expert Declaration of John Fiddes, Ph.D., <i>Sanofi-Aventis U.S. LLC v. Genentech, Inc.</i> , IPR2015-01624 ("Fiddes Decl.")
2020	Transcript of Deposition of Dr. Jefferson Foote, <i>Sanofi-Aventis U.S. LLC v. Genentech, Inc.</i> , IPR2015-01624 (Apr. 21, 2016) ("Foote Dep.")
2021	Expert Declaration of Reiner Gentz, Ph.D., <i>Sanofi-Aventis U.S. LLC v. Genentech, Inc.</i> , IPR2015-01624 ("Gentz Decl.")
2022	Falko G. Falkner & Hans G. Zachau, <i>Expression of Mouse Immunoglobulin Genes in Monkey Cells</i> , Nature, 298:286-288 (1982)
2023	Expert Report of Sir Gregory Winter, CBE, FRS, Regarding Invalidity of U.S. Patent Nos. 6,331,415 and 7,923,221, <i>Eli Lilly and Co. v. Genentech, Inc.</i> , No. 2:13-cv-07248-MRP-JEMx (C.D. Cal.) (Oct. 13, 2014)
2024	Transcript of Deposition of Sir Gregory Winter, <i>Eli Lilly and Co. v. Genentech, Inc.</i> , No. 2:13-cv-07248-MRP-JEMx (C.D. Cal.) (Jan. 19, 2015) ("Winter Dep.")
2025	Keiichi Itakura <i>et al.</i> , <i>Expression of Escherichia coli of a Chemically Synthesized Gene for the Hormone Somatostatin</i> , Science, New Series, 198:1056-1063 (1977)

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