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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF CALIFORNIA

KRISTI LAURIS, et. al.,
Plaintiffs,
v.
NOVARTIS AG, et al.,
Defendants.

Case No. 1:16-cv-00393-LJO-SAB
FINDINGS AND RECOMMENDATIONS
RECOMMENDING DENYING
DEFENDANTS’ MOTION TO DISMISS
(ECF No. 33-35, 44, 45)
OBJECTIONS DUE WITHIN FOURTEEN
DAYS

On June 20, 2016, Defendant Novartis Pharmaceuticals Corporation (“NPC”) filed a motion to dismiss which was referred to the undersigned for issuance of findings and recommendations pursuant to 28 U.S.C. § 636(b)(1)(B) and Local Rule 302. (ECF Nos. 33, 38.)

Oral argument on the motion to dismiss was conducted on July 20, 2016. Richard Elias and Tamara Spicer appeared for Plaintiffs, Julie Park appeared telephonically for Defendant Novartis AG, and Robert Johnston and Kelly Matayoshi appeared for Defendant Novartis Pharmaceuticals Corp. For the reasons set forth below, the Court recommends that Defendants’ motion to dismiss be denied.

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I.

BACKGROUND

On March 22, 2016, Plaintiff Kristi Lauris filed this action on behalf of herself and as guardian ad litem for minor Plaintiffs L.L. and Taylor Lauris against Defendants Novartis AG and Novartis Pharmaceuticals Corporation. (ECF No. 1.) After Defendant Novartis Pharmaceutical Corporation filed a motion to dismiss, Plaintiffs filed a first amended complaint on June 3, 2016. (ECF No. 18-20, 28.)

On June 20, 2016, Defendant Novartis Pharmaceuticals Corporation filed a motion to dismiss.¹ (ECF No. 33-35.) On June 22, 2016, District Judge Lawrence J. O’Neill referred the motion to the undersigned for issuance of findings and recommendations. (ECF No. 38.) On July 5, 2016, Defendant Novartis AG filed a notice of joinder in the motion to dismiss. (ECF No. 42.) Plaintiff filed an opposition on July 7, 2016. (ECF No. 44.) Defendants filed a reply on July 13, 2016. (ECF No. 45.)

II.

LEGAL STANDARD FOR MOTION TO DISMISS

Under Federal Rule of Civil Procedure 12(b)(6), a party may file a motion to dismiss on the grounds that a complaint “fail[s] to state a claim upon which relief can be granted.” A motion under Rule 12(b)(6) tests the legal sufficiency of a claim. Navarro v. Block, 250 F.3d 729, 732 (9th Cir. 2001). In deciding a motion to dismiss, the court is to accept as true “all material allegations of the complaint, . . . as well as all reasonable inferences to be drawn from them.” Navarro, 250 F.3d at 732. “[T]o be entitled to the presumption of truth, allegations in a complaint . . . may not simply recite the elements of a cause of action, but must contain sufficient allegations of underlying facts to give fair notice and to enable the opposing party to defend itself effectively.” Starr v. Baca, 652 F.3d 1202, 1216 (9th Cir. 2011). While detailed factual allegations are not required, the factual allegations of the complaint must plausibly suggest an entitlement to relief. Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009); Starr, 652 F.3d at 1216.

¹ The Court decides this motion based upon the allegations contained in the first amended complaint and has not considered the declaration and attached documents in deciding this motion to dismiss.

1 Dismissal of the complaint is appropriate where the complaint fails to state a claim supportable
2 by a cognizable legal theory. Balistreri v. Pacifica Police Dep't, 901 F.2d 696, 699 (9th Cir.
3 1988). Where it is apparent on the face of the complaint that the limitations period has run,
4 defendants may raise a statute of limitations defense in a motion to dismiss. Jablon v. Dean
5 Witter & Co., 614 F.2d 677, 682 (9th Cir. 1980); Von Saher v. Norton Simon Museum of Art at
6 Pasadena, 592 F.3d 954, 969 (9th Cir. 2010).

7 **III.**

8 **ALLEGATIONS IN FIRST AMENDED COMPLAINT**

9 Defendants manufactured Tasigna which is a prescription medication for the treatment of
10 chronic myeloid leukemia (“CML”). (First Am. Compl. ¶ 12, ECF No. 28.) CML is a cancer
11 that starts in the blood forming stem cells of the bone marrow. (Id.) Tasigna is a tyrosine-kinase
12 inhibitor that blocks chemical enzymes in the cancer cells called tyrosine kinases inhibiting their
13 growth and division. (Id.) Defendants developed Tasigna to replace Gleevec, a drug for which
14 Defendants’ patent expired on July 4, 2015. (Id. at ¶¶ 13-15.) Defendants developed an
15 aggressive advertising campaign to convince physicians to prescribe, and patients to take,
16 Tasigna rather than Gleevec. (Id. at 15.) As early as 2010, Defendants strategy was to have
17 Tasigna take over Gleevec’s business as the patent expiration date approached. (Id.)

18 Plaintiffs contend that Defendants promoted the efficacy of Tasigna while failing to
19 disclose any safety information, misrepresented that Tasigna was approved as a first-line therapy
20 for CML when it had only been approved as a second-line therapy, and described Tasigna as the
21 “next generation” treatment for CML which misleadingly suggested that it was superior to other
22 similar drugs when this had not been demonstrated by substantial evidence or clinical
23 experience. (Id. at ¶ 16.) On July 29, 2010, the FDA issued a cease and desist letter to Novartis
24 finding that Defendants had misbranded Tasigna in violation of FDA regulations and demanding
25 that Defendants immediately cease its misleading and illegal advertising. (Id.) Plaintiff also
26 alleges that Defendants paid illegal kickbacks, disguised as rebates and discount payments to
27 specialty pharmacies in exchange for recommendations that patients take Tasigna and hid reports
28 of adverse reactions in clinical studies of patients taking Tasigna. (Id. at ¶¶ 17, 18.)

1 Plaintiffs allege that Tasigna causes several dangerous adverse conditions, as relevant
2 here, several forms of severe, accelerated, and irreversible atherosclerosis-related conditions.²
3 (Id. at ¶ 19.) These conditions include peripheral arterial occlusive disease, coronary
4 atherosclerosis, and cerebral atherosclerosis which are life threatening and can lead to
5 amputations, heart attacks, strokes, and death. (Id.) Defendants have been aware of the risk of
6 these atherosclerosis-related conditions since at least 2011 from multiple medical studies and
7 reports linking Tasigna to the conditions, the higher rate of severe atherosclerosis-related
8 conditions occurring among patients in a randomized clinical trial, and information gathered
9 from a safety database reporting hundreds of incidents after taking Tasigna. (Id. at ¶ 20.)

10 A Canadian health agency investigated the risks of Tasigna; and in April 2013,
11 Defendants issued an advisory to Canadian health care professionals and the Canadian public of
12 the risks of atherosclerosis associated with taking Tasigna. (Id. at ¶ 21.) Around this same time,
13 Defendants updated the document used by Canadian health care professionals when prescribing
14 medication to warn of the risks of atherosclerosis. (Id. at ¶ 22.) Although Defendants provided
15 warnings to physicians and patients in Canada, Defendants did not warn physicians and patients
16 in the United States that Tasigna caused several forms of severe, accelerated, and irreversible
17 atherosclerosis-related conditions. (Id. at ¶ 23.)

18 Dainis Lauris (“decedent”) was diagnosed with CML in 2001, and took Gleevec until
19 October 2012. (Id. at ¶ 25.) In October 2012, decedent was prescribed Tasigna by his
20 oncologist. (Id. at ¶ 26.) At this time, decedent did not have any atherosclerosis-related
21 conditions and was not warned of the risk associated with taking Tasigna. (Id. at ¶¶ 26, 27.)
22 After taking Tasigna, decedent began experiencing cramping and tightening of his shins and legs
23 which was interpreted as muscle cramping. (Id. at ¶ 28.) Decedent developed severe,
24 accelerated, and irreversible atherosclerosis-related conditions. (Id.) Decedent’s condition
25 deteriorated rapidly over the next year, and in May 2013, his ability to engage in his normal
26 activities was significantly impaired. (Id. at 29.)

27
28 ² Atherosclerosis is arteriosclerosis characterized by lipid deposits causing narrowing in the large and medium sized
arteries. Stedman’s Medical Dictionary 174 (28th Ed. 2006).

1 counter that the date the statute of limitations began to run would be after it was discovered that
2 the decedent had cerebral atherosclerosis; and therefore, this action is timely.

3 **A. Survival Cause of Action**

4 1. Legal Standard

5 Defendants do not challenge the wrongful death claim, but only the timeliness of the
6 survival cause of action. Under California law, “a cause of action for or against a person is not
7 lost by reason of the person’s death, but survives subject to the applicable limitations period.”
8 Cal. Civ. Proc. Code § 377.20(a). “Unlike wrongful death, a survival claim is not a new cause of
9 action that vests in heirs on the death of the decedent, but rather is a separate and distinct cause
10 of action which belonged to the decedent before death but, by statute, survives that event; the
11 survival statutes do not create a cause of action, but merely prevent abatement of a cause of the
12 injured person and provide for its enforcement by or against the personal representative of the
13 deceased.” Medrano v. Kern Cty. Sheriff’s Officer, 921 F.Supp.2d 1009, 1016 (E.D. Cal. 2013);
14 see also Hayes v. Cty. of San Diego, 736 F.3d 1223, 1229 (9th Cir. 2013) (“In a survival action,
15 a decedent’s estate may recover damages on behalf of the decedent for injuries that the decedent
16 has sustained. In a wrongful death action, by comparison, the decedent’s dependents may only
17 pursue claims for personal injuries they have suffered as a result of a wrongful death.”). By
18 statute, the damages recoverable in a survival action are those which the decedent would have
19 been entitled to recover had he lived. Cty. of Los Angeles v. Superior Court, 21 Cal. 4th 292,
20 295, 981 P.2d 68, 70 (1999) (citing Cal. Civ. Proc. Code § 377.34).

21 A plaintiff must bring a cause of action within the limitations period applicable to the
22 accrual of the cause of action. Norgart v. Upjohn Co., 21 Cal.4th 383, 389 (1999). The statute
23 of limitations does not begin to run until the cause of action accrues. Fox v. Ethicon Endo-
24 Surgery, Inc., 35 Cal.4th 797, 806 (2005). In California, the general rule is that a cause of action
25 accrues at the time when the cause of action is complete in all its elements. Norgart, 21 Cal.4th
26 at 389.

27 An important exception to the general rule is the discovery rule, which exists to postpone
28 accrual of the cause of action until the plaintiff discovers or has reason to discover the cause of

1 action. Norgart, 21 Cal.4th at 389; Fox, 35 Cal.4th at 807. “A plaintiff has reason to discover a
2 cause of action when he or she ‘has reason at least to suspect a factual basis for its elements.’ ”
3 Fox, 35 Cal.4th at 807 (quoting Norgart, 21 Cal.4th at 398). “Under the discovery rule,
4 suspicion of one or more of the elements of a cause of action, coupled with knowledge of any
5 remaining elements, will generally trigger the statute of limitations period.” Fox, 35 Cal.4th at
6 807. This refers to the generic elements of wrongdoing, causation, and harm. Id. The court
7 does not examine whether the plaintiff’s suspect facts support each specific element of the cause
8 of action, but looks to whether the plaintiff had a reason to at least suspect that he was injured by
9 a type of wrongdoing. Id. A plaintiff is required to conduct a reasonable investigation after
10 becoming aware of an injury and is charged with knowledge of the information that would have
11 been revealed by such an investigation. Id. at 808.

12 To rely on the discovery rule to delay the accrual of the cause of action, “[a] plaintiff
13 whose complaint shows on its face that his claim would be barred without the benefit of the
14 discovery rule must specifically plead facts to show (1) the time and manner of discovery and (2)
15 the inability to have made earlier discovery despite reasonable diligence.” Fox, 35 Cal.4th at 808
16 (quoting McKelvey v. Boeing North American, Inc., 74 Cal.App.4th 151, 160 (1999)). “In order
17 to adequately allege facts supporting a theory of delayed discovery, the plaintiff must plead that,
18 despite diligent investigation of the circumstances of the injury, he or she could not have
19 reasonably discovered facts supporting the cause of action within the applicable statute of
20 limitations period.” Fox, 35 Cal.4th at 809. The parties here agree that the relevant statute of
21 limitations for the survival action on strict products liability and negligence is section 335.1 of
22 the California Code of Civil Procedure which provides that an action must be filed within two
23 years. Cal. Civ. Proc. Code § 335.1.

24 2. Discussion

25 Defendants argue that decedent was aware of all the elements of his cause of action by at
26 least November 2013; and the later discovery that the atherosclerosis was more extensive than
27 originally discovered does not extend the statute of limitations as the later discovered injuries are
28 of the same type. Plaintiffs counter that the discovery that the decedent had cerebral

1 atherosclerosis was latent and undetected which could not be discovered until after an autopsy
2 and is therefore a new injury that extends the limitations period. The question to be considered
3 in this matter is whether the discovery that decedent’s atherosclerosis effected his cerebral
4 arteries is a separate and distinct injury from the earlier discovered atherosclerosis in his legs.

5 “[I]f a plaintiff’s reasonable and diligent investigation discloses only one kind of
6 wrongdoing when the injury was actually caused by tortious conduct of a wholly different sort,
7 the discovery rule postpones accrual of the statute of limitations on the newly discovered claim.”
8 Fox, 35 Cal.4th at 813. “[A] diligent plaintiff’s investigation may only disclose an action for one
9 type of tort (e.g., medical malpractice) and facts supporting an entirely different type of tort
10 action (e.g., products liability) may, through no fault of the plaintiff, only come to light at a later
11 date. Although both claims seek to redress the same physical injury to the plaintiff, they are
12 based on two distinct types of wrongdoing and should be treated separately in that regard. Id. at
13 814-15. Similarly, the California Supreme Court recently held that, “when a later-discovered
14 disease is separate and distinct from an earlier-discovered disease, the earlier disease does not
15 trigger the statute of limitations for a lawsuit based on the later disease.” Poosh v. Phillip
16 Morris USA, Inc., 51 Cal.4th 788, 792 (2011).

17 In Grisham v. Philip Morris U.S.A., Inc., 40 Cal.4th 623 (2007), the California Supreme
18 Court held that a plaintiff is not barred by the statute of limitations in bringing qualitatively
19 different causes of actions based upon the same misconduct. Grisham, 40 Cal.4th at 645. In
20 Grisham, the Court held that the cause of action for economic injury due to addiction to smoking
21 did not start the limitations period for a later discovered cause of action for physical injury due to
22 smoking. Id. However, the Court left for another day the issue of whether two physical injuries
23 with different manifestation periods that arose out of the same misconduct could be brought in
24 different lawsuits. Id. at 646. This was the issue addressed in Poosh.

25 In Poosh, the California Supreme Court addressed the question, “When multiple distinct
26 personal injuries allegedly arise from smoking tobacco, does the earliest injury trigger the statute
27 of limitations for all claims, including those based on the later injury?” Poosh, 51 Cal.4th at
28 792. The Court held that two physical injuries “can, in some circumstances, be considered

1 ‘qualitatively different’ for purposes of determining when the applicable statute of limitations
2 period begins to run.” Id. (quoting Grisham, 40 Cal.4th at 645). The plaintiff in Pooshs brought
3 a claim that cigarette smoking caused her lung cancer. Pooshs, 51 Cal.4th at 793. The defendant
4 argued that the plaintiff had been previously diagnosed with chronic obstructive pulmonary
5 disease (“COPD”) and periodontal disease caused by her smoking habits and the statute of
6 limitations for her third disease from smoking, lung cancer, began to run when she was aware of
7 these prior diagnoses. Id. The plaintiff responded that her lung cancer was a separate disease
8 and was the basis for a distinct primary right. Id. at 796. It was undisputed that the etiology for
9 lung cancer was distinct from the etiology for plaintiff’s COPH and periodontal disease. Id. at
10 793.

11 The California Supreme Court noted that generally, the infliction of appreciable and
12 actual harm, no matter how uncertain the amount, will commence the statutory period. Pooshs,
13 51 Cal.4th at 792. However, in Pooshs the Supreme Court accepted as true that the plaintiff’s
14 COPD was a separate illness that did not predispose the plaintiff to lung cancer and had nothing
15 medically, biologically, or pathologically to do with lung cancer. Id. at 802. The court held that
16 where a later-occurring disease is separate and distinct from the earlier occurring disease, the
17 statute of limitations can apply to one disease without applying to the other. Id. What was
18 considered significant is that the later-occurring disease was a disease that is separate and distinct
19 from the earlier occurring disease. Id.

20 Plaintiffs argue that Pooshs was applied in a case which is factually similar to the instant
21 action, Viramontes v. Pfizer, Inc., No. 2:15-CV-1754 TLN AC (PS), 2015 WL 5734946 (E.D.
22 Cal. Sept. 29, 2015). In Viramontes, the plaintiffs alleged that after taking Celebrex the wife
23 developed dermatomyositis and brought claims for negligence, strict product liability, and lack
24 of consortium. Id. at *1. The defendants alleged that the action was barred by the statute of
25 limitations, collateral estoppel and res judicata. Id. The defendants argued that the plaintiff was
26 aware of her first injury in 2005 well before she filed suit in the district court. Id. at *5. The
27 court concluded that the statute of limitations on the plaintiffs’ allegations regarding her
28 dermatomyositis did not begin to run with her prior diagnosis of severe arthritis, leuko

1 lymphopenia, and drug induced lupus where the plaintiff was alleging the dermatomyositis was a
2 separate and distinct disease. Id.

3 As alleged in the first amended complaint, Tassigna has been found to cause hardening
4 and narrowing of the arteries supplying blood to the legs and arms, heart, and brain. (ECF No.
5 28 at ¶ 19.) By September 2013, decedent had a decreased pedal pulse meaning that the blood
6 supply in his lower extremities had been severely diminished. (Id. at ¶ 30.) Around September
7 2013, an aortogram on decedents leg showed that “he had 100-percent occlusion (abnormal
8 narrowing) in his superficial right femoral artery, 90-percent occlusion in his right profunda
9 (deep) femoral artery, and 90-percent occlusion in his left profunda femoral artery. (Id.) Around
10 that time, decedent’s treating oncologist read an article that discussed the link between Tassigna
11 and severe, accelerated atherosclerosis related conditions. (Id. at ¶ 32.) Unbeknown to decedent,
12 Tassigna had also caused atherosclerosis to the arteries supplying blood to his brain and heart.
13 (Id. at ¶ 33.) Decedent had approximately 70-percent narrowing of the lumen of his left and
14 right middle cerebral arteries, and 60-percent narrowing of the lumen of his coronary arteries.
15 (Id.)

16 In this instance, decedent was diagnosed with peripheral arterial occlusive disease which
17 is the hardening and narrowing of arteries supplying blood to the legs and arms and contends that
18 the cerebral atherosclerosis which is the hardening and narrowing of the cerebral arteries is
19 separate and distinct and resulted in a separate and distinct injury, a stroke. (ECF No. 2-3.)
20 Defendants argue that the conditions have the same etiology which makes them the same disease
21 and the discovery that the hardening and narrowing of the arteries is in a different part of the
22 same body system goes to the extent of damage from Tassigna. See Miller v. Lakeside Village
23 Condominium Assn., 1 Cal.App.4th 1611, 1623 (1991) (quoting Evans v. Eckelman, 216
24 Cal.App.3d 1609, 1620 (1990) (“[t]he extent of damage is not an element of a cause of action in
25 tort, and the general rule is that the cause of action is complete on the sustaining of ‘actual and
26 appreciable harm,’ on which the recoverable damages would be more than nominal.”).

27 Defendants argue that Pooshs does not overturn the holding of Davies v. Krasna, 14
28 Cal.3d 502 (1975). In Davies, the California Supreme Court stated that the statute of limitations

1 is not tolled because the nature and extent of the damages is not determined or readily provable
2 within the limitations period. Davies, 14 Cal.3d at 515. The limitations period commences with
3 the infliction of appreciable and actual harm no matter how uncertain the amount. Id. at 514.

4 In the first amended complaint, Plaintiffs allege that decedent was aware that he had
5 hardening of the arteries of the lower extremities by November 2013. In November 2013,
6 decedent's treating oncologist informed him to stop taking the Tassigna. At this time, decedent
7 had symptoms, and testing showed that the blood supply to his lower extremities had been
8 severely diminished. Whether the later discovered cerebral atherosclerosis is the same disease or
9 a separate and distinct disease is an issue that this Court cannot decide on a motion to dismiss.
10 While the allegations in the complaint are that the decedent had atherosclerosis in various
11 arteries, the factual determination of whether this is a single disease affecting a single bodily
12 system or separate and distinct diseases affecting separate body systems is a complex medical
13 issue that will require the testimony of a medical expert. See Monroe v. Zimmer U.S. Inc., 766
14 F. Supp. 2d 1012, 1028 (E.D. Cal. 2011) ("Where demonstrating causation requires a discussion
15 of complex medical and scientific issues, expert testimony is required.")

16 For the reasons stated, the Court recommends that Defendants' motion to dismiss the
17 survivor action be denied.

18 **B. Punitive Damages**

19 Defendants move to dismiss Plaintiffs' claims for punitive damages and seek to have the
20 request for punitive damages stricken from the first amended complaint. Plaintiffs respond that
21 since the survivor claims were not barred by the limitations period they are entitled to seek
22 punitive damages. Plaintiffs appear to concede that they are not entitled to punitive damages for
23 the wrongful death claim.

24 The right to recover punitive damages on behalf of the decedent in a survivor action
25 belongs to the decedent's representative and not to his heirs. Estate of McNeil v.
26 Freestylemx.com, Inc., ___ F. Supp.3d ___, 2016 WL 1394262, at *13 (S.D. Cal. Apr. 8, 2016).
27 Under section 377.34 the damages the decedent's representatives may recover are limited to the
28 loss or damage that the decedent sustained or incurred before death, including any penalties or

1 punitive or exemplary damages. . . .” Cal. Civil Proc. Code § 377.34.

2 California law provides that punitive damages are available in a survivor action. Since
3 the recommendation is for the survivor claims to proceed in this action, Court recommends that
4 Defendants’ motion to dismiss the request for punitive damages be denied.³

5 V.

6 **CONCLUSION AND RECOMMENDATION**

7 Based on the foregoing, it is HEREBY RECOMMENDED that Defendants Novartis
8 Pharmaceutical Corporation and Novartis AG’s motion to dismiss be DENIED.

9 These findings and recommendations are submitted to the district judge assigned to this
10 action, pursuant to 28 U.S.C. § 636(b)(1)(B) and this Court’s Local Rule 304. Within fourteen
11 (14) days of service of this recommendation, any party may file written objections to these
12 findings and recommendations with the Court and serve a copy on all parties. Such a document
13 should be captioned “Objections to Magistrate Judge’s Findings and Recommendations.” The
14 district judge will review the magistrate judge’s findings and recommendations pursuant to 28
15 U.S.C. § 636(b)(1)(C). The parties are advised that failure to file objections within the specified
16 time may result in the waiver of rights on appeal. Wilkerson v. Wheeler, 772 F.3d 834, 839 (9th
17 Cir. 2014) (citing Baxter v. Sullivan, 923 F.2d 1391, 1394 (9th Cir. 1991)).

18 IT IS SO ORDERED.

19 Dated: July 22, 2016

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21 _____
22 UNITED STATES MAGISTRATE JUDGE

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28 ³ Since the recommendation is to deny the motion to dismiss, the Court does not address Plaintiffs’ request for leave to file an amended complaint.