

Date Filed: October 6, 2016

Filed on behalf of: Aventis Pharma S.A.

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN LABORATORIES LIMITED

Petitioner,

v.

AVENTIS PHARMA S.A.

Patent Owner.

Case IPR2016-00712
U.S. Patent No. 8,927,592

**PATENT OWNER'S OBJECTIONS UNDER 37 C.F.R. § 42.64
TO EVIDENCE SUBMITTED BY MYLAN DURING
A PRELIMINARY PROCEEDING**

Pursuant to 37 C.F.R. § 42.64(b)(1), Aventis Pharma S.A. (“Aventis”) objects to the admissibility of the following exhibits on the grounds set forth below. All evidence objected to below was submitted by Petitioner Mylan Laboratories Limited (“Mylan”) with its Petition seeking *inter partes* review of U.S. Patent No. 8,927,592 (“the ’592 patent”). The Board instituted review of the ’592 patent on September 22, 2016. *See* Paper 9. Therefore, these objections are timely.

In this paper, a reference to “F.R.E.” means the Federal Rules of Evidence, and a reference to “C.F.R.” means the Code of Federal Regulations. All objections under F.R.E. 802 (hearsay) apply to the extent Mylan relies on the exhibits identified in connection with that objection for the truth of the matters asserted therein.

Aventis objects as follows:

Exhibit 1002 Seth Declaration

Aventis objects to Exhibit 1002 under F.R.E. 702 (improper expert testimony) and F.R.E. 703 (bases for expert opinion) as the testimony is not based on sufficient facts or data, is not the product of reliable principles and methods, and the principles and methods have not been reliably applied to the facts of the case.

Aventis objects to Exhibit 1002 under 35 U.S.C. § 312(a)(3); 37 C.F.R. §§ 42.65(a) and 42.104(b)(5); and F.R.E. 702 (improper expert testimony), 402 (relevance), and 403 (confusing, waste of time) for failing to identify with particularity the underlying facts and data on which the opinion is based: ¶¶ 15, 43-44, 46-47, 57, 69-73, 91, 97-98, 116, 132, 145, 167, 181, 183, 198, 201, 217-220, 223-226 fail to cite any support at all, or include statements that do not cite any support, and ¶¶ 25-27, 48, 60-61, 71, 73, 76, 98 include statements that cite or refer to entire articles or other references without identifying which aspects of those references are relied upon.

Aventis objects to Exhibit 1002 ¶¶ 25-26, 28-30, 51-52, 55, 78, 82-93, 95-97, 99-109, 111, 134, 203-204, 216-219 under F.R.E. 402 (relevance) and 403 (confusing, waste of time) as these paragraphs are not cited in Mylan's Petition.

Aventis further objects to Exhibit 1002 ¶¶ 73, 162-169, 171, 173-196, 198, 200-202, 206-212, 220-221 under F.R.E. 402 (relevance) and 403 (confusing, waste of time) as these paragraphs are cited in Mylan's Petition only with respect to grounds for which *inter partes* review was not authorized.

Aventis also objects to Exhibit 1002 ¶¶ 25-27, 42, 48-50, 52-53, 55, 57, 59-80, 82-111, 115-123, 126-130, 132-135, 137, 139-143, 145-155, 157-181, 183-186, 188-189, 191-192, 194-199, 201-212, 215-216, 219-223, 225-226 under F.R.E. 702 (improper expert testimony), 703 (bases for expert opinion), 402 (relevance),

and 403 (confusing, waste of time) as these paragraphs include expert opinion based on documents that are inadmissible (Exhibits 1008-1013, 1015-1034) under at least F.R.E. 802 (hearsay), 702 (improper expert testimony), 703 (bases for expert opinion), 402 (relevance), or 403 (confusing, waste of time).

Aventis also objects to Exhibit 1002 ¶¶ 79-80, 142, 198, 223-224 under F.R.E. 702 (improper expert testimony), 703 (bases for expert opinion), 402 (relevance), and 403 (confusing, waste of time). The declarant is not stated to have expertise with respect to solid state forms of drugs, improving solubility of drugs, or design and economics of clinical trials.

Exhibit 1004 File History

Aventis objects to Exhibit 1004 under F.R.E. 901 (authenticity), 403 (confusing, waste of time), and 106 (completeness) because it is not a certified copy of the file history, and it includes only a portion of a larger document that in fairness ought to be considered in connection with Exhibit 1004. For example, Exhibit 1004 is missing publications that were part of the file history.

Exhibit 1008 Tropic Listing

Aventis objects to Exhibit 1008 under F.R.E. 901 (authenticity), 802 (hearsay), 402 (relevance), and 403 (confusing, waste of time). Exhibit 1008 on its face does not demonstrate that the information within it was publicly available by October 23, 2008. Exhibit 1026, the Affidavit of Christopher Butler, does not state

that the declarant has any personal knowledge that the information in Exhibit 1008 was publicly available in 2008. Instead, Exhibit 1026 states that the date assigned by the Internet Archive “applies to the HTML file but not to image files linked therein. Thus images that appear on a page may not have been archived on the same date as the HTML file.” Exh. 1026 at 1. Exhibit 1026 does not identify what content in Exhibit 1008 is part of the HTML file versus images that might have been archived on a different date. Furthermore, Exhibit 1008 contains substantially the same disclosure as a listing for the TROPIC study at clinicaltrials.gov last updated on December 28, 2006 that was previously considered by the patent examiner during prosecution of the ’592 patent; therefore Exhibit 1008 needlessly confuses the issues, wastes time, and presents cumulative evidence of the materials that were previously considered by the patent examiner. *See* Exh. 2100; Exh. 1001 at 2; Exh. 1004 at 1891.

Exhibit 1009 Winqvist

Aventis objects to Exhibit 1009 under F.R.E. 802 (hearsay), 402 (relevance), and 403 (confusing, waste of time). Exhibit 1009 contains substantially the same disclosure as the National Horizon Scanning Center (University of Birmingham), Cabazitaxel (XRP-6258) for Hormone Refractory, Metastatic Prostate Cancer – Second Line after Docetaxel (April 2009) that was previously considered by the patent examiner during prosecution of the ’592 patent; therefore Exhibit 1009

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