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 IPR2016-00510[1]
Patent 6,858,650 B1

PATENT OWNER'S REPLY TO OPPOSITION TO 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.

UCB Pharma GmbH ("UCB" or "Patent Owner") submits this reply in support of its motion to exclude evidence of Mylan Pharmaceuticals Inc. and Mylan Laboratories Limited ("Petitioner") pursuant to 37 C.F.R. §§ 42.64(c), 42.23 and the Scheduling Order entered in this proceeding.

I. PETITIONER'S COMMERCIAL SUCCESS EVIDENCE (EXHIBIT NOS. 1033-1034, 1036-1049) SHOULD BE EXCLUDED

A. Petitioner Identifies No Precedent Supporting Its Introduction of Commercial Success Evidence

An affirmative showing of commercial success may suggest long felt need, as in *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 546 (Fed. Cir. 1998), cited by Petitioner. This does not lead to Petitioner's proposed legal proposition – that a patent challenger can introduce evidence of a product's purported market share and marketing spend to somehow disprove medical evidence of therapeutic need. In fact, Petitioner cites no case in which a patent challenger was allowed to introduce commercial success evidence when the patent owner had not first introduced evidence of commercial success.

Petitioner cites *Santarus, Inc. v. Par Pharm., Inc.*, 720 F. Supp. 2d 427 (D. Del. 2010) for the proposition that commercial success is relevant to the long felt need inquiry. Petitioner's Response (Paper 39) at 2. The *Santarus* court, after considering the evidence of long felt need (unrelated to sales), held there was no need "for advancements on the existing prior art," but rather, if anything, only a

need for recognition of the "commercial potential of what already existed in the prior art." *Santarus*, 720 F. Supp. 2d at 455. The court continued, in dicta cited by Petitioner, that "even this commercial and marketing 'need' has not proven to be substantial, since [ ] sales continue to be dwarfed…" *Id.* Although Petitioner's Opposition would suggest otherwise, the *Santarus* court's findings on long felt need did not turn on commercial success evidence, which was of record only because patent owner had advanced it as a separate indicium of non-obviousness.

The additional authority cited by Petitioner does not help its argument either. Unlike UCB, the patent owner in *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litigation*, 794 F. Supp. 2d 517 (D. Del. 2011) "did not present expert testimony on [long felt need], instead relying on the commercial success of the immediate release [version of the compound] to show that an ER version was needed." *Id.* at 538. Here, UCB has offered no commercial success evidence, but has offered expert testimony from a chemist, Dr. Chyall (Ex. 2024), and a urologist, Dr. MacDiarmid (Ex. 2023), to demonstrate long felt need. The *Cyclobenzaprine* court found commercial success evidence "insufficient to show long felt need," which, if anything, suggests that long felt need and commercial success are not as closely linked as Petitioner argues. *Id.* The court in *Vanda Pharmaceuticals Inc. v. Roxane Laboratories, Inc.*, 13-cv-1973-GMS, 2016 WL 4490701 (D. Del. Aug. 25, 2016) does not consider commercial success in

assessing long-felt need, but rather identifies increased valuation of a product (prior to launch) as an indicator of long-felt need. *Id.* at *10. Finally, Petitioner's quote from Chisum explains "the nexus between *commercial success and nonobviousness*," not the "connection between commercial success and long-felt need," as Petitioner claims. Chisum§5.05[2][a].

Petitioner argues that Exhibits 1039 and 1049 "provide useful background regarding the knowledge of one of ordinary skill in the art," (Paper 39 at 5-6), but they do no such thing. Exhibits 1039 and 1049 present OAB market share and a consumer price index, and the Petition does not explain their relevance. In short, Petitioner's authority is silent on the issue it seeks to advance: that a patent challenger can introduce commercial evidence, such as market share and marketing spend, when the Patent Owner has not raised the issue of commercial success.

B. Commercial Success Evidence Is Not Relevant to the Nexus Between the Claimed Invention and Long Felt Need

Petitioner argues that its commercial evidence, particularly the testimony of its economist, DeForest McDuff (Ex. 1033), support its contention that there is no "nexus" between long felt need and the merits of the claimed invention. Paper 39 at 4-5. Petitioner's economist is not qualified to respond to the testimony of UCB's expert chemist or urologist regarding nexus between long felt need and the benefits of the claimed invention. Paper 20 at 64-65.

Moreover, the cases cited by Petitioner finding a lack of nexus involve entirely different facts and are uninformative. *See* Paper 39 at 5; *Ethicon Endo-Surgery, Inc. v. Covidien LP*, 812 F.3d 1023, 1035 (Fed. Cir. 2016) (need for staples of different heights rather than claimed surgical device); *Merck Sharpe & Dohme B.V. v. Warner Chilcott Co.*, 13-cv-2088-GMS, 2016 WL 4497054, at *14 (D. Del. Aug. 26, 2016) (no need for the alleged inventive aspect of the claimed vaginal drug delivery system); *Mark Sharp & Dohme Corp. v. Hospira Inc.*, 14-cv-915-RGA, 2016 WL 5872620, at *11 (D. Del. July 10, 2016) (need for the chemical compound, not the claimed formulation). As in *Hospira*, the need that existed prior to the introduction of Toviaz® was for the chemical compound fesoterodine. Petitioner's cited cases, including *Hospira*, are inapposite because they involved patent claims to related formulations or devices. The patents-at-issue here claim the source of the need, i.e., the chemical compound.

II. EXHIBIT NOS. 1050-1072 SHOULD BE EXPUNGED

Petitioner agrees that "it would have been proper to wait" to submit its supplemental evidence. Paper 39 at 9. Petitioner is mistaken that UCB should have objected to its improperly filed supplemental evidence when it was filed. *Id.* at 8. The Board has advised that "there is only one round of supplemental evidence filed in response to objections," and "no objection should be made to supplemental evidence to trigger another round of supplemental evidence." *Pier 1*

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.