## IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

MIREK MACHALA,	)
Plaintiff, v.	) ) ) C.A. No.: N16C-12-231-PRA
BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.; BOEHRINGER INGELHEIM INTERNATIONAL GMBH; BOEHRINGER INGELHEIM VETMEDICA, INC.; and BOEHRINGER INGELHEIM USA CORPORATION,	) ) ) ) )
Defendants.	) )

Submitted: April 13, 2017 Decided: June 29, 2017

Upon Defendants Boehringer Ingelheim Pharmaceuticals, Inc. and Boehringer Ingelheim USA Corp. 's Motion to Dismiss Plaintiff's Complaint **GRANTED** 

James D. Heisman, Esquire, Napoli Shkolnik, LLC, Wilmington, DE, Attorney for Plaintiff Mirek Machala

Michael P. Kelly, Esquire, Daniel J. Brown, Esquire, McCarter & English, LLP, Wilmington, DE, Eric E. Hudson, Esquire, Butler Snow, LLP, Memphis, TN, *Attorneys for Defendants Boehringer Ingelheim Pharmaceuticals, Inc. and Boehringer Ingelheim USA Corp.* 

## DAVIS, J.

### I. INTRODUCTION

This is a products liability case arising out of the use of the drug Pradaxa. Plaintiff Mirek

Machala filed a Complaint (the "Complaint") against Defendants Boehringer Ingelheim

Pharmaceuticals, Inc. ("Boehringer Pharmaceuticals"), Boehringer Ingelheim International

GmBH ("Boehringer International"), Boehringer Ingelheim Vetmedica, Inc. ("Boehringer

Vetmedica"), and Boehringer Ingelheim USA Corp. ("Boehringer USA") (collectively, "Defendants"). The Complaint asserts causes of action for: (i) Strict Liability, (ii) Strict Liability – Design Defect, Marketing Defect and Manufacturing Defect, (iii) Negligence, (iv) Breach of Express Warranty, and (v) Breach of Implied Warranty.

On February 16, 2017, Defendants Boehringer Pharmaceuticals and Boehringer USA (together, "the Boehringer Defendants") moved to dismiss the Complaint and filed Defendants Boehringer Ingelheim Pharmaceuticals, Inc. and Boehringer Ingelheim USA Corp.'s Motion to Dismiss Plaintiff's Complaint (the "Motion to Dismiss").<sup>1</sup> The Boehringer Defendants allege that the claims in the Complaint are barred by Delaware's two-year statute of limitations. Mr. Machala opposes the Motion to Dismiss and responded to the Motion to Dismiss on March 31, 2016 with Plaintiff's Opposition to Defendants' Boehringer Ingelheim Pharmaceuticals, Inc.'s and Boehringer Ingelheim USA Corp.'s Motion to Dismiss Plaintiff's Complaint (the "Response").

The Court held a hearing and heard oral argument on the Motion to Dismiss on April 7, 2017. At the conclusion of the hearing, the Court asked the parties to submit additional briefing on the issue of whether Delaware's Borrowing Statute applies to and bars the claims in this case. On April 13, 2017, the Boehringer Defendants filed Defendants Boehringer Ingelheim Pharmaceuticals, Inc. and Boehringer Ingelheim USA Corp.'s Supplemental Brief in Support of its Motion to Dismiss Plaintiffs' Complaints Pursuant to Rule 12(b)(6) (the "Supplemental Motion")<sup>2</sup> and Mr. Machala's counsel filed Letter Brief in Further Opposition to Defendants' Motion to Dismiss Plaintiff's Complaint (the "Supplemental Response"). After receiving the

<sup>&</sup>lt;sup>1</sup> The other named Defendants, Boehringer Vetmedica and Boehringer International, do not appear or join the Motion to Dismiss. The Boehringer Defendants represent in the Motion to Dismiss that these additional defendants have not yet been served. Defs.' Mot. at p. 1, fn. 1.

<sup>&</sup>lt;sup>2</sup> The Supplemental Motion addresses issues raised in this case and a related case (C.A. No. N16C-12-282-PRA) before the Court involving the same Defendants.

Supplemental Motion and the Supplemental Response, the Court took the Motion to Dismiss under advisement.

This is the Court's decision on the Motion to Dismiss. For the reasons set forth below, the Court **GRANTS** the Motion to Dismiss.

## II. RELEVANT FACTS<sup>3</sup>

Mr. Machala is an individual and resident of the District of Columbia.<sup>4</sup> Boehringer Pharmaceuticals, Boehringer USA, and Boehringer Vetmedica are Delaware corporations doing business in Delaware.<sup>5</sup> Boehringer International is a foreign corporation with a principal place of business in Rhein, Germany.<sup>6</sup>

Defendants were involved in the manufacturing, marketing, advertising, and distribution of the drug Pradaxa.<sup>7</sup> Pradaxa is a blood-thinning medication used to reduce the risk of stroke and blood clots in certain individuals.<sup>8</sup> Pradaxa was approved by the Food and Drug Administration ("FDA") on October 19, 2010, making it the first new treatment alternative to Coumadin.<sup>9</sup> Prior to FDA approval, Coumadin was the only oral anticoagulation available in the United States for reducing stroke and systemic embolism in patients with atrial fibrillation.<sup>10</sup>

After FDA approval, Defendants promoted Pradaxa as a viable alternative to Coumadin in patients with atrial fibrillation.<sup>11</sup> Defendants' marketing campaign emphasized that Pradaxa,

<sup>8</sup> *Id.*  $\P$  7.

<sup>10</sup> *Id.* ¶ 9.

<sup>&</sup>lt;sup>3</sup> As the Motion to Dismiss is a motion filed under Superior Court Civil Rule 12 ("Civil Rule \_\_"), the Court will, unless otherwise indicated, be using the facts as alleged in the Complaint ("Pl.'s Compl."). *See, e.g., Central Mortg. Co. v. Morgan Stanley Mortg. Capital Holdings LLC*, 227 A.3d 531, 536 (Del. 2011)

<sup>&</sup>lt;sup>4</sup> Pl.'s Compl. ¶ 1.

<sup>&</sup>lt;sup>5</sup> *Id.* ¶¶ 2, 4–5.

<sup>&</sup>lt;sup>6</sup> *Id.* ¶ 3. <sup>7</sup> *Id.* ¶ 6.

<sup>&</sup>lt;sup>9</sup> *Id.* ¶ 8.

<sup>&</sup>lt;sup>11</sup> *Id.* ¶ 10.

unlike Coumadin, did not require blood monitoring, dose adjustment, or changes to diet.<sup>12</sup> Pursuant to this marketing campaign, Mr. Machala's doctors received promotional materials from Defendants, and Mr. Machala also received direct-to-consumer advertisements.<sup>13</sup> Based on the information contained in these promotional materials, Mr. Machala began taking Pradaxa for atrial fibrillation on January 1, 2013.<sup>14</sup> Subsequently, Mr. Machala suffered a stroke on December 18, 2013 and was admitted to the hospital in the District of Columbia for several days.<sup>15</sup>

On December 16, 2016, Mr. Machala filed the Complaint against Defendants. In short, the Complaint alleges that through their marketing campaign, "Defendants overstated the efficacy of Pradaxa with respect to preventing stroke and systemic embolism, failed to adequately disclose to or warn patients that there is no drug or means to reverse the anticoagulation effects of Pradaxa, and that such irreversibility could have permanently disabling, life-threatening and fatal consequences" such as increased risk of bleeding.<sup>16</sup> The Complaint further alleges that Defendants' actions directly and proximately caused Mr. Machala's injuries.<sup>17</sup>

#### **III. PARTIES' CONTENTIONS**

#### A. THE BOEHRINGER DEFENDANTS

The Boehringer Defendants' main argument is that Mr. Machala's tort claims are barred by Delaware's two-year statute of limitations. The Boehringer Defendants contend that the language of Delaware's Borrowing Statute mandates that Delaware's—not the District of

 $<sup>^{12}</sup>$  *Id*.

<sup>&</sup>lt;sup>13</sup> *Id.* ¶¶ 16, 20.

<sup>&</sup>lt;sup>14</sup> *Id.*  $\P$  56.

<sup>&</sup>lt;sup>15</sup> *Id.* ¶¶ 56–57.

<sup>&</sup>lt;sup>16</sup> *Id.* ¶ 14.

<sup>&</sup>lt;sup>17</sup> *Id.* ¶¶ 50, 57–58.

Columbia's—limitations period applies to and bars this case. Alternatively, the Boehringer Defendants argue that the Complaint fails to state a claim upon which relief can be granted because there is no causal connection between the claimed injury and the negligent acts of Defendants alleged in the Complaint.

#### **B.** MR. MACHALA

Mr. Machala contests the applicability of Delaware's Borrowing Statute, arguing that it does not apply because there is no evidence that Mr. Machala engaged in forum shopping. However, even if the Borrowing Statute did apply, Mr. Machala argues that the limitations period was tolled by reason of Defendants' fraudulent concealment. As to the alternative argument, Mr. Machala contends that the Complaint is properly pleaded because Defendants' failure to warn of specific dangers, including but not limited to when Pradaxa fails to act as intended, establishes a causal connection between the negligent acts of Defendants and the claimed injury.

#### **IV. STANDARD OF REVIEW**

Upon a motion to dismiss under Civil Rule 12(b)(6), the Court (i) accepts all wellpleaded factual allegations as true, (ii) accepts even vague allegations as well-pleaded if they give the opposing party notice of the claim, (iii) draws all reasonable inferences in favor of the non-moving party, and (iv) only dismisses a case where the plaintiff would not be entitled to recover under any reasonably conceivable set of circumstances.<sup>18</sup> However, the Court must "ignore conclusory allegations that lack specific supporting factual allegations."<sup>19</sup>

<sup>&</sup>lt;sup>18</sup> See Cent. Mortg. Co. v. Morgan Stanley Mortg. Cap. Holdings LLC, 227 A.3d 531, 536 (Del. 2011); Doe v. Cedars Academy, No. 09C-09-136, 2010 WL 5825343, at \*3 (Del. Super. Oct. 27, 2010).

<sup>&</sup>lt;sup>19</sup> Ramunno v. Crawley, 705 A.2d 1029, 1034 (Del. 1998).

#### **V. DISCUSSION**

# A. WHETHER DELAWARE'S BORROWING STATUTE MANDATES APPLICATION OF DELAWARE'S STATUTE OF LIMITATIONS

The Boehringer Defendants argue that Mr. Machala's tort claims are controlled and

barred by Delaware's statute of limitations. As between Delaware and the District of Columbia

("D.C."), the Boehringer Defendants maintain that under Delaware's Borrowing Statute,

Delaware's statute of limitations applies because it is the shorter of the two limitations periods.

The Court agrees that Delaware's statute of limitations applies based on the express language of

Delaware's Borrowing Statute.

As a general rule, the law of the forum governs in matters relating to the statute of limitations.<sup>20</sup> However, Delaware's Borrowing Statute (the "Borrowing Statute") modifies this general rule in certain circumstances:

Where a cause of action arises outside of this state, an action cannot be brought in a court of this State to enforce such cause of action after the expiration of whichever is shorter, the time limited by the law of this State, or the time limited by the law of the state or country where the cause of action arose for bringing an action upon such cause of action.<sup>21</sup>

Under the Borrowing Statute, Delaware courts must apply the Delaware limitations period if it is shorter than the limitations period that might apply from another jurisdiction.<sup>22</sup>

Applying the plain language of the Borrowing Statute, the Court finds that the Borrowing Statute governs the limitations period in this case. Here, the facts are that the cause of action arose in D.C. and not Delaware. Mr. Machala was proscribed Pradaxa and ingested Pradaxa in D.C., and subsequently suffered a stroke in D.C. As between the Delaware limitations period and the D.C. limitations period, the Borrowing Statute mandates that the Court apply the shorter

<sup>&</sup>lt;sup>20</sup> See e.g., Furnari v. Wallpang, C.A. No. 13C-04-287, 2014 WL 1678419, at \*4 (Del. Super. Apr. 16, 2014).

<sup>&</sup>lt;sup>21</sup> 11 Del. C. § 8121.

<sup>&</sup>lt;sup>22</sup> Burrell v. Astrazeneca LP, C.A. No. 07C-01-412, 2010 WL 3706584, at \*4 (Del. Super. Sept. 20, 2010).

of the two periods. Delaware's limitations period for tort claims is two years.<sup>23</sup> D.C's is three years.<sup>24</sup> As such, the Borrowing Statute dictates that Delaware's two-year limitations period applies.

Mr. Machala asks the Court to ignore the plain language of the Borrowing Statute and read-in a forum shopping exception. Mr. Machala relies on the decisions in *Saudi Basic Industries Corporation v. Mobil Yanbu Petrochemical Company*<sup>25</sup> and *Furnari v. Wallpang* in support of his argument.<sup>26</sup> In these cases, the particular court declined to apply the Borrowing Statute, in part, based on a lack of evidence that the plaintiffs engaged in forum shopping when selecting Delaware to litigate their claims. The Court finds that these cases are both exceptional and distinguishable from the rest of the Delaware's Borrowing-Statute jurisprudence.

In *Saudi Basic*, the plaintiff, Saudi Basic Industries Corporation ("SABIC"), brought a declaratory judgment action against defendants, Mobil Yanbu Petrochemical Company and Exxon Chemical Arabia, Inc. (collectively, "ExxonMobil") in Delaware.<sup>27</sup> ExxonMobil then asserted counterclaims in tort and for breach of contract.<sup>28</sup> In response, SABIC argued that the Borrowing Statute applied to and barred ExxonMobil's counterclaims.<sup>29</sup> SABIC relied on the plain language of the Borrowing Statute and argued that because (i) the counterclaims arose in Saudi Arabia, and (ii) Delaware's limitations period was shorter than Saudi Arabia's limitations period, Delaware's limitations period applied to and barred the counterclaims.<sup>30</sup>

In ruling, the *Saudi Basic* court noted that the Borrowing Statute, if applied, would bar ExxonMobil's counterclaims, despite the fact that ExxonMobil did not choose to litigate the

<sup>&</sup>lt;sup>23</sup> See 10 Del. C. § 8119.

<sup>&</sup>lt;sup>24</sup> See D.C. Code § 12-301(8).

<sup>&</sup>lt;sup>25</sup> 866 A.2d 1 (Del. 2005).

<sup>&</sup>lt;sup>26</sup> C.A. No. 13C-04-297, 2014 WL 1678419, at \*1 (Del. Super. Apr. 16, 2014).

<sup>&</sup>lt;sup>27</sup> Saudi Basic, 866 A.2d 1, 6 (Del. 2005).

 $<sup>^{28}</sup>$  *Id*.

<sup>&</sup>lt;sup>29</sup> Id.

<sup>&</sup>lt;sup>30</sup> *Id.* at 13.

claims in Delaware and that the counterclaims, if brought in Saudi Arabia, would not have been barred.<sup>31</sup> Based on these facts, the *Saudi Basic* court rejected the "literal construction" of the Borrowing Statute and read-in a limited forum shopping exception in order to preserve ExxonMobil's counterclaims.<sup>32</sup> The *Saudi Basic* court explained that the Borrowing Statute was designed for the very specific purpose of preventing a non-resident plaintiff from forum shopping, *i.e.* "circumventing the shorter limitations period mandated by the jurisdiction where the cause of action arose."<sup>33</sup> The Saudi Basic court found that the "literal construction" of the Borrowing Statute, if applied to these facts, would subvert the statute's underlying purpose and deprive ExxonMobil of any forum to assert its counterclaims because "the party that was shopping for the most favorable forum was SABIC, not ExxonMobil. . . ."<sup>34</sup> The *Saudi Basic* court thus crafted an exception that rejected SABIC's attempt to use Delaware and Delaware law for the sole strategic purpose of insulating itself from ExxonMobil's counterclaims.<sup>35</sup>

This Court in *Furnari* similarly declined to apply the plain language of the Borrowing Statute in favor of a forum shopping exception.<sup>36</sup> The plaintiff, a Florida resident, sued defendant, a Delaware corporation based in Ontario, Canada, in a Florida court on two separate occasions.<sup>37</sup> Both lawsuits were dismissed for lack of jurisdiction.<sup>38</sup> Consequently, plaintiff filed a lawsuit in Delaware for the sole purpose of obtaining jurisdiction over defendant.<sup>39</sup> This Court found that the Borrowing Statute did not apply to or bar plaintiff's claims because "plaintiff was not attempting to circumvent the expiration of his claims by filing in Delaware, but

<sup>25</sup> *Ia*. a

<sup>&</sup>lt;sup>31</sup> *Id.* at 16.

<sup>&</sup>lt;sup>32</sup> Id.

<sup>&</sup>lt;sup>33</sup> *Id.* at 16–17. <sup>34</sup> *Id.* at 17.

<sup>&</sup>lt;sup>35</sup> *Id.* 

<sup>&</sup>lt;sup>36</sup> *Furnari*, 2014 WL 1678419, at \*1.

<sup>&</sup>lt;sup>37</sup> *Id.* 

<sup>&</sup>lt;sup>38</sup> *Id.* at 5. <sup>39</sup> *Id.* 

only [sought] jurisdiction over the parties."<sup>40</sup> The *Furnari* court thus crafted an exception that preserved plaintiff's claims when plaintiff was forced, for jurisdictional reasons, to file in Delaware.<sup>41</sup>

The Court does not find that any of the concerns raised by the *Saudi Basic* or *Furnari* courts are implicated in this case. This is not a case where Mr. Machala was brought as a defendant to Delaware to litigate this action. Moreover, Mr. Machala did not have to file this action in Delaware in order to assert jurisdiction over the Boehringer Defendants. Mr. Machala is a non-resident plaintiff who chose to file his claims in Delaware. In fact, Mr. Machala's counsel admitted at the hearing on the Motion to Dismiss that this case could been filed in D.C., but that counsel chose to file in Delaware because Delaware courts have experience litigating claims involving Pradaxa.<sup>42</sup> The Court concedes that this civil action does not present as the standard scenario of shopping for a forum with a longer limitations period, but it is forum shopping nonetheless. As such, even if the Court chose to read-in a forum shopping exception to the Borrowing Statute, such an exception would not preclude application of the Borrowing Statute.

Given the facts of this case, the Court chooses to follow the majority of decisions that have applied the plain language of the Borrowing Statute in situations similar to the one presently before the Court. In *Huffington v. T.C. Group, LLC*<sup>43</sup>, this Court applied the plain language of the Borrowing Statute and held that plaintiff's claim was time barred.<sup>44</sup> In rendering its decision, the Court rejected plaintiff's assertion that *Saudi Basic* created a broad ruling

<sup>&</sup>lt;sup>40</sup> *Id*.

<sup>&</sup>lt;sup>41</sup> *Id*.

<sup>&</sup>lt;sup>42</sup> See Tr. of Apr. 7, 2017 Hr'g.

<sup>&</sup>lt;sup>43</sup> C.A. No. N11C-01-030, 2012 WL 1415930, at \*1 (Del. Super. Apr. 18, 2012).

<sup>&</sup>lt;sup>44</sup> *Huffington*, 2012 WL 1415930, at \* 9.

limiting the Borrowing Statute to only those instances where the plaintiff seeks to avoid a jurisdiction with a shorter limitations period.<sup>45</sup>

The Delaware Court of Chancery reached a similar conclusion in *TrustCo Bank v*. *Mathews*.<sup>46</sup> The court found that the Borrowing Statute applied "when a plaintiff's cause of action arose out of state, irrespective of whether the plaintiff is forum shopping."<sup>47</sup> The court further explained that the application of *Saudi Basic* was limited to instances where "an absurd outcome or result that subverts the Borrowing Statute's fundamental purpose would otherwise occur."<sup>48</sup> The court left any greater alternation of the Borrowing Statute to the Delaware Legislature.<sup>49</sup>

Finally, then-Chancellor, now-Chief Justice Strine reached the same conclusion in *Century Mortgage Co. v. Morgan Stanley Mortgage Capital Holdings, LLC.*<sup>50</sup> In that case, the court refrained from any statutory analysis or legislative history of the Borrowing Statute and opted to apply the statute's plain language.<sup>51</sup> The court succinctly held that, where the cause of action arose in New York, Delaware's shorter three-year limitations period for contract disputes applied rather than New York's six-year limitations period.<sup>52</sup>

<sup>&</sup>lt;sup>45</sup> See id. ("Saudi Basic did not create a broad ruling banning the use of the borrowing statute in all situations except for the 'typical' scenario. Rather, it demonstrates the Delaware Supreme Court's unwillingness to allow the borrowing statute to be abused by a party shopping for a forum to avoid an adversary's counterclaims . . . At most, *Saudi Basic* provides a very narrow holding with respect to borrowing statute jurisprudence in that the Supreme Court recognized that applying the borrowing statute in that scenario would 'basically turn the borrowing statute on its head for the purpose for which it was enacted.").

<sup>&</sup>lt;sup>46</sup> C.A. No. 8374, 2015 WL 295373, at \*1 (Del. Ch. Jan. 22, 2015).

<sup>&</sup>lt;sup>47</sup> *TrustCo Bank*, 2015 WL 295373, at \*8.

<sup>&</sup>lt;sup>48</sup> *Id*.

<sup>&</sup>lt;sup>49</sup> *Id*.

<sup>&</sup>lt;sup>50</sup> C.A. No. 5140, 2012 WL 3201139, at \*1 (Del. Ch. Aug. 7, 2012).

<sup>&</sup>lt;sup>51</sup> Cent. Mortg., 2012 WL 3201139, at \*16.

<sup>&</sup>lt;sup>52</sup> *Id.* ("Here, Delaware's three-year limitations period governs Central Mortgage's breach of contract claims under the Master Agreement and transaction-specific agreements because it is shorter than the equivalent period prescribed by New York law, which is six years.").

Mr. Machala has pointed to no exceptional reason why the Court should depart from the clear and unambiguous language of the Borrowing Statute.<sup>53</sup> Mr. Machala chose to file his claims in Delaware and is now subject to the terms of the Borrowing State. Accordingly, the Court finds that Delaware's statute of limitations governs the claims in this case.

# **B.** WHETHER MR. MACHALA'S TORT CLAIMS ARE BARRED BY DELAWARE'S TWO-YEAR STATUTE OF LIMITATIONS

The question before the Court now becomes, as argued by the Boehringer Defendants, whether Mr. Machala's tort claims are barred by Delaware's two-year statute of limitations. Mr. Machala contends that his tort claims are not time barred because the two-year limitations period was tolled due to Defendants' fraudulent concealment. The Court agrees with the Boehringer Defendants and finds that the claims are time barred.

Under Delaware law, the limitations period for personal injury claims is two years "from the date upon which it is claimed that such injuries were sustained."<sup>54</sup> The moving party bears the burden of proving that a limitations period has lapsed and that the claim is time-barred.<sup>55</sup> However, "when a complaint asserts a cause of action that on its face accrued outside the statute of limitations, the plaintiff has the burden of pleading facts leading to a reasonable inference that one of the tolling doctrines" applies.<sup>56</sup>

To make this determination on a Civil Rule 12 motion, the court typically conducts a three-part analysis.<sup>57</sup> From the pleadings, a court looks to determine: (i) the cause of action's accrual date, (ii) whether the plaintiff has pleaded facts sufficient to create a reasonable inference that the limitations period has been tolled, and (iii) assuming a tolling exception has been

<sup>&</sup>lt;sup>53</sup> See Leatherbury v. Greenspun, 939 A.2d 1284, 1288 (Del. 2007) (explaining that unambiguous statutes are not subject to judicial interpretation).

<sup>&</sup>lt;sup>54</sup> 10 Del. C. § 8119.

<sup>&</sup>lt;sup>55</sup> SPX Corp. v. Garda USA, Inc. C.A. No. N10C-10-162, 2012 WL 6841398, at \* 2 (Del. Super. Dec. 6, 2012).

<sup>&</sup>lt;sup>56</sup> Winner Acceptance Corp. v. Return on Capital Corp., C.A. No. 3088, 2008 WL 5352063, at \*14 (Del. Ch. Dec. 23, 2008).

<sup>&</sup>lt;sup>57</sup> SPX Corp., 2012 WL 6841398, at \*2.

pleaded adequately, when the plaintiff was on inquiry notice of a claim based on the allegations.<sup>58</sup> On this third step, inquiry notice is defined as the date when the plaintiff discovers "the facts constituting the basis of the cause of action or the existence of facts sufficient to put a person of ordinary intelligence and prudence on inquiry which, if pursued, would lead to the discovery of [of the injury]."<sup>59</sup>

The Court must first determine when the cause of action accrued. A cause of action in tort accrues at the time of injury.<sup>60</sup> Mr. Machala's claimed injury is that he suffered a stroke after Pradaxa failed to work as intended. Mr. Machala's claims therefore accrued, at the very latest, on December 18, 2013—the date Pradaxa purportedly failed to work as intended and Mr. Machala suffered the stroke. The statute of limitations expired two years later on December 18, 2015. Mr. Machala did not file the Complaint until December 16, 2016—almost one year after the statute of limitations expired. Absent tolling, all of Mr. Machala's claims fall outside the statute of limitations, and consequently, Mr. Machala has the burden of proving that one of the tolling doctrines applies.

The Court must next determine whether a tolling doctrine applies. Delaware courts recognize three tolling doctrines: (i) inherently unknowable injuries, (ii) fraudulent concealment, and (iii) equitable tolling.<sup>61</sup> The Complaint asserts that the fraudulent concealment doctrine has tolled the statute of limitations.<sup>62</sup> Under the fraudulent concealment doctrine, the statute of limitations is tolled "if there was an affirmative act of concealment or some misrepresentation that was intended 'to put a plaintiff off the trail of inquiry' until such time as the plaintiff is put

<sup>&</sup>lt;sup>58</sup> Id. (quoting Winner, 2008 WL 5352063, at \*14).

<sup>&</sup>lt;sup>59</sup> In re Dean Witter P'ship. Litig., C.A. No. 14816, 1998 WL 442456, at \*5 (Del. Ch. July 17, 1998).

<sup>&</sup>lt;sup>60</sup> Winner, 2008 WL 5352063, at \*14.

<sup>&</sup>lt;sup>61</sup> *Id.* at \*15.

<sup>&</sup>lt;sup>62</sup> Compl. ¶¶ 52–55.

on inquiry notice."<sup>63</sup> Mere ignorance of the facts by a plaintiff, where there has been no act of concealment or misrepresentation, does not toll the statute of limitations.<sup>64</sup>

The Court finds that Mr. Machala has not pleaded sufficient facts to support the tolling of the statute of limitations based on fraudulent concealment. The Complaint asserts that Defendants failed to disclose the truth about the safety and efficacy of Pradaxa.<sup>65</sup> The Complaint further asserts that Defendants misrepresented Pradaxa as safe and effective for its intended use and "actively concealed" the true risks associated with Pradaxa.<sup>66</sup> The Complaint, however, does not provide any specific way in which Defendants engaged in an affirmative act of concealment.<sup>67</sup> Moreover, the Complaint does not provide any factual allegations that Defendants intended to put Pradaxa users like Mr. Machala "off the trail of inquiry" or otherwise conceal Pradaxa's efficacy.<sup>68</sup>

Instead, the Complaint simply points to Defendants' purportedly negligent acts as evidence that Defendants engaged in fraudulent concealment. The Court finds that this approach is insufficient to toll the limitations period for two reasons. First, Defendants did not in fact actively conceal or misrepresent the efficacy of Pradaxa with respect to the claimed injury. Pradaxa's label has contained, since its original approval in 2010, language addressing efficacy for stroke prevention.<sup>69</sup> Mr. Machala knew he was using Pradaxa and he was aware that he had a

<sup>63</sup> Winner, 2008 WL 5352063, at \*14.

<sup>&</sup>lt;sup>64</sup> Id.

<sup>&</sup>lt;sup>65</sup> Compl. ¶ 52.

<sup>&</sup>lt;sup>66</sup> Id.

 <sup>&</sup>lt;sup>67</sup> Contra Council of Unit Owners of Sea Colony East, Phase III Condo. v. Carl M. Freeman, Assoc. Inc., 1988 WL
90569, at \*5 (Del. Super. Aug. 16, 1988) (finding that there existed a genuine issue of material fact as to whether defendants engaged in fraudulent concealment in a negligent design case where plaintiffs produced letters, reports, and confidential memoranda proving that defendants knew of the negligent design and did nothing).
<sup>68</sup> Id.

<sup>&</sup>lt;sup>69</sup> The "Indications and Usage" section states that "Pradaxa is a direct thrombin inhibitor indicated to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation." The Court, pursuant to Rule 201 of the Delaware Uniform Rules of Evidence, has taken discretionary judicial notice of Pradaxa's 2010 label, which is publicly available on the FDA's website. *See In re Gen. Motors Shareholders Litig.*, 897 A.2d 162, 171 ("[I]t was

stroke. At that point, Mr. Machala could have engaged in due diligence on whether Pradaxa was the proximate cause of his injuries. Any failure by Mr. Machala to engage in due diligence about Pradaxa's efficacy is not a basis for tolling the limitations period in this case.<sup>70</sup> Moreover, in negligence actions, a plaintiff must assert more than the negligence itself in order to support the occurrence of fraudulent concealment.<sup>71</sup> Therefore, absent specific information above and beyond the claims of negligence, the Complaint does not assert facts to support tolling the statute of limitations based on fraudulent concealment.

Even if the Complaint asserted such facts, the Court still finds that the claims are time barred. Under the third factor, the Court must determine when Mr. Machala was placed on inquiry notice of the claims. As just discussed, Mr. Machala received inquiry notice of the claims on December 18, 2013— the date he suffered a stroke and the injury occurred. Once Pradaxa failed to work as intended by causing a stroke, Mr. Machala knew or reasonably should have known that Defendants engaged in concealment or misrepresentations regarding the efficacy of Pradaxa.<sup>72</sup> December 18, 2013 is the same date Mr. Machala's claims accrued in the first instance. This means that the limitations period still would have expired two years later on December 18, 2015, making the Complaint filed on December 16, 2016 time barred. Therefore,

proper for the Court of Chancery to take judicial notice of the publicly available fact, reported by GM in a Form 10-Q filed with the SEC, that a majority of both classes of GM stockholders voted to approve the Hughes transaction."). <sup>70</sup> *See Shockley v. Dyer*, 456 A.2d 798, 800 (Del. 1983) (explaining that if a plaintiff could have discovered her rights by exercising due diligence, the statute of limitations was not tolled).

<sup>&</sup>lt;sup>71</sup> See id. (rejecting plaintiff's argument that her physician engaged in fraudulent concealment when he failed to disclose all the facts surrounding the operation because "this argument has no relevance" to whether or not the statute of limitations was tolled).

<sup>&</sup>lt;sup>72</sup> See In re Dean Witter, 1998 WL 442456, at \*7 ("Inquiry notice does *not* require *actual* discovery of the reason for the injury. Nor does it require plaintiffs' awareness of all the aspects of the alleged wrongful conduct. Rather, the statute of limitations begins to run when plaintiffs *should have* discovered the general fraudulent scheme.") (emphasis in original).

regardless of whether the statute of limitations was or was not tolled, the claims in this case are barred by the statute of limitations.<sup>73</sup>

## **VI. CONCLUSION**

For the reasons set forth above, the Court **GRANTS** Defendants Boehringer Ingelheim Pharmaceuticals, Inc. and Boehringer Ingelheim USA Corp.'s Motion to Dismiss Plaintiff's Complaint. Accordingly, the Court will dismiss the Complaint with prejudice.

## IT IS SO ORDERED.

Dated: June 29, 2017 Wilmington, Delaware

/s/Eric M. Davis Eric M. Davis, Judge

<sup>&</sup>lt;sup>73</sup> Because the Court is granting the Motion to Dismiss on this basis, it need not address the Boehringer Defendants' alternative argument that the Complaint fails to state a claim for relief under Civil Rule 12(b)(6).