UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

KRISTI LAURIS, Individually and as Successor In Interest to the Estate of DAINIS LAURIS; KRISTI LAURIS as Guardian Ad Litem for L.L.; and TAYLOR LAURIS,

Plaintiffs,

v.

NOVARTIS AG, a Global Healthcare Company; NOVARTIS PHARMACEUTICALS CORPORATION, a Delaware Corporation,

Defendants.

Case No.: 1-16-cv-00393-SEH

LETTERS ROGATORY

REQUEST FOR INTERNATIONAL JUDICIAL ASSISTANCE

LETTERS ROGATORY

The United States District Court for the Eastern District of the State of California, United States of America, presents its compliments to the appropriate judicial authority having jurisdiction over civil causes in the City of Dorval, Quebec, Canada, and requests international judicial assistance to obtain evidence to be used in a civil proceeding pending before this Court in the above entitled matter. A trial is scheduled on this matter for January 23, 2018 in Fresno, California, United States of America.

This Court requests the assistance described herein as necessary in the interests of justice. The assistance requested is that the appropriate judicial authority of Quebec, Canada, compel the production of documents from the below listed Canadian entity and to allow service of process to be effected as is customary in your jurisdiction:

Novartis Pharmaceuticals Canada Inc. ("Novartis Canada"), with corporate address at 385 Bouchard Blvd., Dorval, Quebec, Canada H9S 1A9.

The above entitled matter pending before this Court is a commercial dispute between Plaintiffs and Novartis Pharmaceuticals Corporation and Novartis AG concerning alleged atherosclerosis-related events associated with Tasigna®. It has been suggested to us that there are witnesses residing within your jurisdiction with documents relevant to this dispute.

The documents to be produced are business records of the company. Specifically, we request documents related to Novartis Canada's actions around its knowledge of atherosclerotic disease associated with the prescription drug, Tasigna®. Plaintiffs allege that defendants in this matter, Novartis Pharmaceuticals Corporation and Novartis AG, knew of risks atherosclerotic-related conditions caused by Tasigna® but failed to warn American doctors and patients of these risks. In April 2013, Novartis Canada issued advisories to Canadian health care professionals and the Canadian public. These advisories warned of possible risks of atherosclerosis associated with Tasigna® and that patients taking Tasigna® should be monitored for signs of atherosclerosis-related conditions when taking Tasigna®. At or around that time, Novartis Canada updated its Canadian Product Monograph—the reference document that Canadian health professionals use when prescribing medication—to add information about atherosclerosis-related conditions.

Based on this information, Plaintiffs seek documents dated January 1, 2011 through December 31, 2013, from two Novartis Canada employees relating to atherosclerotic events associated with Tasigna®.

Based on search terms agreed to by counsel in this case designed to identify relevant documents without undue burden or expense, Plaintiffs seek the following:

Category 1: Clinical Study Data reports on Tasigna clinical trials including (i) the quantification of Peripheral Artery Occlusive Disease (PAOD) in chronic myeloid leukemia; (ii) status updates on the ENEST study; (iii) pharmacokinetic study of nilotinib and midazolam; (iv) hepatocellular carcinoma risk in murine models and (v) risk benefit analysis of Cardiovascular risk associated with Tyrosine Kinase Inhibitors. This category further includes study protocols, patient consent forms and amendments to same for CAMN1072303 entitled: "Phase III multi-center open label, randomized study of imatinib versus nilotinib in adult patients with newly diagnosed Philadelphia chromosome positive chronic myelogenous leukemia" and

study AMN107 entitled "Open label, multi-center nilotinib roll-over protocol for patients who have completed a previous Novartis sponsored nilotinib study and are judged by the investigator to benefit from continued nilotinib treatment."

Category 2: Screening Acceptance Letter and correspondence on the modifications to the Product Monograph by the Health Canada Regulatory Project Manager and relevant Product Monographs.

Category 3: Various internal correspondence including (i) Dear Health Professional letter warning of the Atherosclerosis related disease risk with Tasigna (ii) Request for clarification on changes risk factors for Tasigna by the FDA; (iii) response to regulatory on changes to Gleevec product monograph; (iv) marketing documents for patient centered websites relating to Tasigna and (v) Gleevec regional meeting agenda.

We, therefore, request in furtherance of justice that you, by the proper and usual process of your court, cause the aforementioned witnesses, or their agents or attorneys, to produce the aforementioned documents.

Please advise the Parties presenting this request with a statement of Costs incurred in executing these Letters Rogatory and we shall direct their payment.

This Court shall of course be ready and willing to extend the same courtesies should you require.

Dated: 3/21/17

Sam E. Haddon

Honorable Sam E. Haddon
United States District Judge