IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX, INC. Petitioner,

v.

UCB BIOPHARMA SPRL Patent Owner.

U.S. Patent No. 8,633,194 to Fanara *et al.* Issue Date: January 21, 2014 Title: Pharmaceutical composition of piperazine derivatives

Inter Partes Review No.: IPR2019-00400

**Petitioner's Exhibit List** 

| Petitioner<br>Exhibit # | Description  |
|-------------------------|--|
| 1001                    | U.S. Patent No. 8,633,194 ("the '194 patent")  |
| 1002                    | Declaration of Dr. Laskar  |
| 1003                    | CV of Dr. Laskar   |
| 1004                    | European Patent Application Publication No. 0605203 A2 ("EP '203")   |
| 1005                    | Wang D.Y., "Effect of cetirizine, levocetirizine, and dextrocetirizine on histamine-induced nasal response in healthy adult volunteers," Allergy 56 (2001), pp. 339-343 ("Wang")   |
| 1006                    | Kibbe, "Handbook of Pharmaceutical Excipients," 3rd ed. 2000<br>(the "Handbook")   |
| 1007                    | International Patent Application No. WO 2004/050094 ("WO '094")  |
| 1008                    | Tillement, Jean-Paul <i>et al.</i> , "Compared pharmacological characteristics in humans of racemic cetirizine and levocetirizine, two histamine H1-receptor antagonists," Biochemical Pharmacology Volume 66, Issue 7, 1 October 2003, pages 1123-1126      |
| 1009                    | Potter, P.C., "Levocetirizine is effective for symptom relief<br>including nasal congestion in adolescent and adult (PAR)<br>sensitized to house dust mites," Allergy (Oxford, United<br>Kingdom) Volume 58, Issue 9, pages 893-899, Journal 2003            |
| 1010                    | Gandon, J.M. <i>et al.</i> , "Lack of effect of single and repeated doses<br>of Levocetirizine, a new antihistamine drug, on cognitive and<br>psychomotor functions in healthy volunteers," British Journal of<br>Clinical Pharmacology (2002), 54(1), 51-58 |
| 1011                    | Orange Book Entry for XYZAL  |
| 1012                    | R.J. Davies <i>et al.</i> , Antihistamines: topical vs. oral administration,<br>Clinical and Experimental Allergy 26(3):11-17 (1996) ("Davies")  |
| 1013                    | File Wrapper of '194 patent  |
| 1014                    | Gennaro, A. R., Remington: The Science and Practice of<br>Pharmacy 20th ed. (2000)   |
| 1015                    | U.S. Patent No. 5,698,558 to Nancy M. Grey ("US '558")   |
| 1016                    | EPO opposition   |
| 1017                    | Saeedi <i>et al.</i> , "The treatment of atopic dermatitis with licorice gel," Journal of Dermatological Treatment (2003) 14, 1–5  |

## **Petitioner's Exhibit List**

| 1018 | Duconge <i>et al.</i> , "Topical disposition of two strengths of a 125I-rhEGF jelly in rat skin wounds," Biopharm. Drug Dispos. 25: 193–201 (2004)   |
|------|--|
| 1019 | U.S. Patent No. 4,275,076  |
| 1020 | U.S. Patent No. 5,643,584  |
| 1021 | Ansel <i>et al.</i> , Pharmaceutical Dosage Forms and Drug Delivery<br>Systems 7th ed. 1999  |
| 1022 | Soni <i>et al.</i> , "Evaluation of the health aspects of methyl paraben:<br>a review of the published literature," Food and Chemical<br>Toxicology 40 (2002) 1335–1373  |
| 1023 | Sutton <i>et al.</i> , "Development of the Antimicrobial Effectiveness<br>Test as USP Chapter <51>" PDA Journal of Pharmaceutical<br>Science and Technology, Vol. 56, No. 6, 300-311,<br>November/December 2002  |
| 1024 | Darwish <i>et al.</i> , Effect of ethanol, propylene glycol and glycerol on<br>the interaction of methyl and propyl <i>p</i> -hydroxybenzoate with<br><i>Staphylococcus aureus</i> and <i>Pseudomonas aeruginosa</i> ," Int. J. of<br>Pharm. 147:51-60 (1997). |