



Cosmetic Act, based upon its failure to comply with administrative regulations requiring GSK to report certain Avandia safety studies to the Food and Drug Administration in its annual report.

## **I. Factual Background**

Victor Bautista was diagnosed with type II diabetes in 1985. He was initially treated with insulin only, and his physicians later added other medications. The parties do not agree as to the dates on which Bautista began and stopped using Avandia, but, viewing the facts in the light most favorable to Plaintiff, the Court will assume, for the purpose of these motions only, that Bautista began using Avandia in 2000, and filled his last prescription for Avandia on May 23, 2007. The record does not show why Avandia was discontinued. Bautista continued using insulin while taking Avandia.

In 2001, Bautista was diagnosed with coronary artery disease, arterial stenting, abnormal ECG, angina, dyspnea, heart failure, and edema—all injuries he claims resulted from Avandia use.<sup>3</sup> He also suffered from hypertension, which predated his Avandia use.<sup>4</sup> In December 2005, he had angioplasty and stenting to treat his coronary artery disease. Bautista was again diagnosed with edema sometime in 2006. He did not claim that he discovered any new Avandia-related injuries after the end of 2006. There is no evidence that he ever suffered a myocardial infarction. In addition to diabetes and the problems listed above, Bautista also was diagnosed with chronic obstructive pulmonary disease, renal disease, and obesity.<sup>5</sup>

Bautista spoke, understood, and read only Spanish. Plaintiff asserts that because Bautista did not understand English, he first became aware that Avandia may have caused his heart

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<sup>3</sup> Plaintiff's Fact Sheet.

<sup>4</sup> *Id.*

<sup>5</sup> *Id.*

problems in 2012 or 2013,<sup>6</sup> when a Spanish-language news program covered GSK's July 2012 guilty plea for failing to disclose certain Avandia safety studies in reports to the FDA. Watching that program, Bautista learned that the risk of certain adverse cardiac events may be heightened when Avandia is used in conjunction with insulin.

## **II. Standard of Review and Choice of Law**

Upon motion of a party, summary judgment is appropriate if “the materials in the record” show “that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.”<sup>7</sup> A fact is “material” if it could affect the outcome of the suit, given the applicable substantive law.<sup>8</sup> A dispute about a material fact is “genuine” if the evidence presented “is such that a reasonable jury could return a verdict for the nonmoving party.”<sup>9</sup>

The law to be applied in this case is that of the place of Bautista's treatment and injury, New York.<sup>10</sup>

## **III. Discussion**

### *A. Statute of Limitations on Failure to Warn and Negligence Claims (Counts 1 & 2)*

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<sup>6</sup> Plaintiff's complaint states that he saw the relevant news program in January 2013. His response brief and cross motion states that he viewed the program in August 2012. And his sur-reply states that he learned of the guilty plea in 2013. The precise date is immaterial. The Court will assume that Bautista learned of the guilty plea sometime after it was entered, in July 2012, but before he filed his complaint, in June 2013.

<sup>7</sup> Fed. R. Civ. P. 56(a), (c)(1)(A).

<sup>8</sup> *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

<sup>9</sup> *Id.*

<sup>10</sup> See *Faheem v. GlaxoSmithKline LLC*, No. 11-695 (*In re Avandia Mktg., Sales Practices & Products Liab. Litig.*, MDL 1871 (Doc. No. 2522)), 2012 WL 3205620, at \*2 (E.D. Pa. Aug. 7, 2012) (holding that the governing law should be the law of the state where plaintiff received medical treatment, including prescriptions for Avandia).

A statute of limitations delineates the time before which an action must be commenced in order for a plaintiff to recover. The statute begins to run at the time of an injury unless there is provision that tolls the statute.

In New York, the statute of limitations for product liability actions (including failure to warn and negligence claims) is three years.<sup>11</sup> New York has a discovery rule, pursuant to which “the three year period within which an action to recover damages for personal injury . . . caused by the latent effects of exposure to any substance or combination of substances, in any form, upon or within the body . . . shall be computed from the date of discovery of the injury by the plaintiff or from the date when through the exercise of reasonable diligence such injury should have been discovered by the plaintiff, whichever is earlier.”<sup>12</sup> “[W]here the discovery of the cause of the injury is alleged to have occurred less than five years after discovery of the injury or when with reasonable diligence such injury should have been discovered, whichever is earlier,” the statute of limitations may be tolled and “an action may be commenced or a claim filed within one year of such discovery of the cause of the injury; provided, however, if any such action is commenced or claim filed after the period in which it would otherwise have been authorized . . . the plaintiff or claimant shall be required to allege and prove that technical, scientific or medical knowledge and information sufficient to ascertain the cause of his injury had not been discovered, identified or determined prior to the expiration of the period within which the action or claim would have been authorized.”<sup>13</sup>

This Court has previously held “that a reasonable person who knew that he or she had suffered cardiovascular injury and had taken Avandia would have been put on notice by the end

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<sup>11</sup> N.Y. C.P.L.R. § 214(5).

<sup>12</sup> N.Y. C.P.L.R. § 214-c(2).

<sup>13</sup> N.Y. C.P.L.R. § 214-c(4)

of 2007 of the need to investigate a possible link between Avandia and the injury.”<sup>14</sup> Plaintiff argues that notice cannot be imputed to Bautista, however, because Bautista did not speak English and therefore did not benefit from the news coverage regarding Avandia in 2007. Plaintiff argues that Bautista first learned that Avandia could be the cause of his 2001-2006 injuries in 2012 or 2013. Therefore, Plaintiff argues that the 2013 Complaint was filed within one year of *Bautista’s* discovery of the cause. However, in focusing upon Bautista’s personal knowledge, Plaintiff fails to address two nuances of New York state law with regard to tolling.

First, Plaintiff fails to acknowledge that more than five years lapsed between Bautista’s discovery of his injury and his discovery of the cause of the injury, and thus, no tolling is permitted under § 214-c(4). Second, under §214-c(4), tolling applies only if Plaintiff can demonstrate “that technical, scientific or medical knowledge and information sufficient to ascertain the cause of his injury had not been discovered, identified or determined prior to the expiration of the period within which the action or claim would have been authorized.”<sup>15</sup> In *Faheem*, this Court found that GSK sent a series of “Dear Healthcare Professional” letters from May through November 2007, which summarized studies of Avandia and cardiovascular health, including the Nissen study which found a significant increase in the risk of heart attacks for patients taking Avandia, and regulatory actions with regard to Avandia.<sup>16</sup> The Court further found that “any physician receiving these letters would be aware that there was concern about

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<sup>14</sup> *Faheem*, 2012 WL 3205620, at \*4.

<sup>15</sup> N.Y. C.P.L.R. 214-c(4). *See also Giordano v. Market America, Inc.*, 915 N.Y.S.2d 884, 890 (N.Y. 2010) (“the statute refers to the time when information is sufficient for the technical, medical or scientific community ‘to ascertain’ the cause of an injury. It is not reasonable to extend the statute of limitations until the time when a reasonable layperson or lawyer could ‘ascertain’ the cause without consulting an expert.”)

<sup>16</sup> *Faheem*, 2012 WL 3205620, at \*3.

cardiovascular health and use of Avandia.”<sup>17</sup> In addition, the Court found that despite GSK’s attempts to encourage physicians to continue prescribing Avandia, by November 2007, Avandia prescriptions had fallen by 54%. This indicates a “general acceptance” of a relationship between Avandia use and an increased risk of cardiac problems in the relevant medical community by late 2007.<sup>18</sup> Thus, under New York law, where tolling for discovery of the cause of the injury applies, an action claiming that Avandia caused a heart-related injury is untimely if filed more than three years from diagnosis of the injury or after December 31, 2008, whichever came later.

In Bautista’s case, where all Avandia-related injuries had been discovered by the end of 2006, the statute of limitations ran no later than December 31, 200. Yet, Plaintiff’s complaint was not filed until 2013. Summary judgment must therefore be entered in favor of GSK on Plaintiff’s personal injury claims (failure to warn and negligence).

*B. Statute of Limitations for Breach of Warranty Claims (Counts 3 & 4)*

Plaintiff also asserts claims for breach of express and implied warranties. Under New York law, the statute of limitations for breach of express or implied warranties is four years from the date of tender of delivery.<sup>19</sup> In this case, Bautista filled his last Avandia prescription on May 23, 2007. Thus, the last date on which he could file a breach of warranty claim was May 23, 2011. Plaintiff filed his action on June 13, 2013, more than six years after filling his last Avandia prescription. Therefore, the Court finds that Plaintiff’s breach of warranty claims are also time-barred and must be dismissed.

*C. Statute of Limitations for Fraud Claims (Count 5)*

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<sup>17</sup> *Id.*

<sup>18</sup> *See Giordano*, 915 N.Y.S.2d at 890.

<sup>19</sup> N.Y. C.L.S. U.C.C. § 2-725.

Plaintiff alleges that GSK purposely misled the public as to the safety of using Avandia, whether alone or in conjunction with insulin, so as to induce individuals with diabetes to purchase and use Avandia. Pursuant to § 213(8), “the time within which [a fraud claim] must be commenced shall be the greater of six years from the date the cause of action accrued or two years from the time the plaintiff . . . discovered the fraud, or could with reasonable diligence have discovered it.”<sup>20</sup> Plaintiff argues that the Complaint was filed within two years from the time Bautista discovered the fraud (after seeing news coverage of GSK’s July 2012 guilty plea), and thus the fraud claim was timely filed.

The New York Appellate Division has repeatedly held that the longer statute of limitations for fraud claims, set forth in N.Y. C.P.L.R. § 213(8), is only applicable in cases in which there would be no injury but for the fraud.<sup>21</sup> Where “the genesis of plaintiff’s claim is that [he] was injured by a defective product” and the alleged fraud “consisted of representations made while marketing”<sup>22</sup> the product, the plaintiff “cannot, by adding an allegation of *scienter*, invoke the longer [fraud] period of limitations.”<sup>23</sup> Here, the Court finds that the fraud claim is essentially identical to the products liability claims, and particularly the failure to warn claim, with the added element of *scienter*. Therefore, the longer period of limitations does not apply, and the fraud claim is untimely, for the reasons set forth in Section IIIA of this opinion.<sup>24</sup>

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<sup>20</sup> N.Y. C.P.L.R. § 213(8).

<sup>21</sup> *N.Y. Seven-Up Bottling Co. v. Dow Chem. Co.*, 466 N.Y.S.2d 478, 480 (N.Y. App. Div. 1983), *aff’d* 61 N.Y.2d 828 (N.Y. 1984)(in affirming, the Court of Appeals noted that the injury to plaintiff had clearly occurred more than 3 years before the suit was filed); *Frumento v. On Rite Co.*, 887 N.Y.S.2d 620, 622 (N.Y. App. Div. 2009); *Scott v. Fields*, 925 N.Y.S.2d 135, 138 (N.Y. App. Div. 2011).

<sup>22</sup> *Seven-Up*, 466 N.Y.S.2d at 480.

<sup>23</sup> *Id.*

<sup>24</sup> Although Plaintiff argues that GSK has failed to address the provision of § 213(8) that allows suits to be filed within two years from the time the plaintiff discovers the fraud, in fact, the cases upon which GSK relies do not examine which prong of §213(8) would apply if plaintiff was asserting a free-standing fraud claim. Rather, the cases

D. *Estoppel*

Finally, Plaintiff argues that GSK should be equitably estopped from arguing that Plaintiff's claims are time-barred, because GSK's own fraud, misrepresentations, or deception induced Plaintiff not to file a timely action. However, equitable estoppel does not apply where the misrepresentation underlying the estoppel claim is the same act which forms the basis of plaintiff's underlying substantive cause of action.<sup>25</sup> Here, Plaintiff posits that GSK misrepresented the safety of Avandia both as the basis for his substantive claims and as the basis for equitable estoppel. Accordingly, the Court will not estop GSK from asserting the statutes of limitations as an affirmative defense.

**IV. Conclusion**

For the reasons discussed above, GSK's motion for summary judgment will be granted with respect to all claims, and Plaintiff's cross motion for summary judgment will be denied. An appropriate Order follows.

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hold that a plaintiff cannot avoid the three-year products liability statute of limitations by adding a related claim for fraud.<sup>24</sup> Plaintiff has cited no authority for extending the statute of limitations here.

<sup>25</sup> *Rizk v. Cohen*, 73 N.Y.2d 98, 105-06 (N.Y. 1989); *See also Kaufman v. Cohen*, 760 N.Y.S.2d 157 (N.Y. App. Div. 2003).

