

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC. and MYLAN LABORATORIES
LIMITED,
Petitioners,

v.

UCB PHARMA GMBH,
Patent Owner.

Case IPR2016-00510¹
Patent 6,858,650 B1

**PATENT OWNER'S MOTION TO EXCLUDE EVIDENCE
UNDER 37 C.F.R. § 42.64(c)**

¹ Petitioners Alembic Pharmaceuticals Limited from IPR2016-01596, Torrent Pharmaceuticals Limited from IPR2016-01636, and Amerigen Pharmaceuticals Limited from IPR2016-01665 have been joined as Petitioners to this proceeding.

I. INTRODUCTION

Pursuant to 37 C.F.R. § 42.64(c), Patent Owner UCB Pharma GmbH (“UCB” or “Patent Owner”) moves to exclude from evidence, in their entirety, Exhibit Nos. 1033 and 1034 (the Declaration and CV of economist DeForest McDuff) and Exhibit Nos. 1036-1049 (related to sales, costs, and/or market share of Toviaz®), which were submitted by Mylan Pharmaceuticals Inc. and Mylan Laboratories Limited (“Petitioner”). This motion is timely pursuant to the Consolidated Scheduling Order entered in this proceeding on July 26, 2016.²

II. STATEMENT OF MATERIAL FACTS

Petitioner filed the Exhibits challenged herein with its Petition dated January 28, 2016. Petitioner relies on the challenged Exhibits on pages 54-56 of its Corrected Petition.³ *See* Paper 5. Following institution on July 20, 2016 (Paper 12), UCB timely objected to Exhibit Nos. 1033, 1034, and 1036-1049 by filing Patent Owner’s Notice of Objections to Evidence Pursuant to 37 C.F.R. § 42.64 on August 3, 2016. *See* Paper 16. Petitioner served a Response and Supplemental Evidence on August 17, 2016. *See* Paper 17.

² *See* IPR2016-00516 (Paper 13) (consolidating the schedule in this case with the schedule of related cases: IPR2016-00512, IPR2016-00514, IPR2016-00516, and IPR2016-00517).

³ Exhibits 1039 and 1049 are not cited in the Corrected Petition or in Petitioner’s Declarations.

III. LEGAL STANDARDS

A. Only Relevant Evidence Is Admissible

The Federal Rules of Evidence govern the admissibility of evidence and expert testimony in an *inter partes* review. 37 C.F.R. § 42.62(a). Irrelevant evidence is not admissible. FED. R. EVID. 402. Additionally, relevant evidence may be excluded “if its probative value is substantially outweighed by a danger of ... unfair prejudice, [or] confusing the issues.” FED. R. EVID. 403.

Further, expert opinion “testimony is admissible only if it is both relevant and reliable.” *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999).

B. It Is Patent Owner’s Burden To Produce Commercial Success Evidence

The legal conclusion as to obviousness is based on an underlying factual inquiry into the “Graham factors:” (1) the level of ordinary skill in the art, (2) the scope and content of the prior art, (3) the differences between the claimed subject matter and the prior art, and (4) any objective evidence of nonobviousness. *Eisai Co. v. Dr. Reddy’s Labs., Ltd.*, 533 F.3d 1353, 1356 (Fed. Cir. 2008) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966)). The Fourth *Graham* Factor, objective evidence, may include, *inter alia*, evidence that the claimed invention has been a commercial success. *See, e.g., Procter & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 998 (Fed. Cir. 2009).

“Patent Owners bear a burden of production with respect to evidence of commercial success.” *Torrent Pharm. Ltd. v. Novartis AG*, IPR2014-00784 (P.T.A.B. Sept. 24, 2015) (Paper 112) at 27 (citing *Ecolochem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1361, 1377 (Fed. Cir. 2000)). “If Patent Owners make such a showing, Petitioners may rebut the evidence of commercial success by showing that the commercial success was instead due to other factors extraneous to the patented invention.” *Id.* (internal quotations omitted) (emphasis added); see also *Lupin Ltd. v. Senju Pharm. Co.*, IPR2015-01099 (P.T.A.B. Sept. 12, 2016) (Paper 69) at 36 (“Once a patentee makes the required showing, the burden shifts to the challenger to prove that the commercial success is instead due to other factors extraneous to the patented invention, such as advertising or superior workmanship.”) (internal quotation omitted) (emphasis added).

IV. ARGUMENT

A. Petitioner’s Exhibits Related to Commercial Success (Exhibits 1033-1034 and 1036-1049) Are Not Relevant and Are Inadmissible

UCB, as Patent Owner, bears the burden of production with respect to evidence related to commercial success. See *Torrent*, IPR2014-00784 (Paper 112) at 27. Only after UCB makes a showing of commercial success would the burden shift to Petitioner to present evidence to challenge such a showing. *Id.*; *Lupin*, IPR2015-01099 (Paper 69) at 36. UCB has not introduced as a secondary

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consideration of nonobviousness, the commercial success of Toviaz®. Petitioner's evidence, in the form of expert testimony and exhibits, intended to rebut such a showing of commercial success, is entirely irrelevant and should be excluded. FED. R. EVID. 401-402; *Kumho Tire Co.*, 526 U.S. at 141. The Exhibits that are the subject of this motion are cited, if at all, only in the section of the Corrected Petition related to commercial success (Paper 5 at 54-56) or in the Declaration of Petitioner's economist (Exhibit 1033).

Exhibits 1039 and 1049 should additionally be excluded because Petitioner has not cited them in its papers, nor made no attempt to explain their relevance to its arguments.

B. Petitioner's Improperly Filed Supplemental Evidence (Exhibits 1050-1072) Did Not Resolve UCB's Objections and Should Be Expunged

After UCB objected to Petitioner's Exhibits 1033, 1034, and 1036-1049 (Paper 16), Petitioner filed a Response to Patent Owner's Objections and Supplemental Evidence Pursuant to 37 C.F.R. § 42.64(b)(2). *See* Paper 17. With its Response, Petitioner filed 23 additional Exhibits (Exhibit Nos. 1050 – 1072) as supplemental evidence, intended to “provide additional foundation and authenticity support” and to resolve the objections to the Exhibits that are the subject of this motion. Paper 17 at 10. As supplemental evidence, Exhibits 1050-1072 “may be relied upon to support admissibility arguments but not arguments on the merits.”

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