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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

1 doctors and patients of these risks.

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

10 **JURISDICTION AND VENUE**

11 3. This Court has diversity subject matter jurisdiction under 28 U.S.C. § 1332 because
12 Plaintiffs and Novartis are citizens of different states, and the amount in controversy exceeds
13 \$75,000.

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

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

19 **THE PARTIES**

20 **A. The Plaintiffs**

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

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

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

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

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

6 **B. The Defendants**

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

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

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

18 **IV. GENERAL ALLEGATIONS**

19 **C. Novartis's Aggressive and Illegal Marketing of Tasigna**

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

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

1 approximately \$4.7 billion for Novartis.

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

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

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

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

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

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

10 **D. Novartis Failed to Warn Americans of Known Risks that Tazigna Causes**
11 **Atherosclerosis**

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

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

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

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

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

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

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

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

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

1 2012, Lauris was prescribed and took Gleevec.

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

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

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

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

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

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

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

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

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

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

22 **CLAIMS FOR RELIEF**

23 **COUNT I: STRICT PRODUCTS LIABILITY**

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

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

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

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

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

7 40. Novartis’s failure to properly warn of atherosclerosis was intentional. Driven
8 by its desire for Tasigna to dominate the multi-billion dollar TKI market in the wake of Gleevec’s
9 patent expiration, Novartis intentionally failed to warn Americans of known risks that Tasigna
10 caused severe, accelerated, and irreversible atherosclerosis-related conditions. Such conduct was
11 wanton—done with an oppressive, fraudulent, or malicious motive and in deliberate and conscious
12 disregard for the health and safety of Dainis Lauris and others similarly situated. Therefore,
13 Plaintiffs are entitled to an award of punitive damages against Novartis under Cal. Civ. Code §
14 3294.

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

17 **COUNT II: NEGLIGENCE**

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

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

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

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

1 atherosclerosis, and cerebral atherosclerosis – and died.

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

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

11 **COUNT III: WRONGFUL DEATH**

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

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

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

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

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

28 ///

1 incur funeral, burial and incidental expenses.

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

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

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

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

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

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

17 **PRAYER FOR RELIEF**

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

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

- 1 defendants, under Cal. Civ. Code § 3294, according to proof;
- 2 8. Plaintiffs' reasonable attorneys' fees and costs;
- 3 9. Prejudgment interest, and
- 4 10. For any other relief this Court deems appropriate.

5 **DEMAND FOR A JURY TRIAL**

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

7 DATE: March 21, 2016

8 WEAKLEY & ARENDT, LLP

9
10 By: /s/ James D. Weakley
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