Filed on behalf of Petitioner CIPLA LIMITED

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CIPLA LIMITED

Petitioner

v.

GILEAD SCIENCES, INC.,

Patent Owner

Case No.: IPR2025-00033

U.S. Patent No. 11,744,802

Issued: September 5, 2023

Title: THERAPETUTIC COMPOSITIONS FOR TREATMENT OF HUMAN IMMUNODEFICIENCY VIRUS

EXHIBIT LIST

LIST OF EXHIBITS

Exhibit No.	Description
EX-1001	U.S. Patent No. 11,744,802 ("the '802 Patent")
EX-1002	U.S. Patent No. 11,744,802 File History ("the '802 File History")
EX-1003	Declaration of Prasanna Jagannathan
EX-1004	Declaration of Jeffrey Winkler
EX-1005	WO 2014/100323 A1 ("WO '323")
EX-1006	WO 2015/022351 A1 ("WO '351")
EX-1007	U.S. Patent Publication 2015/231079 ("US '079")
EX-1008	Michael J. Bowker, "A Procedure for Salt Selection and Optimization" *in* HANDBOOK OF PHARMACEUTICAL SALTS: PROPERTIES, SELECTION, AND USE 161–89 (P. Heinrich Stahl & Camille G. Wermuth eds., 2002) ("Bowker")
EX-1009	Paulekuhn et al., "Trends in Active Pharmaceutical Ingredient Salt Selection Based on Analysis of the Orange Book Database," 50 J. MED. CHEM. 6665–72 (2007) ("Paulekuhn")
EX-1010	Ruane et al., "Antiviral Activity, Safety, and Pharmacokinetics/Pharmacodynamics of Tenofovir Alafenamide as 10-Day Monotherapy in HIV-1-Positive Adults," 63 J. AQUIR. IMMUNE DEFIC. SYNDR., 449–55 (2013) ("Ruane")
EX-1011	U.S. Patent No. 10,58,846 ("the '846 Patent")
EX-1012	Complaint for Patent Infringement, filed in Gilead Sciences, Inc. v. Lupin Ltd., Laurus Labs Limited, and Cipla Limited, No. 22-cv-00165 (D.Del.) (Docket Entry 1).
EX-1013	Excerpts of Second Amended Complaint, filed in Gilead Sciences, Inc. v. Lupin Ltd., Laurus Labs Limited, and Cipla Limited, No. 22-cv-00165 (D. Del.) (Docket Entry 170).

Exhibit No.	**Description**
EX-1014	PANEL ON ANTIRETROVIRAL GUIDELINES FOR ADULTS AND ADOLESCENTS – A WORKING GROUP OF THE OFFICE OF AIDS RESEARCH ADVISORY COUNCIL (OARAC), GUIDELINES FOR THE USE OF ANTIRETROVIRAL AGENTS IN HIV-I-INFECTED ADULTS AND ADOLESCENTS, DEPARTMENT OF HEALTH & HUMAN SERVICES (revised Apr. 8, 2015) ("2015 DHHS Guidelines")
EX-1015	Highlights and Prescribing Information on Truvada, revised July 2012 ("Truvada 2012 Label")
EX-1016	Highlights and Prescribing Information on Isentress, revised October 2007 ("Isentress Label")
EX-1017	Dorothy E. Dow & John A. Bartlett, "Dolutegravir, the Second-Generation of Integrase Strand Transfer Inhibitors (INSTIs) for the Treatment of HIV," 3 INFECTIOUS DISEASES & THERAPY 83–102 (2014) ("Dow")
EX-1018	Serrao et al., "Raltegravir, elvitegravir, and metoogravir: the birth of the "me-too" HIV-1 integrase inhibitors," 6 RETROVIROLOGY, Art. 25, 1–14 (2009) ("Serrao")
EX-1019	Highlights and Prescribing Information on Stribild, revised and issued August 2012 ("Stribild Label")
EX-1020	Highlights and Prescribing Information on Vitekta, revised and issued September 2014 ("Vitekta Label")
EX-1021	WO 2010/068253 A1 ("WO '253")
EX-1022	Highlights and Prescribing Information on Tivicay, © 2013, revised August 2013 ("Tivicay Label")
EX-1023	Shah et al., "Dolutegravir: A New Integrase Strand Transfer Inhibitor for the Treatment of HIV," 34(5) PHARMACOTHERAPY 506–20 (2014) ("Shah")

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EX-1024	Highlights and Prescribing Information on Triumeq, © 2014, revised and issued August 2014 ("Triumeq Label")
EX-1025	Sax et al., "Tenofovir Alafenamide Vs. Tenofovir Disoproxil Fumarate in Single Tablet Regimens for Initial HIV-1 Therapy: A Randomized Phase 2 Study," 67(1) J. ACQUIRED IMMUNE DEFICIENCY SYNDROMES 52–58 (2014) ("Sax")
EX-1026	Noemi Astuti & Franco Maggiolo, "Single-Tablet Regimens in HIV Therapy," 3 INFECTIOUS DISEASES & THERAPY 1–17 (2014) ("Astuti")
EX-1027	Llibre et al., "Once-Daily Single-Tablet Regimens: A Long and Winding Road to Excellence in Antiretroviral Treatment," 14 AIDS REVIEWS 168–78 (2012) ("Llibre").
EX-1028	Mathias et al., "Bioequivalence of the Emtricitabine/Rilpivirine/Tenofovir Disoproxil Fumarate Single Tablet Regimen", 4(7) J. BIOEQUIVALENCE AND BIOAVAILABILITY 100–05 (2012) ("Mathias")
EX-1029	ClinicalTrials.gov, NCT02275065 Protocol, Study to Evaluate Safety, Pharmacokinetics, and Antiviral Activity of Bictegravir (GS-9883) in Human Immunodeficiency Virus (HIV)-1 Infected Participants, https://clinicaltrials.gov/study/NCT02275065 (February 6, 2015) ("NCT '065 February 2015")
EX-1030	Gilead, 2014 Form 10-K, signed by CEO John C. Martin, Ph.D. on February 25, 2015 ("Gilead 2014 10-K")
EX-1031	Highlights and Prescribing Information on Atripla, © 2006, dated July 6, 2006 ("Atripla Label")
EX-1032	Highlights and Prescribing Information on Complera, revised and issued August 2011 ("Complera Label")

Exhibit No.	**Description**
EX-1033	Günthard et al., "Antiretroviral Treatment of Adult HIV Infection 2014 Recommendations of the International Antiviral Society-USA Panel", 312(4) JAMA 410–25 (2014) ("Günthard")
EX-1034	Press Release, Gilead, "Gilead Announces Phase 3 Result for Investigational Once-Daily Single Tablet HIV Regimen Containing Tenofovir Alafenamines (TAF)" (February 26, 2015) ("Gilead February 2015 Press Release")
EX-1035	ClinicalTrials.gov, NCT02397694 Protocol, Safety and Efficacy of Bictegravir + Emtricitabine/ Tenofovir Alafenamide Versus Dolutegravir + Emtricitabine/ Tenofovir Alafenamide in HIV-1 Infected, Antiretroviral Treatment-Naive Adults, https://clinicaltrials.gov/study/NCT02397694 (March 20, 2015) ("NCT '065 March 2015")
EX-1036	Press Release, Gilead, "Gilead's Investigational Fixed-Dose Combination of Emtricitabine/Tenofovir Alafenamide (F/TAF) Meets Primary 48-Week Objective in Phase 3 Study" (Sept. 2, 2015) ("Gilead September 2015 Press Release")
EX-1037	WO 2015/196116 (WO '116)
EX-1038	US Patent Publication 2016/0016973 (US '973)
EX-1039	Tsiang et al., "Antiviral Activity of Bictegravir (GS-9883), a Novel Potent HIV-1 Integrase Strand Transfer Inhibitor with an Improved Resistance Profile," 60(12) ANTIMICROBIAL AGENTS AND CHEMOTHERAPY 7086–97 (2016) ("Tsaing")
EX-1040	U.S. Patent 10,548,846 File History ("the '846 file history")
EX-1041	Johns et al., "Carbamoyl Pyridone HIV-1 Integrase Inhibitors 3. A Diastereomeric Approach to Chiral Nonracemic Tricyclic Ring Systems and the Discovery of Dolutegravir (S/GSK1349572) and (S/GSK1265744)," 56 J. MEDICINAL CHEMISTRY 5901–16 (2013) ("Johns")

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EX-1042	DEPARTMENT OF HEALTH AND HUMAN SERVICES, CENTER FOR DRUG EVALUATION AND RESEARCH (CDER), "Guidance for Industry: Size, Shape, and Other Physical Attributes of Generic Tablets and Capsules," (June 2015) ("CDER Guidance")
EX-1043	Sabin et al., "Use of nucleoside reverse transcriptase inhibitors and risk of myocardial infarction in HIV-infected patients enrolled in the D:A:D study: a multi-cohort collaboration," 371 LANCET 1417–26 (2008) ("Sabin")
EX-1044	Press Release, Gilead, "Gilead Announces Phase 3 Result for Investigational Once-Daily Single Tablet HIV Regimen Containing Tenofovir Alafenamide (TAF)" (November 5, 2015) ("Gilead November 2015 Press Release")
EX-1045	Stellbrink et al., "Dolutegravir in Antiretroviral-naive Adults with HIV-1: 96-week Results from a Randomized Dose-ranging Study," 27 AIDS 1771–78 (2013) ("Stellbrink")
EX-1046	Highlights and Prescribing Information on Epzicom, © 2004 ("Epzicom Label")
EX-1047-A	Benjamin E. Blass, "Drug Discovery and Development: An Overview of Modern Methods and Principles" *in* BASIC PRINCIPLES OF DRUG DISCOVERY AND DEVELOPMENT 1–34 (Elsevier Sci. & Tech., 2015), published April 27, 2015 ("Blass Chapter 1")
EX-1047-B	Benjamin E. Blass, "Medicinal Chemistry" *in* BASIC PRINCIPLES OF DRUG DISCOVERY AND DEVELOPMENT 203–43 (Elsevier Sci. & Tech., 2015), published April 27, 2015 ("Blass Chapter 5")
EX-1048	Chen et al., "Prediction of Absolute Hydroxyl pK_a Values for 3-Hydroxypyridin-4-ones," 3 J. PHYSICAL CHEMISTRY LETTERS 2980–85 (2012) ("Chen")
EX-1049	Bastin et al., "Salt Selection and Optimisation Procedures for Pharmaceutical New Chemical Entities, 4 ORGANIC PROCESS RSCH. & DEV. 427–35 (2000) ("Bastin")

Exhibit No.	**Description**
EX-1050	James Wells, "Pharmaceutical Preformulation: The Physicochemical Properties of Drug Substances" *in* 2 PHARMACEUTICS: THE SCIENCE OF DOSAGE FORM DESIGN 113–38 (M.E. Aulton ed. 1988) ("Wells")
EX-1051	Berge et al., "Pharmaceutical Salts," 68 J. PHARM. SCI. 1–19 (1977) ("Berge")
EX-1052	WO 2006/116764 ("WO '764")
EX-1053	Frederick G. Bordwell, "Equilibrium Acidities in Dimethyl Sulfoxide Solution," 21 ACCT. CHEM. RSCH. 456–63 (1988) ("Bordwell")
EX-1054	Highlights and Prescribing Information on Truvada, © 2004, issued July 2004 ("Truvada Label")
EX-1055-A	Michael R. Franklin & Donald N. Franz, "Chapter 57: Drug Absorption, Action, and Disposition," *in* 21 REMINGTON: THE SCIENCE AND PRACTICE OF PHARMACY 1142–70 (Lippincott Williams & Wilkins ed., 2006) ("Remington Chapter 57")
EX-1055-B	Paul M. Beringer & Michael E. Winter, "Chapter 59: Clinical Pharmacokinetics and Pharmacodynamics," *in* 21 REMINGTON: THE SCIENCE AND PRACTICE OF PHARMACY 1191–1205 (Lippincott Williams & Wilkins ed., 2006) ("Remington Chapter 59")
EX-1055-C	Raymond E. Galinsky & Craig K. Svensson, "Chapter 58: Basic Pharmacokinetics and Pharmacodynamics," *in* 21 REMINGTON: THE SCIENCE AND PRACTICE OF PHARMACY 1171–90 (Lippincott Williams & Wilkins ed., 2006) ("Remington Chapter 58")
EX-1055-D	"Chapter 17: Ionic Solutions and Electrolytic Equilibria," *in* 21 REMINGTON: THE SCIENCE AND PRACTICE OF PHARMACY 231–49 (Lippincott Williams & Wilkins ed., 2006) ("Remington Chapter 17")
EX-1055-E	Alfonso R. Gennaro, "Chapter 25:Organic Pharmaceutical Chemistry," *in* 21 REMINGTON: THE SCIENCE AND PRACTICE OF PHARMACY 386–409 (Lippincott Williams and Wilkins ed., 2006) ("Remington Chapter 25")

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EX-1055-F	Howard Y. Ando & Galen W. Radebaugh, "Chapter 38: Property-Based Drug Design and Preformulation," *in* 21 REMINGTON: THE SCIENCE AND PRACTICE OF PHARMACY 720–44 (Lippincott Williams and Wilkins ed., 2006) ("Remington Chapter 38")
EX-1056	Zolopa et al., "Activity of Elvitegravir, a Once-Daily Integrase Inhibitor, against Resistant HIV Type 1: Results of a Phase 2, Randomized, Controlled, Dose-Ranging Clinical Trial," 201 J. INFECTIOUS DISEASES 814–22 (2010) ("Zolopa")
EX-1057	U.S. Patent No. 8,129,385 ("the '385 Patent")
EX-1058	U.S. Patent No. 7,390,791 ("the '791 Patent")
EX-1059	U.S. Patent No. 8,754,065 ("the '065 Patent")
EX-1060	Memorandum from Katherine K. Vidal, Director of the United States Patent and Trademark Office, to Members of the Patent Trial and Appeal Board, Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation (June 21, 2022) ("Vidal Memo")
EX-1061	Press Release, Gilead, "Gilead Presents Preliminary Data on Bictegravir, an Investigational Integrase Strand Transfer Inhibitor for the Treatment of HIV" (June 20, 2016) ("Gilead 2016 Press Release")