

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

WATSON LABORATORIES, INC.
Petitioner

v.

UNITED THERAPEUTICS CORP.
Patent Owner

Case : IPR2017-01621
U.S. Patent 9,358,240 B2

Before the Honorable LORA M. GREEN, ERICA A. FRANKLIN, and DAVID
COTTA, *Administrative Patent Judges*.

**PETITIONER'S FIRST SET OF OBJECTIONS
TO PATENT OWNER'S EXHIBITS**

Pursuant to 37 C.F.R. § 42.64(b)(1), the undersigned, on behalf of and acting in a representative capacity for Petitioner Watson Laboratories, Inc., hereby submit the following objections to Patent Owner United Therapeutics Corp.'s ("Patent Owner") Exhibits 2001, 2006, 2009-2020, 2026-2030, and any reference to/reliance on the foregoing. As required by 37 C.F.R § 42.62, Petitioners' objections below apply the Federal Rules of Evidence and are based on currently-applicable law.

Petitioner reserves the right to amend or supplement its objections in response to any change in law or fact.

I. OBJECTIONS TO EXHIBIT 2001

Evidence objected to: Exhibit 2001

Grounds for objection: Exhibit 2001, a document titled “Declaration of Dr. Richard Dalby,” is objected to under Fed. R. Evid. 401, 403, 801 and 802. Exhibit 2001 includes statements that do not make any fact relevant to the grounds upon which trial was instituted more or less probable and any facts that might be established based on this exhibit is of no consequence in determining the issues on which trial was instituted. Introduction and evaluation of Exhibit 2001 would further lead to undue delay, confusion, and a waste of time. Exhibit 2001 also contains out-of-court statements made by one or more declarants for the purpose of proving the truth of the matter asserted, and on which Petitioner has not had a chance to cross exam.

II. OBJECTIONS TO EXHIBIT 2006

Evidence objected to: Exhibit 2006

Grounds for objection: Exhibit 2006, a document titled “Declaration Under 37 C.F.R. § 1.132 of Dr. Edmund J. Elder, Jr.,” and allegedly filed with the United States Patent and Trademark Office in connection with Application No. 12/591,200, is objected to under Fed. R. Evid. 401 and 403. Exhibit 2006 does not make any fact

relevant to the grounds upon which trial was instituted more or less probable and any facts that might be established based on this exhibit is of no consequence in determining the issues on which trial was instituted. Introduction and evaluation of Exhibit 2006 would further lead to undue delay, confusion, and a waste of time.

III. OBJECTIONS TO EXHIBIT 2009

Evidence objected to: Exhibit 2009

Grounds for objection: Exhibit 2009, a document titled “Plaintiff United Therapeutics’ Memorandum of Law in Support of Its Motion for Leave to Amend Its Complaint,” and allegedly filed in connection with an action styled *United Therapeutics Corporation v. Watson Laboratories, Inc.*, Civ. A. No. 3:15-cv-05723-PGS-LHG (D. N.J.) and identified by document number 46-1, is objected to under Fed. R. Evid. 401 and 403. Exhibit 2009 does not make any fact relevant to the grounds upon which trial was instituted more or less probable and any facts that might be established based on this exhibit is of no consequence in determining the issues on which trial was instituted. Introduction and evaluation of Exhibit 2009 would further lead to undue delay, confusion, and a waste of time.

IV. OBJECTIONS TO EXHIBIT 2010

Evidence objected to: Exhibit 2010

Grounds for objection: Exhibit 2010, an email with the subject line: “United Therapeutics Corp. v. Watson Laboratories, Inc.: Civ A. No. 3:15-cv-05723 –

Motion for leave to file an amended complaint,” is objected to under Fed. R. Evid. 401 and 403. Exhibit 2010 does not make any fact relevant to the grounds upon which trial was instituted more or less probable and any facts that might be established based on this exhibit is of no consequence in determining the issues on which trial was instituted. Introduction and evaluation of Exhibit 2010 would further lead to undue delay, confusion, and a waste of time.

V. OBJECTIONS TO EXHIBIT 2011

Evidence objected to: Exhibit 2011

Grounds for objection: Exhibit 2011, an order allegedly granting Plaintiff’s Motion for Leave to File an Amended Complaint and allegedly filed in connection with an action styled *United Therapeutics Corporation v. Watson Laboratories, Inc.*, Civ. A. No. 3:15-cv-05723-PGS-LHG (D. N.J.) is objected to under Fed. R. Evid. 401 and 403. Exhibit 2011 does not make any fact relevant to the grounds upon which trial was instituted more or less probable and any facts that might be established based on this exhibit is of no consequence in determining the issues on which trial was instituted. Introduction and evaluation of Exhibit 2011 would further lead to undue delay, confusion, and a waste of time.

VI. OBJECTIONS TO EXHIBIT 2012

Evidence objected to: Exhibit 2012

Grounds for objection: Exhibit 2012, a document that is allegedly an entry in the online version of the Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, specifically relating to NDA 022387, is objected to under Fed. R. Evid. 401 and 403. Exhibit 2012 does not make any fact relevant to the grounds upon which trial was instituted more or less probable and any facts that might be established based on this exhibit is of no consequence in determining the issues on which trial was instituted. Introduction and evaluation of Exhibit 2012 would further lead to undue delay, confusion, and a waste of time.

VII. OBJECTIONS TO EXHIBIT 2013

Evidence objected to: Exhibit 2013

Grounds for objection: Exhibit 2013, a document titled “Notification of Certification for U.S. Patent Nos. 6,521,212; 6,756,033; and 8,497,393 pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act,” is objected to under Fed. R. Evid. 401 and 403. Exhibit 2013 does not make any fact relevant to the grounds upon which trial was instituted more or less probable and any facts that might be established based on this exhibit is of no consequence in determining the issues on which trial was instituted. Introduction and evaluation of Exhibit 2013 would further lead to undue delay, confusion, and a waste of time.

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