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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS CORPORATION,	)	
Plaintiff,	)	
v.	)	C.A. No. 20-755 (RGA)
LIQUIDIA TECHNOLOGIES, INC.,	)	**REDACTED - PUBLIC VERSION**
Defendant.	)	

PLAINTIFF'S MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF THEIR MOTION FOR ISSUANCE OF A REQUEST FOR JUDICIAL ASSISTANCE

Plaintiff United Therapeutics Corporation ("United Therapeutics") respectfully submits this Memorandum of Law in support of its Motion for the Issuance of a Hague Convention Letter of Request to take the depositions of fact witnesses located in South Korea, pursuant to 28 U.S.C. § 1781(b), Fed. R. Civ. P. 28(b) and the Convention of 18 March 1970 on the Taking of Evidence Abroad in Civil or Commercial Matters (the "Hague Convention"). Specifically, United Therapeutics seeks the production of the requested documents and property of Yonsung relating to the alleged infringing manufacturing process and the resulting active pharmaceutical ingredient ("API") product used in Defendant Liquidia Technologies Inc.'s proposed generic copy of UTC's Tyvaso® (treprostinil) Inhalation Solution, 0.6 mg/ml ("Proposed Generic Product"). It is also requested that testimony be obtained from three employees of Yonsung – Chang Young Oh, Yong Hyun Kim, and Eunhee Ban – regarding the manufacturing process and the resulting API product used in Defendant Liquidia Technologies Inc.'s Proposed Generic Product, and that the answers to those questions be recorded verbatim by a court reporter, at the expense of Plaintiff. United

Therapeutics' proposed Letter of Request was submitted to the Court for review and consideration as Exhibit "A" to this Motion.

I. THE DISTRICT COURT HAS THE AUTHORITY TO ISSUE LETTERS OF REQUEST UNDER THE HAGUE CONVENTION

The Hague Convention provides that "[i]n civil or commercial matters a judicial authority of a Contracting State may, in accordance with the provision of the law of that State, request the competent authority of another Contracting State, by means of a Letter of Request, to obtain evidence, or to perform some other judicial act." Hague Convention, Art. 1. Both the United States and the Republic of Korea are parties to the Hague Convention. The Republic of Korea ratified the Hague Convention on August 20, 1997. *See* Hague Conf. on Private Int'l Law, Status Table, Member: Republic of Korea, http://www.hcch.net/index_en.php?act=states.details&sid=48 (last visited April 22, 2021).

The Hague Convention authorizes the District Court for the District of Delaware to issue the Letter of Request. *See Societe Nationale Industrielle Aerospatiale v. U.S. Dist. Court for S. Dist. of Iowa*, 482 U.S. 522, 535 (1987) (stating that "a judicial authority in one contracting state 'may' forward a letter of request to the competent authority in another contracting state for the purpose of obtaining evidence"); *see, e.g.*, 28 U.S.C. § 1781(b)(2) (permitting "the transmittal of a letter rogatory or request directly from a tribunal in the United States to the foreign or international tribunal, officer, or agency to whom it is addressed and its return in the same manner" and reproducing the Hague Convention). The purpose of the Hague Convention is to establish a system, based on international comity, that enables a requesting state to obtain evidence abroad in a manner "tolerable" to the state executing the request. *See Societe Nationale*, 482 U.S. at 530.

Accordingly, United Therapeutics requests that the Court issue the attached Letter of Request to the Korean Judicial Authorities on behalf of United Therapeutics. *See Ingenico Inc. v.*

IOENGINE, LLC, C.A. No. 18-826-WCB (D. Del. Mar. 17, 2021) (granting motion to issue Letters of Request to Israel under Hague Convention); *Helios Streaming, LLC v. Vudu, LLC*, C.A. Nos. 19-1792-CFC-SRF, -1978-CFC-SRF (D. Del. Mar. 12, 2021) (granting motion to issue Letters of Request to Korea and to Japan to compel testimony under Hague Convention); *Pfizer Inc. v. Apotex, Inc.*, C.A. No. 18-795-RGA (D. Del. May 21, 2019) (granting motion to issue Letter of Request to China under Hague Convention); *3G Licensing, S.A. v. HTC Corp.*, C.A. No. 1-17-cv-00083-LPS (D. Del. Apr. 6, 2020) (granting motion to issue Letter of Request to the Netherlands under Hague Convention); *Mallinckrodt IP Unlimited Co. v. B Braun Medical Inc.*, C.A. Nos. 1-17-cv-00365-LPS, -00660-LPS (D. Del. Apr. 24, 2018) (granting motion to issue Letter of Request under Hague Convention); *Plastic Ominum Advanced Innovation and Research v. Donghee America, Inc.*, C.A. No. 16-187-LPS-CJB (D. Del. May 11, 2017) (granting motion to issue Letter of Request to Korea under Hague Convention); *Pronova BioPharma Norge AS v. Teva Pharm. USA, Inc.*, 708 F. Supp. 2d 450, 456 (D. Del. 2010) (granting motion to issue Letters of Request to Sweden under Hague Convention); *AstraZeneca v. Ranbaxy Pharm. Inc.*, 2008 WL 314627 at *6 (D. N.J. Jan. 29, 2008) (granting motion to issue Letter of Request for oral deposition testimony and to obtain related documents in Sweden under Hague Convention); cf. *Miller v. Holzmann*, No. 95-1231, 2006 WL 3093122 (D.D.C. Oct. 31, 2006) (granting motion to issue Letters of Request to Germany under Hague Convention).

II. BACKGROUND

Plaintiff United Therapeutics Corporation ("UTC") holds New Drug Application No. 022387, which has been approved for Tyvaso® (treprostinil) Inhalation Solution, 0.6 mg/ml, indicated for the treatment of pulmonary arterial hypertension, which UTC markets and sells under the registered trademark Tyvaso®. UTC owns three U.S. patents covering Tyvaso® and its United

States Food and Drug Administration's ("FDA") approved manufacture and uses, which have been listed in connection with Tyvaso® in the FDA's *Approved Drug Products with Therapeutic Equivalents* publication (also known as the "Orange Book"): United States Patent Nos. 9,593,066 ("the '066 patent"), 9,604,901 ("the '901 patent"), and 10,716,793 ("the '793 patent") (collectively, "the asserted patents").

Defendant Liquidia Technologies Inc. ("Liquidia") submitted New Drug Application No. 213005 under § 505(b)(2) of the Federal Food, Drug and Cosmetic Act ("Liquidia's 505(b)(2) Application") to the FDA seeking approval, prior to the expiration of the '066 patent, the '901 patent, and the '793 patent, to manufacture, market, and sell a generic copy of UTC's Tyvaso® (treprostinil) Inhalation Solution, 0.6 mg/ml ("Liquidia's Proposed Generic Product").

In June 2020, UTC filed the present lawsuit. UTC claims that Liquidia's Proposed Generic Product infringes the asserted patents. Liquidia denied these claims, even though (1) Liquidia's Proposed Generic Product contains the same active compound, treprostinil, as UTC's approved Tyvaso® product; (2) Liquidia's 505(b)(2) Application seeks approval from the FDA to market Liquidia's Proposed Generic Product for the same indication as UTC's approved Tyvaso® product; and (3) Liquidia's 505(b)(2) Application refers to and relies upon UTC's NDA No. 022387 for Tyvaso® (treprostinil) Inhalation Solution, 0.6 mg/ml. In this case, UTC must show that the process by which Liquidia prepares its Proposed Generic Product (and Liquidia's Proposed Generic Product itself) is the same as the process and product covered by the claims of the asserted patents.

Accordingly, Yonsung Fine Chemicals Co., Ltd. ("Yonsung") is a critical third party to this case. It manufactures the active pharmaceutical ingredient ("API") in Liquidia's Proposed Generic Product. Documents produced by Liquidia include Supply and Quality agreements with

Yonsung, referencing for example, that the API will be manufactured for Liquidia by Yonsung pursuant to a Drug Master File (DMF) prepared by Yonsung, testing, manufacturing, quality checks, processing, reporting, auditing, and other interactions; portions of the DMF submitted on behalf of Yonsung; and correspondence with Yonsung employees, regarding, for example, materials, synthesized materials, processes, and FDA submissions relating to Yonsung's manufacturing process and the resulting API product. However, the partial correspondence, agreements, and partial documents (e.g., portions of a single DMF version confirming the existence of other sections and versions) produced by Liquidia to-date are incomplete and do not fully explain the interactions or information relevant to the infringement inquiry. Therefore, it is critical that Yonsung produce the requested documents and property of Yonsung relating to the alleged infringing manufacturing process and the resulting API product, and that at least certain Yonsung employees testify about their knowledge of Yonsung's alleged infringing manufacturing process and resulting API product. The requested documents, property and testimony, are necessary, in the interests of justice, for UTC to support its infringement case at trial.

III. ARGUMENT

The issuance of the Letter of Request is warranted for several reasons. First, documents produced by Liquidia including Supply and Quality agreements with Yonsung, referencing for example, that [redacted] portions of a 2020 version of the DMF submitted on behalf of Yonsung as a manufacturer; and correspondence with Yonsung employees, regarding, for example, materials, synthesized materials, processes, and FDA submissions relating to Yonsung's manufacturing

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