Paper No. 14 Filed: March 20, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEPTUNE GENERICS, LLC

PETITIONER

V.

AVENTIS PHARMA S.A.

PATENT OWNER

CASE NO.: IPR2019-00136 PATENT NO. 5,847,170 FILED: MARCH 26, 1996 ISSUED: DECEMBER 8, 1998 INVENTORS: HERVÉ BOUCHARD, JEAN-DOMINIQUE BOURZAT, ALAIN COMMERÇON

TITLE: TAXOIDS, THEIR PREPARATION, AND PHARMACEUTICAL COMPOSITIONS CONTAINING THEM

PETITIONER'S UPDATED EXHIBIT LIST

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PETITIONER'S UPDATED EXHIBIT LIST

Petitioner Neptune Generics, LLC hereby submits its updated exhibit list to

accompany the submission of Exhibit 1056:

DOCKET

Α

Exhibit No.	Description
Exhibit 1001	U.S. Patent No. 5,847,170 to Hervé Bouchard, Jean-Dominique Bourzat, and Alain Commerçon ("'170 patent")
Exhibit 1002	Expert Declaration of Dr. John L. Wood, Ph.D.
Exhibit 1003	C.V. of Dr. John L. Wood
Exhibit 1004	Prosecution file history to U.S. Patent No. 5,847,170 ("FH")
Exhibit 1005	P. Potier et al., Chemical Studies of 10-Deacetyl Baccatin III: Hemisynthesis of Taxol Derivatives 42 TETRAHEDRON 4451- 4460 (1986)
Exhibit 1006	L. Kelland et al., Comparative In Vitro Cytotoxicity of Taxol and Taxotere against Cisplatin- Sensitive and Resistant Human Ovarian Carcinoma Cell Lines, 30 CANCER CHEMOTHER. PHARMACOL. 444 (1992)
Exhibit 1007	J. Verweij et al., <i>Paclitaxel (Taxol) and Docetaxel (Taxotere): Not Simply Two of a Kind</i> , 5 ANN. ONCOL. 495 (1994)
Exhibit 1008	J. S. Abrams et al., New Chemotherapeutic Agents for Breast Cancer, 74 CANCER SUPP. 1164 (1994)
Exhibit 1009	Commerçon et al., <i>Practical Semisynthesis and Antimitotic Activity</i> of Docetaxel and Side-Chain Analogues, in TAXANE ANTICANCER AGENTS (Chapter 17), pp. 233-246 (Georg, G. et al. ed., American Chemical Society Symposium Series, 1994) ("Commerçon")
Exhibit 1010	J. Kant et al, A Chemoselective Approach to Functionalize the C- 10 Position of 10- Deacetylbaccatin III Synthesis and Biological Properties of Novel C-10 Taxol Analogues, 35 TETRAHEDRON LETTERS No. 31, pp. 5543-5546 (1994) ("Kant")
Exhibit 1011	U.S. Patent No. 6,201,140 to Henry Wong and Mark. D. Wittman ("Wong")

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Exhibit No.	Description
Exhibit 1012	Y. Ueda et al., Synthesis and Antitumor Evaluation of 2'- Oxycarbonylpaclitaxels (Paclitaxel-2'-Carbonates), 4 BIOORGANIC & MEDICINAL CHEMISTRY LETTERS No. 15, pp. 1861- 1864 (1994)
Exhibit 1013	Y. Ueda et al., Novel Water Soluble Phosphate Prodrugs of Taxol® Possessing In Vivo Antitumor Activity, 3 BIOORGANIC & MEDICINAL CHEMISTRY LETTERS No. 8, pp. 1761-1766 (1993)
Exhibit 1014	U.S. Patent No. 5,587,493 to Hervé Bouchard, Jean-Dominique Bourzat, and Alain Commerçon (" <i>Bouchard</i> ")
Exhibit 1015	Volume 7, September 28, 2017 Trial Testimony from <i>Sanofi-</i> <i>Aventis U.S. LLC v. Fresenius Kabi USA, LLC</i> , Civil Action Number 3:14-cv-07869-MAS-LHG (D.N.J.).
Exhibit 1016	Klein et al., <i>Chemistry and Antitumor Activity on 9(R)-Dihydrotaxanes, in</i> TAXANE ANTICANCER AGENTS (Chapter 20), pp. 276-287 (Georg, G. et al. ed., American Chemical Society Symposium Series, 1994) ("Klein")
Exhibit 1017	M. Inaba et al., Evaluation of Antitumor Activity in a Human Breast Tumor/Nude Mouse Model with a Special Emphasis on Treatment Dose, 64 Cancer pp. 1577-1582 (1989)
Exhibit 1018	Margraff, Bézard, Bourzat, and Commerçon, <i>Synthesis of 19- Hydroxy Docetaxel from a Novel Baccatin</i> , 4 BIOORGANIC & MEDICINAL CHEMISTRY LETTERS, No. 2, pp. 233-236 (1994)
Exhibit 1019	Untch et al, <i>Comparison of paclitaxel and docetaxel (Taxotere) in gynecologic and breast cancer cell lines with the ATP-cell viability assay, 5</i> ANTI-CANCER DRUGS, pp. 24-30 (1994)
Exhibit 1020	A. Joshi et al., <i>Results of a phase II randomized controlled clinical trial comparing efficacy of Cabazitaxel versus Docetaxel as second line or above therapy in recurrent head and neck cancer</i> , 75 ORAL ONCOLOGY pp. 54-60 (2017)
Exhibit 1021	P. Vrignaud et al, <i>Preclinical Antitumor Activity of Cabazitaxel, a Semisynthetic Taxane Active in Taxane-Resistant Tumors,</i> 19 Clin Cancer Res No. 11 pp. 2973-2983 (2013)
Exhibit 1022	U.S. Patent No. 5,489,601 to Robert Holton and Kasthuri Rengan
Exhibit 1023	Publication information regarding <i>Kant</i> , Ex.1010.

Exhibit No.	Description
Exhibit 1024	National Cancer Institute Division of Cancer Treatment and Diagnosis, Developmental Therapeutics Program (DTP) website and timeline entitled: "Success Story Taxol® (NSC 125973)" at https://dtp.cancer.gov/timeline/flash/success_stories/s2_taxol.htm
Exhibit 1025	U.S. Food & Drug Administration website printout New Drug Application 020262 (Taxol) with Original Approval and Supplements shown, from: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event= overview.process&ApplNo=020262
Exhibit 1026	I. Ojima <i>et al</i> , <i>Structure-Activity Relationships of New Taxoids</i> Derived from 14β-Hydroxy-10-Deacetylbaccatin III, 37 J. MED. CHEM. No. 10 pp. 1408-1410 (1994)
Exhibit 1027	Abstract to E.K. Rowinsky et al., <i>Clinical toxicities encountered</i> <i>with paclitaxel (Taxol)</i> , SEMIN. ONCOLO. 20 (4 Suppl. 3), pp. 1-15 (Aug. 1993)
Exhibit 1028	E.A. Eisenhauer et al., <i>European-Canadian Randomized Trial of</i> <i>Paclitaxel in Relapsed Ovarian Cancer: High-Dose Versus Low-</i> <i>Dose and Long Versus Short Infusion</i> , 12 J. CLINICAL ONCOLOGY, PP. 2654-2666 (Aug. 1993)
Exhibit 1029	K. Diergarten et al., <i>Taxol: A New Antineoplastic Agent</i> , 16 ONKOLOGIE, pp. 329-337 (1993)
Exhibit 1030	J. D. Hainsworth et al., <i>Paclitaxel Administered by 1-Hour</i> <i>Infusion—Preliminary Results of a Phase I/II Trial Comparing</i> <i>Two Schedules</i> , 74 CANCER No. 4, pp. 1377-1382 (Aug. 15, 1994)
Exhibit 1031	R.S. Finley et al., <i>Patient Care Issues: The Management of</i> <i>Paclitaxel-Related Toxicities</i> , 28 THE ANNALS OF PHARMACOTHERAPY, pp. S27-S30 (May 1994)
Exhibit 1032	"Taxol Approved for Breast Cancer," THEPHARMALETTER—UP TO DATE NEWS FOR THE PHARMACEUTICAL AND BIOTECHNOLOGY INDUSTRIES <u>https://www.thepharmaletter.com/article/taxol-</u> <u>approved-for-breast-cancer</u> (April 25, 1994) (visited July 2, 2018)
Exhibit 1033	L. Webster et al., Measurement of Cremophor EL Following Taxol: Plasma Levels Sufficient to Reverse Drug Exclusion Mediated by the Multidrug Resistant Phenotype, 85 J. NATL. CANCER INST., No. 20 pp. 1685-1690 (October 20, 1993)

Exhibit No.	Description
Exhibit 1034	F. Gueritte-Voegelein, P. Potier et al., Relationships between the
	Structure of Taxol Analogues and Their Antimitotic Activity, 34 J.
	МЕД. СНЕМ., No. 3 pp. 992-998 (1991)
Exhibit 1035	I. Ojima et al., Syntheses and Structure-Activity Relationships of
	New Taxoids, in TAXANE ANTICANCER AGENTS (Chapter 19), pp.
	262-275 (Georg, G. et al. ed., American Chemical Society
F 1.1.4 1026	Symposium Series, 1994)
Exhibit 1036	Golick J. et al., Phosphonooxymethyl ethers of taxane derivatives,
	European Patent Application Publication No. 0 604 910 A1, Application No. 93120801.1, filed December 23, 1993, published
	July 6, 1994.
Exhibit 1037	H. Lataste, V. Senilh, M. Wright, D. Guenard, and P. Potier,
	Relationships between the structures of taxol and baccatine III
	derivatives and their in vitro action on the disassembly of
	mammalian brain and Physarum amoebal microtubules, in 81
	PROC. NATL. ACAD. SCI USA, pp. 4090-4094 (July 1984)
Exhibit 1038	A. Greene, Pierre Potier et al., A Highly Efficient, Practical
	Approach to Natural Taxol, in 110 J. AM. CHEM. SOC. No. 17, pp.
	5917-5919 (1988) ("Potier 1988")
Exhibit 1039	Excerpt [Chapter 2] from R. SILVERMAN, THE ORGANIC
F 1.1.1 1040	CHEMISTRY OF DRUG DESIGN AND DRUG ACTION, pp. 4-51 (1992)
Exhibit 1040	D. Guenard, F. Gueritte-Voegelein, and P. Potier, <i>Taxol and Taxotere: Discovery, Chemistry, and Structure-Activity</i>
	Relationships, 26 ACC. CHEM. RES. No. 4, pp. 160-167 (1993)
	("Potier 1993")
Exhibit 1041	J. Pezzuto et al., A Mixed Micellar Formulation Suitable for the
	Parenteral Administration of Taxol, in 11 PHARMACEUTICAL
	RESEARCH No. 2, pp. 206-212 (1994)
Exhibit 1042	Second Declaration of Alain Commerçon, dated April 23, 1998,
	excerpted from prosecution history (Ex.1004) of the U.S. Patent
	No. 5,847,170 (Ex.1001) ("Commerçon Declaration" or
	"Declaration").
Exhibit 1043	Bissery, M.C. et al., <i>Experimental Antitumor Activity of Taxotere</i>
	(<i>RP 56976, NSC 628503</i>), a Taxol Analogue, in 51 CANCER
F 1.11 4 40.44	RESEARCH, pp. 4845-4852 (Sept. 15, 1991)
Exhibit 1044	Riou, J.F. et al., <i>Effects of Taxotere on Murine and Human Tumor</i>
	Cell Lines, in 187 BIOCHEMICAL AND BIOPHYSICAL RESEARCH
	COMMUNICATIONS, No. 1, pp. 164-170 (Aug. 31, 1992)

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