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Attorneys for Plaintiffs, 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

IN THE UNITED STATES DISTRICT COURT

FOR THE 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. **COMPLAINT FOR WRONGFUL DEATH AND PERSONAL INJURIES** **JURY TRIAL DEMANDED**

INTRODUCTION

1. This is an action brought by Plaintiffs against Defendants Novartis AG and Novartis Pharmaceuticals Corporation (collectively "Novartis") to recover for injuries resulting from Novartis's intentional failure to warn of dangerous and known risks associated with Tasigna—a Novartis-manufactured prescription medication for treatment of chronic myeloid leukemia (CML). Specifically, Novartis failed to warn of risks that Tasigna caused severe, accelerated, and irreversible forms of atherosclerosis-related conditions—i.e., the narrowing and hardening of arteries delivering blood to the arms, legs, heart, and brain. Despite warning doctors and patients in Canada of the risks of atherosclerosis, Novartis intentionally failed to warn United States

doctors and patients of these risks.

2. Decedent Dainis Lauris, a California resident, was prescribed and took Tasigna for over a year. Upon taking Tasigna, Dainis Lauris developed severe, accelerated, and irreversible atherosclerosis-related conditions, which caused, among other things, 100-percent narrowing of his femoral arteries, 40- to 60-percent narrowing of his coronary arteries, and 70-percent narrowing of his cerebral arteries. At no time while he was prescribed and took Tasigna did Novartis properly warn Dainis Lauris or his prescribing doctors about the atherosclerosis-related risks Novartis knew were associated with Tasigna. As a proximate result of Dainis Lauris's atherosclerosis-related conditions and Novartis's intentional failure to warn of them, Dainis Lauris died.

JURISDICTION AND VENUE

3. This Court has diversity subject matter jurisdiction under 28 U.S.C. § 1332 because Plaintiffs and Novartis are citizens of different states, and the amount in controversy exceeds $75,000.

4. Venue is appropriate in this Court under 28 U.S.C. § 1391(a) & (b) because a substantial part of the events and omissions giving rise to this action occurred in this district, and because Novartis resides in this district.

5. This Court has personal jurisdiction over Novartis, as Novartis marketed Tasigna in California and sold Tasigna to Dainis Lauris in California.

THE PARTIES

A. The Plaintiffs

6. Dainis Lauris and Kristi Lauris were legally married on May 24, 1995, and were husband and wife prior to and as of the date of Dainis Lauris's death on March 31, 2014. Together they have two children – Plaintiffs Taylor Lauris and L.L.

7. Plaintiffs Kristi Lauris, L.L., and Taylor Lauris are the sole heirs of decedent Dainis Lauris for the purposes of bringing this wrongful death lawsuit. They reside in Fresno County, California.

8. Kristi Lauris is the sole legal guardian of Plaintiff L.L.

9. Plaintiff Kristi Lauris is the Successor in Interest to the Estate of Dainis Lauris.

Prior to or coincident with the commencement of this action, Plaintiff Kristi Lauris filed a declaration as successor in interest of decedent Dainis Lauris, pursuant to California Code of Civil Procedure § 377.32. Said declaration accompanies and is served with this Complaint. In such capacity, plaintiff Kristi Lauris brings this claim for a Survival Cause of Action for Decedent pursuant to Code of Civil Procedure § 377.30, *et seq*.

B. The Defendants

10. Defendant Novartis AG is a global healthcare company based in Switzerland. Novartis AG is in the business of, among other things, manufacturing, marketing, distributing, promoting, testing, labeling, and selling Tasigna. Novartis AG sells Tasigna to patients in the United States through its wholly-owned subsidiary, Novartis Pharmaceuticals Corporation.

11. Defendant Novartis Pharmaceuticals Corporation is a Delaware Corporation with its principal place of business in East Hanover, New Jersey. Novartis Pharmaceuticals Corporation is in the business of, among other things, manufacturing, marketing, distributing, promoting, testing, labeling, and selling Tasigna.

12. Defendants, and each of them, were the agents, servants, representatives and employees of the remaining defendants, and each of them, and were at all times herein acting within the purpose and scope of said agency, service, representative and employment.

IV. GENERAL ALLEGATIONS

C. Novartis's Aggressive and Illegal Marketing of Tasigna

13. Tasigna is a prescription medication used to treat adults who have CML. CML is a cancer which starts in certain blood-forming cells of the bone marrow, where a genetic change occurs in an immature version of certain cells that make red blood cells, platelets, and most types of white blood cells. Tasigna is part of a group of treatments known as tyrosine-kinase inhibitors (TKIs), which target a protein—BCR-ABL—which is unique to CML cells.

14. The first TKI drug—Gleevec—was introduced in 2001, and, like Tasigna, is produced and sold by Novartis. At an annual cost that has more than tripled since it was introduced and is now over $100,000 per patient, Gleevec earned Novartis billions of dollars per year while it maintained patent exclusivity. For example, in 2012, Gleevec sales generated

approximately $4.7 billion for Novartis.

15. Novartis's patent on Gleevec expired on July 4, 2015, and there are currently several generic forms of Gleevec on the market, which cost as little as $500 per year.

16. In the years leading up to the expiration of Novartis's patent on Gleevec, Novartis developed Tasigna as a replacement for Gleevec, and began an aggressive campaign to attempt to convince doctors to prescribe, and patients to take, Tasigna over Gleevec. Beginning as early as 2010, Novartis's strategy was, in the words of one senior Novartis executive, to have Tasigna "cannibalize" Gleevec as Gleevec's patent approached expiration. This, the executive said, would "create a fairly large amount of the Gleevec business that will be indirectly protected because it [would be] switched already to Tasigna."

17. In furtherance of its strategy to have Tasigna cannibalize Gleevec, Novartis engaged in aggressive, and, at times, unethical and illegal marketing of Tasigna. One illegal and unethical practice was Novartis's disseminating widely-shared social media content that (1) promoted the efficacy of Tasigna while failing to disclose any safety information, including known risks of potentially fatal adverse reactions, (2) misrepresented that Tasigna was approved as a first-line therapy for CML (like Gleevec), when, at the time, it had only been approved as a second-line therapy for CML, and (3) described Tasigna as a "next generation" treatment for CML, which, in the words of the Food & Drug Administration, "misleadingly suggests superiority over other" TKI drugs (including Gleevec), "when this advantage has not been demonstrated by substantial evidence or substantial clinical experience." These practices caused the FDA to issue Novartis a cease and desist letter on July 29, 2010, finding that Novartis had misbranded Tasigna in violation of FDA regulations, and demanding that Novartis immediately cease the misleading and illegal advertising.

18. Another unethical practice involved Novartis, beginning in at least 2007, paying illegal kickbacks disguised as rebates and discount payments to specialty pharmacies in exchange for those pharmacies recommending to patients, doctors, and other healthcare managers the ordering and refilling of Tasigna, among other drugs. Novartis took steps to steer patients to these specialty pharmacies, who then encouraged patients and their doctors to switch to or stay on

Tasigna through several aggressive intervention programs designed by Novartis. These kickbacks paid to specialty pharmacies in exchange for their promotion of Tasigna were done in violation of the Federal Healthcare Program Anti-kickback Statute, 42 U.S.C. § 1320a-7b(b).

19. Another unethical practice involved Novartis's Japanese operations, where Novartis staff hid reports of adverse reactions in clinical studies of patients taking Tasigna. Novartis staff shredded or deleted thousands of reports of side effects associated with Tasigna, and in multiple instances, Novartis's sales staff helped doctors rate the severity of side effects. This egregious conduct resulted in the Japanese government ordering an unprecedented 15-day suspension of Novartis's Japanese operations.

D. Novartis Failed to Warn Americans of Known Risks that Tasigna Causes Atherosclerosis

20. Tasigna causes several dangerous adverse conditions, including severe, accelerated, and irreversible atherosclerosis-related conditions. These atherosclerosis- related conditions include peripheral arterial occlusive disease (hardening and narrowing of arteries supplying blood to the legs and arms), coronary atherosclerosis (hardening and narrowing of the arteries supplying blood to the heart), and cerebral atherosclerosis (hardening and narrowing of the arteries supplying blood to the brain). These conditions are life-threatening and lead to amputations, heart-attacks, strokes, and death.

21. Since at least 2011, Novartis was aware that Tasigna caused severe, accelerated, and irreversible atherosclerosis-related conditions. This knowledge came from several sources, including (1) multiple medical studies and reports linking Tasigna to accelerated and severe atherosclerosis; (2) multiple instances of patients developing atherosclerosis-related conditions reported during clinical trials and post-marketing experience with the use of Tasigna; and (3) information gathered in a Novartis global safety database reporting hundreds of cases of patients developing accelerated and severe atherosclerosis conditions after taking Tasigna.

22. The clear and alarming link between Tasigna and atherosclerosis prompted a Canadian health agency—Health Canada—to investigate the risks. As a result, in April 2013, Novartis issued an advisory to Canadian health care professionals and the Canadian public, which

Novartis disseminated through its Canadian channels only, and did not disseminate in the United States. These advisories warned of the risks of atherosclerosis associated with Tasigna and that patients taking Tasigna should be monitored for signs of atherosclerosis-related diseases when taking Tasigna.

23. At or around the same time, Novartis updated its Canadian Product Monograph—the reference document that Canadian health professionals use when prescribing medication—to warn of the risks of atherosclerosis-related diseases. This warning was prominently displayed in a box warning entitled "Serious Warnings and Risks." Novartis warned that the atherosclerosis-related condition could result in death, and that the risks of peripheral arterial occlusive disease, "can be severe, rapidly evolving, and may involve more than one site. Peripheral arterial occlusive disease might require repeated revascularization procedures and can result in complications that may be serious such as limb necrosis and amputations."

24. Despite warning in Canada of the risks of atherosclerosis associated with Tasigna, Novartis did not, during the relevant time period alleged herein, properly warn United States doctors and patients of those risks. Novartis did not send advisories to the United States public or to United States doctors. Nor did Novartis properly warn of the atherosclerosis-related risks on the United States Tasigna label. Novartis did not warn of risks of developing atherosclerosis on the highlights page of the United States label—including in the box warning, under the "Warnings and Precautions" heading, or under the "Adverse Reaction" heading. Nor did Novartis warn of atherosclerosis-related conditions under Section 5 of the label describing "Warnings and Precautions," under Section 6 describing "serious adverse reactions," or under section 6.1 describing "Clinical Trial Experience."

25. Novartis's failure to warn United States doctors and patients of the serious risks of developing atherosclerosis-related conditions associated with Tasigna was intentional, and part of an aggressive marketing strategy to sell Tasigna over competing TKI drugs.

E. Dainis Lauris Takes Tasigna, Develops Severe Atherosclerosis-Related Conditions, and Dies

26. Dainis Lauris was diagnosed with CML in 2001. From 2001 through roughly

2012, Lauris was prescribed and took Gleevec.

27. In October 2012, Dainis Lauris's treating physician switched him from Gleevec to Tasigna. As described in paragraph 21 above, the Tasigna label did not properly warn of the risks of atherosclerosis-conditions associated with Tasigna during the relevant time period alleged herein.

28. At the time that Dainis Lauris switched from Gleevec to Tasigna, Lauris had no atherosclerosis-related conditions.

29. Upon taking Tasigna, Dainis Lauris began feeling cramping and tightening in his legs and shins. This cramping and tightening was a symptom of accelerated atherosclerosis-related conditions, including peripheral arterial occlusive disease, which Dainis Lauris developed as a result of Tasigna. But because Novartis failed to warn of the risks of atherosclerosis associated with Tasigna, his cramping and tightening was mistaken as muscle cramping.

30. Dainis Lauris's condition deteriorated dramatically over the next year. By January 2013, he began feeling pain in his legs when conducting routine activities—such as cutting the lawn, walking, and basic exercise. By May 2013, Dainis Lauris's ability to engage in such normal activities were significantly hampered, and by July 2013 he could not walk short distances without having to stop due to extreme pain. Indeed, on July 4, 2013, he had to be driven one block to enjoy a firework display with his family because walking that distance had become impossible for him. He was also, for the first time in 33 years, unable to attend an annual hunting event with his family, and he could not attend a back-to-school event for his children. The pain greatly affected Dainis Lauris's quality of life, and sleeping was difficult. Dainis Lauris's deteriorating condition also caused an enormous amount of stress on his family, who watched him deteriorate from a healthy and active husband and father to a man constantly in pain and unable to perform basic activities.

31. Dainis Lauris's deterioration in health resulted from his severe, accelerated, and irreversible atherosclerosis, including peripheral occlusive arterial disease, coronary artery disease, and cerebral atherosclerosis—all of which was caused by Tasigna.

32. By September 2013, Dainis Lauris's pedal pulse—the pulse of the artery taken at

the dorsal surface of the foot—went from "normal" to "not normal," meaning that the blood supply to his lower extremities had been severely diminished. An angiogram was performed on Dainis Lauris, which revealed that there was 100-percent blockage in Dainis Lauris's right femoral artery near the hip, 90-percent blockage in the artery behind the right knee, and 90-percent blockage in the artery behind his left knee.

33. In November 2013, Dainis Lauris's oncologist happened upon a published article in a medical journal that discussed the link between Tasigna and severe, accelerated atherosclerosis-related conditions. He immediately called Dainis Lauris and told him not to take another Tasigna pill. His oncologist switched Dainis Lauris from Tasigna to Sprycel—a competing drug produced by Bristol Myers Squibb Company with no known links to atherosclerosis-related conditions. The oncologist also notified Novartis that Tasigna had caused Dainis Lauris's atherosclerosis-related conditions, but received no response.

34. The discontinuation of Tasigna, however, was too late—Dainis Lauris's atherosclerosis was advanced and irreversible. On November 22, 2013, in a final effort to reduce further damage to his right leg and avoid amputation, Dainis Lauris had peripheral artery bypass surgery performed on his right leg—an invasive and painful procedure.

35. On March 31, 2014, Dainis Lauris died due to complications from his atherosclerosis. An autopsy after his death revealed that in addition to the blockage in his arteries in his legs, Dainis Lauris had approximately 70-percent narrowing of his middle cerebral arteries, and 40- to 60-percent narrowing of his coronary arteries. All of these conditions were caused by Tasigna.

CLAIMS FOR RELIEF

COUNT I: STRICT PRODUCTS LIABILITY

36. Plaintiffs re-allege the above allegations as if fully set forth herein.

37. At all relevant times, Novartis was engaged in the business of creating, designing, manufacturing, selling, advertising, promoting, and distributing Tasigna throughout the world, including in California.

38. At all relevant times, despite knowing of risks that Tasigna caused severe,

accelerated, and irreversible atherosclerosis-related conditions, and despite warning of such risks in Canada, Novartis failed to reasonably warn patients and doctors in the United States— including Dainis Lauris and the medical professionals that prescribed him Tasigna—of those risks.

39. As a proximate result of Novartis's failure to warn, Dainis Lauris developed atherosclerosis-related conditions—including peripheral arterial occlusive disease, coronary atherosclerosis, and cerebral atherosclerosis—and died.

40. Novartis's failure to properly warn of atherosclerosis was intentional. Driven by its desire for Tasigna to dominate the multi-billion dollar TKI market in the wake of Gleevec's patent expiration, Novartis intentionally failed to warn Americans of known risks that Tasigna caused severe, accelerated, and irreversible atherosclerosis-related conditions. Such conduct was wanton—done with an oppressive, fraudulent, or malicious motive and in deliberate and conscious disregard for the health and safety of Dainis Lauris and others similarly situated. Therefore, Plaintiffs are entitled to an award of punitive damages against Novartis under Cal. Civ. Code § 3294.

WHEREFORE, Plaintiffs respectfully request judgment against defendants named herein, and each of them, as set forth below.

COUNT II: NEGLIGENCE

41. Plaintiffs re-allege the above allegations as if fully set forth herein.

42. Novartis had a duty to exercise reasonable care in warning about the health and safety risks that it knew or reasonably should have known were associated with Tasigna. Novartis breached this duty of care by failing to reasonably warn of the risk that Tasigna caused atherosclerosis-related conditions.

43. Further, in failing to properly warn of the risks that Tasigna causes atherosclerosis, Novartis violated several statutes and regulations, thereby creating a presumption of negligence under California Evidence Code § 669(a), including, but not limited to: 21 C.F.R. § 201.56(a) & (d), and 21 C.F.R. § 201.57(c) & (f).

44. As a proximate result of Novartis's negligence, Dainis Lauris developed atherosclerosis-related conditions – including peripheral arterial occlusive disease, coronary

atherosclerosis, and cerebral atherosclerosis – and died.

45. Novartis's failure to properly warn of atherosclerosis was intentional. Driven by its desire for Tasigna to dominate the multi-billion dollar TKI market, Novartis intentionally failed to warn Americans of known risks that Tasigna caused severe, accelerated, and irreversible atherosclerosis-related conditions. Such conduct was wanton—done with an oppressive, fraudulent, or malicious motive and in deliberate and conscious disregard for the health and safety of Dainis Lauris and others similarly situated. Therefore, Plaintiffs are entitled to an award of punitive damages against Novartis under Cal. Civ. Code § 3294.

WHEREFORE, Plaintiffs respectfully request judgment against defendants named herein, and each of them, as set forth below.

COUNT III: WRONGFUL DEATH

46. Plaintiffs re-allege the above allegations as if fully set forth herein.

47. Prior to and as of March 31, 2014, plaintiff, Kristi Lauris, was the wife of the decedent, Dainis Lauris and they were living together as husband and wife. Plaintiffs L.L. and Taylor Lauris, were the daughters of decedent, Dainis Lauris. Plaintiffs are the sole heirs of decedent Dainis Lauris for the purposes of bringing a claim for wrongful death under the laws of the State of California and United States of America.

48. As a direct and legal result of the acts, conduct and omissions of Novartis, its employees and agents, plaintiffs' decedent, Dainis Lauris, suffered the injuries described above which resulted in and caused his death.

49. As a further direct and proximate result of the acts, conduct and omissions of Novartis, its employees and agents, as alleged herein above, plaintiffs were required to and did employ physicians, medical specialists, and nurses to examine, treat and care for plaintiffs' decedent, and medical and incidental expenses were incurred in an amount not now known to plaintiffs.

50. As a further direct and proximate result of the acts, conduct and omissions of Novartis, its employees and agents, as alleged herein above, plaintiffs were required to and did

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incur funeral, burial and incidental expenses.

51. As a further direct and proximate result of the wrongful death of Dainis Lauris, the plaintiffs, Kristi Lauris, L.L., and Taylor Lauris, have suffered the loss of financial support of their husband and father and are also entitled to compensation for the loss of love, companionship, comfort, affection, society, solace and moral support. These damages are in excess of the jurisdictional limits of this court.

WHEREFORE, Plaintiffs respectfully request judgment against defendants named herein, and each of them, as set forth below.

COUNT IV: SURVIVAL CAUSE OF ACTION
[C.C.P. §377.20 *ET SEQ.*]

52. Plaintiffs re-allege the above allegations as if fully set forth herein.

53. Plaintiff, Kristi Lauris is the successor in interest to the Estate of Dainis Lauris, decedent.

54. Plaintiff seeks recovery for the wrongful death of Dainis Lauris, and claim all damages sustained by Dainis Lauris and his estate as a proximate cause of the wrongful death, as herein stated.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against defendants, awarding Plaintiffs any and all damages available to Plaintiffs under the law, including but not limited to:

1. General damages according to proof;
2. Medical and incidental expenses according to proof;
3. Funeral, burial and incidental expenses according to proof;
4. All losses because plaintiffs will not be able to pursue their usual occupation and activities according to proof;
5. Decedent's pain and suffering according to proof;
6 For loss of consortium, love, companionship, comfort, affection, society, solace, and moral support;
7. Punitive and exemplary damages sufficient to punish and make an example of such

defendants, under Cal. Civ. Code § 3294, according to proof;

8. Plaintiffs' reasonable attorneys' fees and costs;

9. Prejudgment interest, and

10. For any other relief this Court deems appropriate.

DEMAND FOR A JURY TRIAL

Plaintiffs hereby demand a jury trial for all issues so triable in this action.

DATE: March 21, 2016

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