

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INC.

Petitioner

v.

QUALICAPS CO. LTD.

Patent Owner

Case IPR2017-00203

Patent No. 6,649,180

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**PETITIONER MYLAN PHARMACEUTICALS INC.'S RESPONSE TO  
PATENT OWNER'S MOTION FOR OBSERVATION**

## EXHIBIT LIST

<b>Exhibit No.</b>	<b>Description</b>
1001	United States Patent No. 6,649,180
1002	Complaint, <i>Warner Chilcott (US), LLC et al. v. Mylan Pharmaceuticals, Inc., et al.</i> , Case No. 2:15-cv-01740-JRG-RSP (E.D. Texas)
1003	Proof of Service of Complaint, Case No. 2:15-cv-01740-JRG-RSP (E.D. Texas)
1004	United States Patent No. 5,756,123 (“Yamamoto”)
1005	<i>The Japanese Pharmacopeia</i> (The Society of Japanese Pharmacopeia, 13th ed. 1996) (“Japanese Pharmacopeia”)
1006	United States Patent No. 3,493,407 (“Greminger”)
1007	21 C.F.R. § 172.874 (1998)
1008	<i>National Formulary</i> (American Pharmaceutical Association, 12th ed. 1965)
1009	Handbook of Pharmaceutical Excipients (1986)
1010	File History of United States Patent No. 6,649,180
1011	Expert Declaration of Arthur H. Kibbe
1012	Shin-Etsu Chemical Co., Ltd. PHARMACOAT Technical Information Shin-Etsu Chemical Co., Ltd. TC-5 Technical Information
1013	Chichester, C.O., E.M. Mrak, and G.F. Stewart, “Utilization of Synthetic Gums in the Food Industry,” <u>Advances in Food Research, Volume 12, Technical Center, General Foods Corporation, Tarrytown, N.Y., 1963.</u>
1014	Deposition Transcript of Jason T. McConville, Ph.D., Case No. 2:15-cv-1471-JRG-RSP (E.D. Tex.), July 8, 2016

1015	Declaration Of Mr. Jonathan D. Olinger In Support Of Petitioner's Unopposed Motion For <i>Pro Hac Vice</i> Admission Under 37 C.F.R. § 42.10(C)
1016	United States Patent No. 5,756,123 ("Yamamoto") ( <i>Served but not filed, June 14, 2017</i> )
1017	<i>The Japanese Pharmacopeia</i> (The Society of Japanese Pharmacopeia, 13th ed. 1996) ("Japanese Pharmacopeia") ( <i>Served but not filed, June 14, 2017</i> )
1018	21 C.F.R. § 172.874 (1998) ( <i>Served but not filed, June 14, 2017</i> )
1019	<i>National Formulary</i> (American Pharmaceutical Association, 12th ed. 1965) ( <i>Served but not filed, June 14, 2017</i> )
1020	Handbook of Pharmaceutical Excipients (1986) ( <i>Served but not filed, August 11, 2017</i> )
1021	Email exchange between counsel July 25, 2017 ( <i>Served but not filed, August 11, 2017</i> )
1022	Email exchange between counsel August 4, 2017 ( <i>Served but not filed, August 11, 2017</i> )
1023	Email exchange between counsel August 10, 2017 ( <i>Served but not filed, August 11, 2017</i> )
1024	Mylan Pharmaceuticals Inc., Mylan Laboratories Limited, and Mylan Inc.'s Amended Notice Of Videotaped Deposition Of Representative(s) Of Qualicaps Co., Ltd. Pursuant To Federal Rule Of Civil Procedure 30(B)(6) ( <i>Served but not filed, August 11, 2017</i> )
1025	Email exchange between counsel March 21, 2017 ( <i>Served but not filed, August 11, 2017</i> )
1026	Email exchange between counsel April 25, 2017 ( <i>Served but not filed, August 11, 2017</i> )
1027	Amended Docket Control Order, <i>Warner Chilcott (US), LLC v. Teva Pharmaceuticals USA, Inc.</i> , No. 2:15-cv-1471 (E.D. Tex.)

	May 19, 2017), ECF No. 165 ( <i>Served but not filed, August 11, 2017</i> )
1028	Deposition Transcript of Jason T. McConville, Ph.D., August 17, 2017
1029	Reply Expert Declaration of Arthur H. Kibbe

## II. Response to Motion for Observation

1. Patent Owner argues that there is some inconsistency in Dr. Kibbe's testimony regarding what parts of the Petition he may have had when he *drafted his initial declaration*. Motion for Ob., p. 1. Despite Patent Owner's futile fascination with the Declaration, and the Board's advice that wading into this issue is a waste of time, its observation is wrong. Dr. Kibbe's testimony has been consistent throughout the proceedings:

- Ex. 1011, ¶ 48 – Dr. Kibbe reviewed before *filing* the legal section of the Petition
- Ex. 2029, 23:18-25:8 – Dr. Kibbe reviewed draft portions of the Petition before executing his *already written* declaration
- Ex. 1029, ¶ 3 – Dr. Kibbe did not have the Petition when he *wrote* his declaration
- Ex. 2078, 12:9-19 – Dr. Kibbe did not have the Petition when he *wrote* his declaration.

2. Patent Owner argues that Dr. Kibbe's testimony that he would *expect* experimenters to control for residual salts (Ex. 2076, 38:22-39:10) contradicts his declaration that the inventors performed no control of residual salts (Ex. 1029, ¶ 8). There is no contradiction here. Dr. Kibbe explained in his declaration that the documents of inventor Tanjoh-san (Exs. 2064, 2065-2072) show no "analysis of

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