UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA

EMILY RILEY, Plaintiff, v. NOVARTIS PHARMACEUTICALS CORPORATION, Defendant.	CASE NO.

COMPLAINT

1. This is an action brought by Emily Riley (hereinafter, "Plaintiff") against Defendant Novartis Pharmaceuticals Corporation (hereinafter, "Novartis") to recover for injuries resulting from Novartis' 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 several forms of severe, accelerated, and irreversible atherosclerotic-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 atherosclerotic-related conditions, Novartis concealed, and continues to conceal, their knowledge of Tasigna's unreasonably dangerous risks from Plaintiff, other consumers, and the medical community.

2. After beginning treatment with Tasigna, and as a direct and proximate result of Novartis' actions and inaction, Plaintiff suffered serious atherosclerotic-related injuries. Plaintiff's ingestion of Tasigna caused and will continue to cause injury and damage to Plaintiff.

3. Plaintiff accordingly seeks compensatory and punitive damages, monetary restitution, and all other available remedies as a result of injuries caused by Tasigna.

JURISDICTION AND VENUE

4. This Court has diversity subject matter jurisdiction under 28 U.S.C. § 1332 because Plaintiff and Novartis are citizens of different states, and the amount in controversy exceeds $75,000. Specifically, as alleged in more detail below, Plaintiff is a citizen of the State of Florida while Novartis is a citizen of the States of Delaware and New Jersey. Additionally, the damages Plaintiff sustained as a result of Novartis' intentional failure to warn of known, serious, and life-threatening side effects associated with Tasigna substantially exceed $75,000.

5. 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.

6. This Court has specific jurisdiction over Novartis, because Novartis produced, manufactured, marketed, sold, and failed to warn of the risks associated with the very Tasigna pills that injured Plaintiff, all of which were prescribed to, sold to, and ingested by Plaintiff in Florida.

THE PARTIES

A. The Plaintiff

7. At all relevant times, including at the time of his atherosclerotic-related injury(ies) and currently, Plaintiff Emily Riley has been a United States citizen, residing and domiciled in Lakeland, Florida, and is thus a citizen of the State of Florida.

B. The Defendant

8. Defendant Novartis is incorporated in Delaware with its principal place of business in East Hanover, New Jersey, and is thus a citizen of the States of Delaware and New Jersey. Novartis researches, develops, produces, markets, and sells pharmaceuticals, including Tasigna,

throughout the United States.

GENERAL ALLEGATIONS

A. Laws and Regulations Governing the Approval and Labeling of Prescription Drugs

9. The Federal Food, Drug, and Cosmetic Act ("FDCA" or the "Act") requires manufacturers that develop a new drug product to file a New Drug Application ("NDA") in order to obtain approval from the Food and Drug Administration ("FDA") before selling the drug in interstate commerce. 21 U.S.C. § 355.

10. The NDA must include, among other things, data regarding the safety and effectiveness of the drug, information on any patents that purportedly cover the drug or a method of using the drug, and the labeling proposed to be used for the drug. 21 U.S.C. § 355(b).

11. Manufacturers with an approved NDA must review all adverse drug experience information obtained by or otherwise received by them from any source, including but not limited to post marketing experience, reports in the scientific literature, and unpublished scientific papers. 21 C.F.R. § 314.80(b).

12. After FDA approval, manufacturers may only promote drugs in a manner consistent with the contents of the drug's FDA-approved label. 21 C.F.R. § 202.1. The FDA's Division of Drug Marketing, Advertising, and Communications monitors manufacturers' promotional activities and enforces the FDCA and its implementing regulations to ensure compliance.

13. Although the FDA approves the label, the drug manufacturer has the duty to warn of dangerous side effects associated with its drug. Under what is known as the Changes Being Effected ("CBE") regulation, a manufacturer with an approved NDA can, among other things, add or strengthen a warning in its label without prior FDA approval by simply sending the FDA a "supplemental submission." 21 C.F.R. § 314.70(c)(6)(iii).

14. Specifically, the manufacturer can "add or strengthen a contraindication, warning, precaution, or adverse reactions for which the evidence of causal association satisfies the standard for inclusion in the labeling under § 201.57(c) of this chapter" and "to add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product." 21 C.F.R. § 314.70(c)(6)(iii)(A) and (C).

15. A manufacturer must revise its label "to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug; a causal relationship need not have been definitively established." 21 C.F.R. § 201.57(c)(6).

16. The warnings section of the label "must identify any laboratory tests helpful in following the patient's response or in identifying possible adverse reactions. If appropriate, information must be provided on such factors as the range of normal and abnormal values expected in the particular situation and the recommended frequency with which tests should be performed before, during, and after therapy." *Id*. § 201.57(c)(6)(iii). According to an FDA Guidance for Industry on the warnings and precautions section of the labeling, "[i]nformation about the frequency of testing and expected ranges of normal and abnormal values should also be provided if available."[1]

17. Adverse reactions must be added to the label where there "is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event." *Id*. § 201.57(c)(7).

18. An August 22, 2008 amendment to these regulations provides that a CBE

[1] FDA Guidance Document, Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products – Content and Format, October 2011, https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM075096.pdf (last visited, February 12, 2020).

supplement to amend the labeling for an approved product must reflect "newly acquired information." 73 Fed. Reg. 49609. "Newly acquired information" is not limited to new data but also includes "new analysis of previously submitted data." *Id*. at 49606. "[I]f a sponsor submits adverse event information to FDA, and then later conducts a new analysis of data showing risks of a different type or of greater severity or frequency than did reports previously submitted to FDA, the sponsor meets the requirement for 'newly acquired information.'" *Id*. at 49607.

B. Novartis' Aggressive and Illegal Marketing of Tasigna

19. Tasigna is a prescription medication used to treat adults who have CML. CML is a cancer which starts in blood-forming stem cells of the bone marrow, where a genetic change occurs in the stem cells that form, among other things, most types of white blood cells. Tasigna is part of a group of treatments known as tyrosine-kinase inhibitors ("TKIs"), which block chemical messengers (enzymes) in the cancer cells called tyrosine kinases, thus inhibiting their growth and division.

20. The first TKI drug – Gleevec – was introduced in 2001, and, like Tasigna, is produced and sold by Novartis. At its peak, the annual cost of Gleevec per patient was over $100,000. Gleevec earned Novartis billions of dollars a year while it maintained patent exclusivity. For example, in 2012, Gleevec was Novartis' number one selling drug, generating approximately $4.7 billion.

21. Novartis' patent on Gleevec expired on July 4, 2015, and there are currently several generic forms of Gleevec on the market, which cost substantially less.

22. In the years leading up to the expiration of Novartis' patent on Gleevec, Novartis developed Tasigna as a replacement for Gleevec, and began an aggressive campaign to convince doctors to prescribe, and patients to take, Tasigna over Gleevec and other competing drugs.

Beginning as early as 2010, Novartis' 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."

23. To this end, according to Novartis' internal strategic documents, Novartis imposed a global directive to "establish Tasigna as the new standard of care," replace Gleevec "as rapidly as possible," and convert the majority of Novartis' CML sales to Tasigna by 2014. According to an internal strategy document drafted by and for Novartis' senior leadership in 2011, to maintain its global leadership in CML sales, it was critical that "Tasigna [] achieve a market leadership and a premium price vs. [Gleevec] to compensate for lost revenue." The document further stated that "[r]apid transition of the business to Tasigna [was] a *commercial imperative*, given the impending loss of Gleev[ec] exclusivity in major markets, including US (2015) and Western Europe (2016)." (emphasis added).

24. As part of the commercial imperative to switch patients to Tasigna, Novartis promoted Tasigna as a better and safer alternative to Gleevec and other competitors for CML. According to internal marketing strategy documents, Novartis launched an initiative coined "Selling the Switch," where Novartis instructed its sales force to undermine the "strong emotional attachment" doctors had to Gleevec. To this end, Novartis devised a "Loyalty Disruption Project," focused on disrupting the medical community's emotional attachment to Gleevec by, among other things, selling Tasigna as a "super-Gleevec," and inspiring "confidence through bandwagon effect."

25. 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 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 (FDA), "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.

26. Another unethical practice, beginning in at least 2007, involved Novartis paying illegal kickbacks disguised as rebates and discount payments to specialty pharmacies in exchange for 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).

27. Another unethical practice involved Novartis' 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' 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' Japanese operations.

C. Novartis Failed to Warn Americans of Known Risks that Tasigna Causes Severe Atherosclerotic-Related Conditions

28. Tasigna causes several dangerous adverse conditions, including several forms of severe, accelerated, and irreversible atherosclerotic-related conditions. These atherosclerotic-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 and carotid 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.

29. These risks of Tasigna causing severe, accelerated, and irreversible forms of atherosclerosis became known to Novartis no later than 2010, while Novartis was engaged in its aggressive marketing efforts to establish Tasigna as the new standard of care in CML treatment. This knowledge came from several sources, including (1) multiple reports from their clinical investigators (whom Novartis described as "Key Opinion Leaders"), who informed Novartis of patients developing severe and accelerated atherosclerotic-related conditions while on Tasigna, and urged Novartis to warn doctors and patients of these risks (which Novartis refused to do); (2) multiple medical studies and reports linking Tasigna to accelerated and severe atherosclerosis; (3) a significantly higher rate of severe atherosclerotic-related conditions occurring amongst Tasigna patients in a phase 3 randomized clinical trial comparing the efficacy of Tasigna to Gleevec, and (4) information gathered in a Novartis global safety database reporting hundreds of cases of patients developing accelerated and severe atherosclerotic-related conditions after taking Tasigna.

30. In February 2011, after repeated communications throughout 2010 of what he

described as a crisis of Tasigna patients developing atherosclerotic-related conditions, one of Novartis' clinical investigators and Key Opinion Leaders wrote a formal letter to Novartis' safety leaders, urging them to warn doctors of the risks. The doctor noted that twenty-five percent (25%) of patients in his clinic had developed atherosclerotic-related diseases, which in many patients were "unexpected … extremely severe, or extremely unusual" in nature. He urged Novartis to send a "Dear Doctor Letter" to all doctors and to join him in writing a special report to the FDA on this issue, including the relevant literature and other information establishing an association between Tasigna and accelerated atherosclerosis. To date, Doctors in the United States have not been sent a "Dear Doctor Letter" addressing these issues.

31. Novartis failed to take such action because of the feared impact that warning doctors and the public would have on sales at a critical time in its "Switch" campaign. Indeed, internal documents reveal that when deliberating on whether to issue the warnings urged by Novartis' investigator, Novartis' safety personnel expressly considered the "financial outcome" that such a warning would have on Novartis.

32. The clear and alarming link between Tasigna and atherosclerosis prompted the Canadian health agency—Health Canada—to investigate the risks. As a result, in July 2012, the agency sent Novartis a 57-page report detailing the epidemiological and other evidence linking Tasigna to accelerated and severe atherosclerotic-related conditions. The report concluded that the evidence "strongly suggest[ed] … an association between the use of Tasigna and the development/exacerbation of atherosclerotic-related diseases." This prompted Novartis, in August 2012, to update its Canadian Product Monograph—the reference document that Canadian health professionals use when prescribing medication—to warn of the risks of atherosclerotic-related diseases. Warnings regarding atherosclerotic-related diseases were prominently displayed in a box

entitled "Serious Warnings and Risks." The box warning directed health professionals to the Warnings and Precautions section, which warned that atherosclerotic-related conditions could result in death, and that Tasigna-related 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." To date, similar warnings have never appeared in the United States label for Tasigna.

33. Further, 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 atherosclerotic-related diseases when taking Tasigna. To date, Physicians in the United States have received no similar notice.

34. Novartis did not warn of the atherosclerotic-related risks in the United States Tasigna label. These risks were not included on the highlights page of the United States label—including as a "black box" warning[2], under the "Warnings and Precautions" heading, or under the "Adverse Reaction" heading. Nor did Novartis warn of atherosclerotic-related risks 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."

35. Novartis failed to warn United States doctors like it did Canadian doctors because of the feared impact that such warning would have on sales. Indeed, in late 2012 and early 2013,

[2] A "black box warning" appears on a prescription drug's label and is designed to call attention to serious or life-threatening risks. *See*, https://www.fda.gov/media/74382/download. This is essentially the equivalent of the "Serious Warnings and Precautions" box in the Canadian Product Monograph.

after the issuance of the warnings in Canada, Novartis, including senior leadership responsible for safety and global regulatory affairs, analyzed the impact that the warning had on Tasigna sales and found that it had done substantial "damage" to Novartis' "billion dollar asset." For this reason, these same personnel decided to reverse a prior decision to warn of atherosclerotic-related risks in the United States.

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

D. Novartis Could Have Unilaterally Strengthened the Tasigna Drug Label After FDA Approval in the United States

37. Novartis could have strengthened the Tasigna label at any time under the CBE regulation without prior FDA approval. The CBE regulation permits manufacturers to strengthen drug labels based on "newly acquired information" – that is, information that was not previously presented to the FDA.

38. As described above, Novartis received significant "newly acquired information" after the launch of Tasigna that, through the CBE regulation, should have resulted in a label change warning of the risks of atherosclerotic-related injury associated with Tasigna. This newly acquired information came in the form of (1) multiple reports from their clinical investigators, (2) multiple medical studies and reports, (3) data from a phase 3 randomized clinical trial, and (4) adverse event information gathered in a Novartis global safety database. *See* ¶ 29, *supra.*

39. While Novartis had ample opportunity to strengthen its label to add a warning similar to the one added to the Canadian Product Monograph, Novartis declined to do so. In fact, though Novartis has made numerous changes to the label throughout the history of Tasigna, none of those changes included a warning that the atherosclerotic-related conditions caused by Tasigna

could result in death, and that the risks of Tasigna related peripheral arterial occlusive disease, "can be severe, rapidly evolving, and may involve more than one site … [p]eripheral arterial occlusive disease might require repeated revascularization procedures and can result in complications that may be serious such as limb necrosis and amputations."

40. Notably, it wasn't until January 22, 2014 that the Tasigna label contained *any* warning regarding cardiovascular events. The label was updated to include cardiovascular events only after a label change was requested by the FDA. In response to FDA's request Novartis modified its label to include the following warning in the "warnings and precautions" section:

> Cardiac and Vascular Events: Cardiovascular events including ischemic heart disease, peripheral arterial occlusive disease and ischemic cerebrovascular events have been reported in patients with newly diagnosed Ph+CML receiving nilotinib. Cardiovascular status should be evaluated and cardiovascular risk factors monitored and managed during Tasigna therapy.

41. This warning was and remains wholly inadequate because it failed to warn doctors of the risk of death and the severe rapidly evolving nature of Tasigna related peripheral arterial occlusive disease that could require repeated revascularization procedures potentially leading to limb necrosis and amputations. In addition, this warning was not added as a "black box warning" as the Canadian warning was.

42. Instead of seizing the opportunity to adequately warn doctors regarding a severe and life-threatening condition, Novartis instead made affirmative efforts to ensure the warning was as innocuous as possible.

43. Indeed, when presented with the request from FDA to update the label, Novartis employees quickly made it clear that rather than ensure the new warning was as robust and accurate as possible, they would instead "work to push back" against the warning. The label was ultimately modified to include nothing more than a severely watered-down, inadequate warning that failed to

put doctors on notice regarding the true atherosclerotic-related risks associated with Tasigna.

44. Further, after the watered-down warning was finalized, a Senior Product Director for Novartis expressed her disappointment that the warning had to be added as written, but made it clear the warning could have been stronger, stating: "[w]e can live with it … [c]ould have been worse … [w]e will count our blessings and move on."

45. In January 2014, following the inadequate label update, Novartis undertook a project to issue a Dear Healthcare Professional Letter to all United States doctors regarding the vascular risks associated with Tasigna. In February 2014, Novartis even drafted the letter, which was titled "**IMPORTANT DRUG WARNING**" and contained the subject line: "**Cardiac and Vascular Events in patients with chronic myelogenous leukemia treated with Tasigna (nilotinib)**" (emphasis in original). Despite this, at the direction of Senior Novartis executives, the letter was never sent. Novartis never told the FDA about their initial decision to send a letter or that one had been drafted.

46. At no time since Tasigna was approved has Novartis proposed to FDA that language similar to the warning provided to doctors in Canada about the atherosclerotic-related risks caused by Tasigna should be added to the label in the United States. Likewise, at no time since Tasigna was approved has Novartis sent a Dear Health Care Professional letter to doctors in the United States warning of atherosclerotic-related risks caused by Tasigna.

47. Since Novartis never proposed the addition of such a warning to the FDA, there is no evidence that FDA would have rejected a supplemental submission by Novartis to add such a warning.

48. To this day, the Tasigna label remains inadequate as it has not been updated to include a warning similar to the one provided in Canada and fails to warn of the atherosclerotic-

related risks associated with Tasigna.

E. Plaintiff Suffered Atherosclerotic-related injury

49. Plaintiff Emily Riley was diagnosed with CML in 2011.

50. Plaintiff took Tasigna from August 2011 to August 2012. As described above, at no time before or during the time that Plaintiff took Tasigna did the Tasigna label adequately warn of the risks of atherosclerotic-related conditions associated with the drug.

51. As a result of his use of Tasigna, Plaintiff suffered a myocardial infarction requiring a stent. Additionally, she suffered severe lower extremity vascular disease resulting in left femoral popliteal artery bypass, a right artery stent and repeat stent, and an angioplasty.

F. Exemplary/Punitive Damages Allegations

52. Novartis' conduct as alleged herein was done with reckless disregard for human life, oppression, and malice. Novartis was fully aware of the safety risks of Tasigna. Nonetheless, Novartis deliberately crafted their label, marketing, and promotion to mislead consumers.

53. This was not done by accident. Rather, Novartis knew that it could turn a profit by convincing physicians and consumers that Tasigna came without certain, harmful risks. Novartis further knew that full disclosure of the true risks of Tasigna would limit the amount of money it would make selling the drug. Novartis' object was accomplished not only through inadequate warnings in their label, but through a comprehensive scheme of misleading marketing and deceptive omissions more fully alleged throughout this pleading. Plaintiff's physician and Plaintiff were denied the right to make an informed decision about whether to prescribe and take Tasigna, knowing the full risks attendant to that use. Such conduct was done with conscious disregard of Plaintiff's rights.

54. Accordingly, Plaintiff requests punitive damages against Novartis for the harms caused to Plaintiff.

CLAIMS FOR RELIEF

COUNT I: STRICT LIABILITY – FAILURE TO WARN

55. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

56. At all relevant times, Novartis engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and promoting Tasigna which is defective and unreasonably dangerous to consumers, including Plaintiff, because it does not contain adequate warnings or instructions concerning its dangerous characteristics. These actions were under the ultimate control and supervision of Novartis. At all relevant times, Novartis registered, researched, manufactured, distributed, marketed, and sold Tasigna within this judicial district. Novartis was, at all relevant times, involved in the sale and promotion of Tasigna products marketed and sold in in this judicial district.

57. Novartis researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released Tasigna into the stream of commerce and in the course of same, directly advertised or marketed Tasigna to consumers and end users, including Plaintiff. Novartis therefore had a duty to adequately warn of the atherosclerotic-related risks associated with the use of Tasigna.

58. At all relevant times, Novartis had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure Tasigna did not cause users, like Plaintiff, to suffer from unreasonable and dangerous risks. Novartis had a continuing duty to warn users, including Plaintiff, of dangers associated with Tasigna. Novartis, as a manufacturer, seller, or distributor of pharmaceutical medications, is held to the knowledge of an expert in the field.

59. At the time of manufacture, Novartis could have provided warnings or instructions regarding the full and complete risks of Tasigna, because Novartis knew, or should have known, of the unreasonable risks of harm associated with the use of and/or exposure to Tasigna.

60. At all relevant times, Novartis failed and deliberately refused to investigate, study, test, or promote the safety or minimize the dangers to those who would foreseeably use or be harmed by Tasigna, including Plaintiff.

61. Even though Novartis knew, or should have known, that Tasigna posed a grave risk of harm, it failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure. The dangerous propensities of Tasigna, as described above, were known to Novartis, or scientifically knowable to Novartis, through appropriate research and testing by known methods, at the time they distributed, supplied, or sold the product, and were not known to end users and consumers, such as Plaintiff.

62. Novartis knew or should have known that Tasigna created significant risks of serious bodily harm to consumers, as alleged herein, and Novartis failed to adequately warn consumers, *i.e.*, the reasonably foreseeable users, of the risks of exposure to the drug. Novartis has wrongfully concealed information concerning the dangerous nature of Tasigna and has made false and/or misleading statements concerning its safety.

63. At all relevant times, Tasigna reached intended consumers, handlers, and users or other persons coming into contact with the product within this judicial district and throughout the United States, including Plaintiff, without substantial change in its condition as designed, manufactured, sold, distributed, labeled, and marketed by Novartis.

64. Plaintiff was exposed to Tasigna without knowledge of its dangerous characteristics.

65. At all relevant times, Plaintiff used and/or was exposed to Tasigna while using the drug for its intended or reasonably foreseeable purpose, without knowledge of its dangerous characteristics.

66. Plaintiff could not have reasonably discovered the defects and risks associated with Tasigna prior to or at the time of consuming Tasigna. Plaintiff relied upon the skill, superior knowledge, and judgment of Novartis to know about and disclose serious health risks associated with using Tasigna.

67. Novartis knew or should have known that the minimal warnings disseminated with Tasigna were inadequate, failed to communicate adequate information on the dangers of sustaining severe atherosclerotic-related injuries, and failed to communicate warnings and instructions that were appropriate and adequate to render Tasigna safe for its ordinary, intended, and reasonably foreseeable use.

68. The information that Novartis did provide or communicate failed to contain relevant, adequate warnings, hazards, and precautions that would have enabled consumers, such as Plaintiff, to consume Tasigna safely. Instead, Novartis disseminated information that was inaccurate, incomplete, false, and misleading, and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with use of Tasigna. In fact, Novartis continued to aggressively promote the efficacy and safety of Tasigna, even after they knew or should have known of the unreasonable risks from use. Novartis also concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of Tasigna.

69. This failure to warn is not limited to the information contained on Tasigna's labeling. Novartis was able, in accord with federal law, to comply with relevant state law by

disclosing the known risks associated with Tasigna through other, non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. Instead, Novartis did not disclose the known, severe risks of Tasigna through any medium.

70. Novartis is liable to Plaintiff for injuries caused by its negligent or willful failure, as described above, to provide adequate warnings or other clinically relevant information and data regarding the risks associated with Tasigna.

71. Had Novartis provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with Tasigna, Plaintiff could have avoided the risk of developing atherosclerotic-related injuries and could have obtained or used alternative medication.

72. As a direct and proximate result of Novartis placing defective Tasigna drugs into the stream of commerce, Plaintiff was injured and has sustained pecuniary loss and general damages in a sum exceeding the jurisdictional minimum of this Court.

73. As a proximate result of Novartis placing defective Tasigna drugs into the stream of commerce, as alleged herein, there was a measurable and significant interval of time during which Plaintiff suffered great mental anguish and other personal injury and damages.

74. As a proximate result of Novartis placing defective Tasigna drugs into the stream of commerce, as alleged herein, Plaintiff sustained loss of income and/or loss of earning capacity.

WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT II: NEGLIGENCE

75. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs

as if fully stated herein.

76. Novartis, directly or indirectly, caused Tasigna to be sold, distributed, packaged, labeled, marketed, promoted, and/or used by Plaintiff. At all relevant times, Novartis registered, researched, manufactured, distributed, marketed, and sold Tasigna within this judicial district and aimed at a consumer market within this district.

77. At all relevant times, Novartis had a duty to exercise reasonable care in the design, research, manufacture, marketing, advertisement, supply, promotion, packaging, sale, and distribution of Tasigna, including the duty to take all reasonable steps necessary to manufacture, promote, and/or sell a product that was not unreasonably dangerous to consumers and users of the product.

78. At all relevant times, Novartis had a duty to exercise reasonable care in the marketing, advertisement, and sale of Tasigna. Novartis' duty of care owed to consumers and the general public included providing accurate, true, and correct information concerning the risks of using Tasigna and appropriate, complete, and accurate warnings concerning the potential adverse effects of Tasigna.

79. At all relevant times, Novartis knew or, in the exercise of reasonable care, should have known of the hazards and dangers of Tasigna.

80. Accordingly, at all relevant times, Novartis knew, or in the exercise of reasonable care should have known, that use of Tasigna could cause severe, atherosclerotic-related injuries, and thus, create a dangerous and unreasonable risk of injury to the users of Tasigna, including Plaintiff.

81. Novartis also knew, or in the exercise of reasonable care should have known, that users and consumers of Tasigna were unaware of the risks and the magnitude of the risks associated

with use of Tasigna.

82. As such, Novartis breached their duty of reasonable care and failed to exercise ordinary care in the design, research, development, manufacture, testing, marketing, supply, promotion, advertisement, packaging, sale, and distribution of Tasigna, in that Novartis manufactured and produced defective Tasigna; knew or had reason to know of the defects inherent in Tasigna; knew or had reason to know that a user's or consumer's use of Tasigna created a significant risk of harm and unreasonably dangerous side effects; and failed to prevent or adequately warn of these risks and injuries.

83. Novartis was negligent in its promotion of Tasigna, outside of the labeling context, by failing to disclose material risk information as part of its promotion and marketing of Tasigna, including the internet, television, print advertisements, *etc*. Nothing prevented Novartis from being honest in its promotional activities, and, in fact, Novartis had a duty to disclose the truth about the risks associated with Tasigna in its promotional efforts, outside of the context of labeling.

84. Despite its ability and means to investigate, study, and test the products and to provide adequate warnings, Novartis failed to do so. Indeed, Novartis wrongfully concealed information and further made false and/or misleading statements concerning the safety of Tasigna.

85. Novartis' negligence included:

a. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and/or distributing Tasigna without thorough and adequate pre- and post-market testing;

b. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and/or distributing Tasigna, while negligently and/or intentionally concealing and failing to disclose the results of trials, tests, and studies of Tasigna and, consequently, the risk of serious harm associated with use of Tasigna;

c. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not Tasigna was safe for its intended consumer use;

d. Failing to provide adequate instructions, guidelines, and safety precautions to those persons Novartis could reasonably foresee would use Tasigna;

e. Failing to disclose to Plaintiff, users/consumers, and the general public that use of Tasigna presented severe risks of atherosclerotic-related injuries;

f. Failing to warn Plaintiff, consumers, and the general public that Tasigna's risk of harm was unreasonable and that there were safer and effective alternative medications available to Plaintiff and other consumers;

g. Systematically suppressing or downplaying contrary evidence about the risks, incidence, and prevalence of the side effects of Tasigna;

h. Declining to make or propose any changes to Tasigna's labeling or other promotional materials that would alert consumers and the general public of the risks of Tasigna;

i. Advertising, marketing, and recommending the use of the Tasigna, while concealing and failing to disclose or warn of the dangers known by Novartis to be associated with or caused by the use of Tasigna;

j. Continuing to disseminate information to their consumers, which indicated or implied that Tasigna was not unsafe; and

86. Novartis knew and/or should have known that it was foreseeable that consumers such as Plaintiff would suffer injuries as a result of its failure to exercise ordinary care in the manufacturing, marketing, labeling, distribution, and sale of Tasigna.

87. Plaintiff did not know the nature and extent of the injuries that could result from the intended use of Tasigna.

88. Novartis' negligence was the proximate cause of Plaintiff's injuries, *i.e.*, absent Novartis' negligence, Plaintiff would not have developed atherosclerotic-related injuries.

89. Novartis' conduct, as described above, was reckless. Novartis regularly risked the lives of consumers and users of its products, including Plaintiff, with full knowledge of the dangers of Tasigna. Novartis has made conscious decisions not to re-label, adequately warn, or inform the

unsuspecting public, including Plaintiff. Novartis' reckless conduct therefore warrants an award of punitive damages.

90. As a direct and proximate result of Novartis placing Tasigna drugs into the stream of commerce, Plaintiff was injured and has sustained pecuniary loss and general damages in a sum exceeding the jurisdictional minimum of this Court.

91. As a proximate result of Novartis placing Tasigna drugs into the stream of commerce, as alleged herein, there was a measurable and significant interval of time during which Plaintiff suffered great mental anguish and other personal injury and damages.

92. As a proximate result of Novartis placing Tasigna products into the stream of commerce, as alleged herein, Plaintiff sustained a loss of income and loss of earning capacity.

WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Novartis, awarding Plaintiff any and all damages available to Plaintiff under the law, including but not limited to:

1. General damages according to proof;
2. Medical and incidental expenses according to proof;
3. All losses because Plaintiff will not be able to pursue Plaintiff's usual occupation and activities according to proof;
4. For loss of consortium, companionship, comfort, affection, fellowship, society, solace, moral support, and assistance according to proof;
5. For pain and suffering and emotional distress according to proof;
6. Punitive and exemplary damages sufficient to punish and make an example

of each Novartis according to proof;

7. Plaintiff's reasonable attorneys' fees and costs;

8. Prejudgment interest; and

9. For any other relief this Court deems appropriate.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a jury trial for all issues so triable in this action.

Dated: April 14, 2021

Respectfully Submitted,

Elias LLC
231 S. Bemiston Avenue,Suite 800
St. Louis, MO 63105
Ph: (314)391-6820

/s/ Richard Elias
Richard Elias, Esq.
Fla. Bar No. 38471
relias@EliasLLC.com
Todd R. Friedman, Esq.
Fla. Bar. No. 97919
tfriedman@EliasLLC.com

James G. Onder (MO Bar. No. 38049)
(to be admitted *Pro Hac Vice*)
Lawana S. Wichmann (MO Bar. No. 053999)
(to be admitted *Pro Hac Vice*)
OnderLaw, LLC
110 East Lockwood, 2nd Floor
St. Louis, MO 63119
Ph: (314) 963-9000
Fax: (314)963-1700
onder@onderlaw.com
wichmann@onderlaw.com

Attorneys for Plaintiff