

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS
GLAXOSMITHKLINE LLC
(b) County of Residence of First Listed Plaintiff New Castle, DE
(c) Attorneys (Firm Name, Address, and Telephone Number) (see attachment)

DEFENDANTS
THE CHEROKEE NATION and TODD HEMBREE in his official capacity as Attorney General of the Cherokee Nation
County of Residence of First Listed Defendant Cherokee County, OK
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED
Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)
1 U.S. Government Plaintiff
2 U.S. Government Defendant
3 Federal Question (U.S. Government Not a Party)
4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
PTF DEF
Citizen of This State 1 1
Citizen of Another State 2 2
Citizen or Subject of a Foreign Country 3 3
Incorporated or Principal Place of Business In This State 4 4
Incorporated and Principal Place of Business In Another State 5 5
Foreign Nation 6 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

Table with 5 columns: CONTRACT, REAL PROPERTY, TORTS, CIVIL RIGHTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES. Includes various legal categories like Insurance, Personal Injury, Labor, etc.

V. ORIGIN (Place an "X" in One Box Only)
1 Original Proceeding
2 Removed from State Court
3 Remanded from Appellate Court
4 Reinstated or Reopened
5 Transferred from Another District
6 Multidistrict Litigation

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):
28 U.S.C. § 2201
Brief description of cause:
Seeks declaration that a settlement agreement adopted by this Court released claims asserted by defendant.

VII. REQUESTED IN COMPLAINT:
CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. DEMAND \$
CHECK YES only if demanded in complaint: JURY DEMAND: Yes No

VIII. RELATED CASE(S) IF ANY
(See instructions): JUDGE Hon. Rya W. Zobel DOCKET NUMBER 12-cr-10206; 11-cv-10398

DATE 11/25/2013 SIGNATURE OF ATTORNEY OF RECORD /s/ Geoffrey E. Hobart

FOR OFFICE USE ONLY
RECEIPT # AMOUNT APPLYING IFP JUDGE MAG JUDGE

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

GLAXOSMITHKLINE LLC,

Plaintiff,

v.

THE CHEROKEE NATION and TODD  
HEMBREE,

Defendants.

Civil Action No.: 13-cv-13010

**COMPLAINT**

Plaintiff, GlaxoSmithKline LLC (“GSK”), for its Complaint against the defendants, the Cherokee Nation (the “Cherokee Nation” or the “Tribe”) and Todd Hembree, respectfully shows to the Court and alleges that:

**INTRODUCTION**

1. This is a declaratory judgment action arising out of a Settlement Agreement between GSK and the United States of America relating to GSK’s allegedly illegal marketing, sale and promotion of Avandia®, Avandamet®, and Avandaryl® (collectively, “Avandia”).<sup>1</sup> The United States entered into the Settlement Agreement on its own behalf, and on behalf of the Cherokee Nation, among others. Accordingly, the Settlement Agreement is binding on the Cherokee Nation.

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<sup>1</sup> A copy of the Agreement (hereafter, the “Avandia Settlement Agreement” or the “Settlement Agreement”) is attached as Exhibit 1.

2. Avandia is an oral medicine used to treat type 2 diabetes and is in a class of drugs called thiazolidinediones. The federal Food and Drug Administration approved Avandia for sale in May 1999 and Avandia has been on the market since then.

3. The Avandia Settlement Agreement is governed by “the laws of the United States.”<sup>2</sup> The “exclusive jurisdiction and venue for any dispute” arising under the Settlement Agreement is the “United States District Court for the District of Massachusetts.”<sup>3</sup>

4. In the face of the Avandia Settlement Agreement’s exclusive jurisdiction and venue provision, on August 9, 2013, the Cherokee Nation filed a Petition against GSK in the District Court of the Cherokee Nation in Tahlequah, Oklahoma (hereafter, “the Tribal Court”). The suit seeks to recover “damages and other relief” for GSK’s allegedly “illegal marketing, sale and promotion” of Avandia.<sup>4</sup>

5. By filing suit in the Tribal Court for conduct relating to the marketing, sale and promotion of Avandia, the Cherokee Nation breached the Avandia Settlement Agreement in three ways. First, the Avandia Settlement Agreement clearly specifies that the exclusive jurisdiction and venue over disputes under the Avandia Settlement Agreement are vested in the United States District Court for the District of Massachusetts.<sup>5</sup> Filing suit in the Tribal Court was a breach of this exclusive jurisdiction and venue provision. Second, the Cherokee Nation’s suit runs afoul of the Avandia Settlement Agreement because it asserts claims that were released

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<sup>2</sup> See Exhibit 1 at ¶ 16.

<sup>3</sup> *Id.*

<sup>4</sup> A copy of the Cherokee Nation’s Third Amended Petition (“Petition”) in the Tribal Court is attached hereto as Exhibit 2.

<sup>5</sup> Exhibit 1 at ¶ 16.

under the Avandia Settlement Agreement.<sup>6</sup> Third, the suit purports to seek relief under the “statutory, common, and decisional laws of the Cherokee Nation,” notwithstanding that disputes under the Settlement Agreement are “governed under the laws of the United States.”<sup>7</sup>

6. In addition, the Tribal Court lacks jurisdiction over the Cherokee Nation’s claims against GSK because GSK is not a member or citizen of the Cherokee Nation.

7. By this action, GSK seeks a declaration determining the scope of the released claims under the Avandia Settlement Agreement, and entry of judgment on any and all claims determined by this Court to have been released. In addition, GSK seeks a declaration that the Tribal Court lacks jurisdiction to hear and determine released claims under the Avandia Settlement Agreement, or to decide claims brought against GSK as a non-citizen of the Cherokee Nation. Finally, if necessary, GSK seeks an injunction barring the Cherokee Nation from pursuing its claims, including all claims released by the Avandia Settlement Agreement, in the Tribal Court.

### **PARTIES**

8. GlaxoSmithKline LLC is a limited liability corporation organized and existing under the laws of the State of Delaware. GSK is a citizen of Delaware. GSK is not a citizen or member of the Cherokee Nation.

9. The Cherokee Nation alleges in its Petition that it is a sovereign body politic created by the Cherokee Nation Constitution and laws of the Cherokee Nation. Todd Hembree is the Attorney General for the Cherokee Nation. Attorney General Hembree is sued in his official capacity.

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<sup>6</sup> *Id.* at ¶ 2.

<sup>7</sup> *Id.*

**JURISDICTION AND VENUE**

10. The Court has jurisdiction pursuant to 28 U.S.C. § 1331, as this action arises under the Constitution, laws, or treaties of the United States, raising the federal question of the scope of the adjudicative jurisdiction of the Tribal Courts of the Cherokee Nation. Moreover, the Court has and retains federal question jurisdiction because the United States agreed, on behalf of the Cherokee Nation and others, that the “exclusive jurisdiction and venue for any dispute arising between and among the Parties” under the Avandia Settlement Agreement is the “United States District Court for the District of Massachusetts.”

11. Venue is proper in this judicial district under 28 U.S.C. § 1391(b). Venue is also proper under the Avandia Settlement Agreement.

**THE AVANDIA SETTLEMENT AGREEMENT**

12. The Avandia Settlement Agreement resolved the United States’ civil investigation concerning the marketing, sale and promotion of Avandia. Paragraph E of the Avandia Settlement Agreement sets forth the government’s civil allegations relating to GSK’s conduct with respect to Avandia.<sup>8</sup>

13. A related criminal proceeding, titled *United States of America v. GlaxoSmithKline, LLC*, Criminal Action No. 12-10206-RWZ, and assigned to the Hon. Rya W. Zobel, also involved the marketing, sale and promotion of Avandia. Count Three of the Information sets forth the government’s allegations relating to GSK’s conduct with respect to Avandia.<sup>9</sup> The United States and GSK resolved the criminal proceeding pursuant to a Plea

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<sup>8</sup> Exhibit 1 at ¶ E.

<sup>9</sup> A copy of the Information is attached as Exhibit 3.

Agreement dated June 27, 2012,<sup>10</sup> the terms of which were adopted by Judge Zobel at a July 5, 2012 plea and sentencing hearing,<sup>11</sup> and embodied in a Judgment.<sup>12</sup> That Plea Agreement also resolved certain civil actions against GSK.<sup>13</sup>

14. In connection with the written Plea Agreement (Exhibit 4) GSK and the United States also entered into the Avandia Settlement Agreement (Exhibit 1). Under the Avandia Settlement Agreement, the terms “United States,” “GSK” and “the parties” are defined as follows (id. at 1):

This Settlement Agreement (“Agreement”) is entered into by and among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General (“OIG-HHS”) of the United States Department of Health and Human Services (“HHS”), the TRICARE Management Activity (“TMA”), the United States Department of Veteran’s Affairs (“VA”), and the United States Office of Personal Management (“OPM”) (collectively the “United States”, and GlaxoSmithKline LLC (“GSK”), through their authorized representatives. Collectively, all of the above will be referred to as “the Parties.”

The definitions of the “United States” and “the Parties” specifically includes the “Department of Health and Human Services (‘HHS’).” The Cherokee Nation is a Party to the Avandia Settlement Agreement by virtue of its legal relationship with HHS.

15. In addition to being a Party to the Settlement Agreement, the Cherokee Nation’s purchases are covered by Paragraph D of the Settlement Agreement, which identifies the “Government Health Care Programs” that purchased Avandia or were caused to purchase

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<sup>10</sup> A copy of the Plea Agreement is attached as Exhibit 4.

<sup>11</sup> A copy of the transcript of the Plea and Sentencing Hearing is attached as Exhibit 5.

<sup>12</sup> A copy of the Judgment is attached as Exhibit 6.

<sup>13</sup> See, e.g., *United States et al. ex rel. Thorpe, et al. v. GSK et al.*, Civ. No. 11-10398, and cases consolidated therein (D. Mass.).

Avandia. One of the Programs identified in Paragraph D is the “Veterans Affairs Program,” referring to the Federal Supply Schedule (“FSS”) for pharmaceutical products administered by the Department of Veterans Affairs (“VA”) under which certain government entities may make purchases. The Tribe purchased Avandia through the FSS administered by the VA based upon a contract between the VA and GSK. Thus, the Tribe’s purchases of Avandia were purchases by a Government Health Care Program as defined in Paragraph D of the Settlement Agreement.

16. Paragraph 2 of the Avandia Settlement Agreement sets forth the terms of the release to GSK:

the United States [including HHS] (on behalf of itself, its officers, agencies and departments) agrees and releases GSK ... from any civil or administrative monetary claim that the United States [including HHS] has or may have for Covered Conduct under ... [certain federal statutes] and common law claims for fraud, payment by mistake, breach of contract, disgorgement and unjust enrichment.<sup>14</sup>

17. Pursuant to Paragraph E of the Avandia Settlement Agreement, the release covers conduct during the period from January 2000 through December 2010. Paragraph 11 provides that the release is intended for the benefit of “the Parties,” a defined term that includes the “United States,” “HHS,” and the “VA.”<sup>15</sup>

**THE CHEROKEE NATION IS A PARTY TO  
THE AVANDIA SETTLEMENT AGREEMENT**

18. The Avandia Settlement Agreement releases claims of “officers, agencies and departments” of the United States, including those within the Department of Health and Human Services.<sup>16</sup> The Cherokee Nation acted as part of the Indian Health Service, which is an agency

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<sup>14</sup> Exhibit 1 at ¶ 2.

<sup>15</sup> Exhibit 1 at p. 1.

<sup>16</sup> Exhibit 1 at ¶ 2.

of HHS,<sup>17</sup> for all or substantially all of the Avandia purchases that are the subject of the Cherokee Nation's Petition.

19. The Cherokee Nation purchased all or substantially all of the Avandia at issue in the Complaint through wholesalers at prices set by the FSS, based upon a contract between the Department of Veterans Affairs and GSK offering federally-mandated, discounted prices for Avandia and other medicines. The "Veterans Affairs Program" is one of the "Government Health Care Programs" covered by the Settlement Agreement.<sup>18</sup> Thus, the Tribe's purchases of Avandia were purchases by a Government Health Care Program as defined in Paragraph D of the Settlement Agreement.

20. When it paid for Avandia at prices set by the FSS, the Cherokee Nation acted as an executive agency and part of HHS because, pursuant to a federal statute, it was "deemed" to be an executive agency and part of HHS for any purchases of Avandia made pursuant to the FSS.<sup>19</sup> The Cherokee Nation's purchase of Avandia at FSS prices was legal only if it was acting as part of HHS.

21. The Cherokee Nation elected to accept federal funds so that it could self-administer health care programs that would otherwise be provided by the federal government.<sup>20</sup>

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<sup>17</sup> IHS is part of the Public Health Service, 25 U.S.C. § 1661(a)(1), (b) and the Public Health Service is established within HHS, 42 U.S.C. § 202.

<sup>18</sup> Exhibit 1 at 1 ¶ D.

<sup>19</sup> 25 U.S.C. § 450j(k)

<sup>20</sup> See, e.g., Cherokee Nation Res. 75-08, "A Resolution Ratifying a Self-Governance Compact with the United States of America, Health and Human Services, and Indian Health Service" (enacted 8/28/2008) (noting that "each annual budget approved by the Council of the Cherokee Nation since [1993] has included programs, services, functions and activities of the IHS and associated funding for self-governance programs which were included in funding agreements," and accepting funding until September 30, 2011); Indian Health Service, JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES: FISCAL YEAR 2014 at 211 (2012), *available at* (continued...)



As part of its election, the Cherokee Nation was given the option of purchasing drugs on a federal contract, the FSS, at federally-negotiated, discounted prices that are typically available only to federal purchasers.<sup>21</sup> The Tribe is an eligible purchaser on the FSS only because, pursuant to 25 U.S.C. § 450j(k), a tribe will be “deemed an executive agency and part of the Indian Health Services [which is part of HHS]” when it is acting to self-administer its tribal healthcare system pursuant to an agreement under the Indian Self-Determination and Education Assistance Act of 1975 (“ISDEAA”). 25 U.S.C. § 450j, *et. seq.* Thus, as a matter of federal law, the Tribe acted as an agency of HHS for the purposes of its Avandia purchases.

22. The Cherokee Nation could not have purchased Avandia through the FSS at federally-procured, discounted prices if it was not acting as part of HHS. Not only did the Tribe purchase all or substantially all of the Avandia at issue pursuant to the FSS, it did so at “big four” price discounts. The FSS is available to federal buyers as outlined in 40 U.S.C. §501-502, but “big four” price discounts are discounts that Congress requires pharmaceutical manufacturers to provide to only four federal agencies: the “Department of Veterans Affairs,” the Department of Defense, “the Public Health Service, including the Indian Health Service,” and the Coast Guard.<sup>22</sup>

23. Agencies receiving “big four” discounts are not permitted to share those discounts with other entities.<sup>23</sup> Accordingly, the Tribe could only access “big four” pricing

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<http://www.ihs.gov/budgetformulation/includes/themes/newihstheme/documents/FY2014BudgetJustification.pdf> (noting IHS funding for Cherokee Nation in fiscal year 2012).

<sup>21</sup> 40 U.S.C. §§ 501-02.

<sup>22</sup> 38 U.S.C. § 8126(a)(4).

<sup>23</sup> “Audit of the Federal Bureau of Prisons Pharmacy Services,” Office of Inspector General (Report 06-03) (Nov. 2005), *available at* <http://www.justice.gov/oig/reports/BOP/a0603/findings.htm> (citing a legal opinion by the Department of Veterans Affairs).

discounts on Avandia by acting as an extension of the Indian Health Service, and thus, an agency of HHS.

24. For the purposes of Cherokee Nation's Avandia purchases, therefore, Cherokee Nation is an executive agency of HHS, a Party to the Avandia Settlement Agreement, and subject to the release from the "United States," including "HHS," to GSK.<sup>24</sup>

**THE CHEROKEE NATION DOES NOT HAVE ADJUDICATORY AUTHORITY OVER GSK'S ALLEGED CONDUCT RELATING TO AVANDIA BECAUSE GSK IS NOT A CITIZEN OR MEMBER OF THE CHEROKEE NATION**

25. The Cherokee Nation does not have adjudicatory authority over GSK because GSK is not a citizen or member of the Cherokee Nation.

26. The Cherokee Nation's purchases of Avandia were made based on orders placed with and delivered from wholesale distributors, and did not involve direct contact with GSK.

27. The Cherokee Nation's ordering and receipt of Avandia from wholesale distributors does not constitute a consensual commercial relationship between GSK and the Cherokee Nation.

28. The Cherokee Nation's purchases of Avandia do not menace the political integrity, the economic security, or the health or welfare of the tribe.

**THE CHEROKEE NATION IS ASSERTING RELEASED CLAIMS IN THE TRIBAL COURT ACTION**

29. As a Party to the Avandia Settlement Agreement, the Cherokee Nation may not pursue released claims for the period from January 2000 through December 2010.<sup>25</sup> The vast majority of the claims it is making in Tribal Court are released claims.

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<sup>24</sup> See Exhibit 1 at ¶ 16.

<sup>25</sup> See Exhibit 1 at ¶ E.

30. The Cherokee Nation's Avandia-related allegations in the Tribal Court closely parallel the Avandia-related allegations made by the United States in Count Three of the Information.<sup>26</sup> They also parallel the factual allegations set forth in the Avandia Settlement Agreement.<sup>27</sup> Thus, the Cherokee Nation's claims derive from the same core allegations that formed the basis for Count Three of the Information (Exhibit 3), the written Plea Agreement (Exhibit 4) and the Avandia Settlement Agreement (Exhibit 1). In short, the Cherokee Nation's Petition in Tribal Court seeks recovery for released claims.

**FIRST CAUSE OF ACTION**  
**(Declaratory Judgment)**

31. GSK realleges and incorporates by reference Paragraphs 1 through 30 of this Complaint.

32. GSK brings this claim for declaratory judgment under 28 U.S.C. §§ 2201-02 and Fed. R. Civ. P. 57. A dispute has arisen between GSK and the Cherokee Nation over the scope of the released claims under the Avandia Settlement Agreement. Such dispute constitutes a justiciable controversy between GSK and the Cherokee Nation that must be determined under the "laws of the United States" in the "United States District Court for the District of Massachusetts."

33. For the reasons stated above, GSK requests that the Court to enter judgment declaring that, under the laws of the United States, the Causes of Action asserted against GSK by the Cherokee Nation in the Tribal Court are released claims, in whole or in part. GSK also seeks entry of judgment on any and all released claims.

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<sup>26</sup> Compare Exhibit 2 at ¶¶ 37-130 (Petition), with Exhibit 3 at ¶¶ 82-95 (Information).

<sup>27</sup> See Exhibit 1 at ¶ E (reciting allegations supporting the United States' claim that GSK engaged in unlawful conduct relating to Avandia).

**SECOND CAUSE OF ACTION**  
**(Declaratory Judgment)**

34. GSK realleges and incorporates by reference Paragraphs 1 through 30 of this Complaint.

35. GSK brings this claim for declaratory judgment under 28 U.S.C. §§ 2201-02 and Fed. R. Civ. P. 57. A dispute has arisen between GSK and the Cherokee Nation over the jurisdiction of the Cherokee Nation courts. Such dispute constitutes a justiciable controversy between GSK and the Cherokee Nation that must be determined under the “laws of the United States” in the “United States District Court for the District of Massachusetts.”

36. For the reasons stated above, GSK requests the Court to enter judgment declaring that, under the laws of the United States, the Cherokee Nation courts do not have jurisdiction over the claims asserted in the Petition, including all claims released under the Avandia Settlement Agreement, because (1) GSK and the Cherokee Nation are Parties to the Avandia Settlement Agreement; (2) the Parties to the Avandia Settlement Agreement agreed that the exclusive jurisdiction and venue for any dispute arising between and among them shall be the United States District Court for the District of Massachusetts; and (3) GSK is not a citizen of the Cherokee Nation, nor did it engage in conduct that vests the Cherokee Nation’s courts with jurisdiction over the claims asserted in the Petition.

**WHEREFORE**, GSK demands judgment against the Cherokee Nation and Attorney General Hembree as follows:

1. For a declaratory judgment that the Cherokee Nation courts do not have jurisdiction over the claims in the Petition, including claims released by the Avandia Settlement Agreement;
2. For a declaratory judgment that the Causes of Action asserted against GSK by the Cherokee Nation in the Tribal Court are released claims under the Avandia Settlement Agreement, in whole or in part;
3. For entry of judgment on any and all released claims;
4. For injunctive relief, to the extent needed, enjoining the Cherokee Nation and Attorney General Hembree from taking any action against GSK in the Tribal Court;
5. For an order awarding GSK the costs and disbursements of this action; and
6. For such other, further and different relief as the Court deems just and proper.

Respectfully submitted,

**/s/ Geoffrey E. Hobart**

Geoffrey E. Hobart (Mass. Bar No. 547499)

*ghobart@cov.com*

Mark H. Lynch

*mlynch@cov.com*

**COVINGTON & BURLING LLP**

1201 Pennsylvania Avenue, NW

Washington, DC 20004-2401

Tel: 202.662.6000

Fax: 202.662.6291

Andrew D. Schau

*aschau@cov.com*

**COVINGTON & BURLING LLP**

The New York Times Building

620 Eighth Avenue

New York, NY 10018

Tel: 212.841-1000

Fax: 212.841-1010

Nina M. Gussack  
*gussackn@pepperlaw.com*  
Anthony Vale  
*valea@pepperlaw.com*  
George Lehner  
*lehnerg@pepperlaw.com*  
Eric Rothschild  
*rothschilde@pepperlaw.com*  
**PEPPER HAMILTON LLP**  
3000 Two Logan Square  
Eighteenth and Arch Streets  
Philadelphia, Pennsylvania 19103-2799  
Tel: 215.981.4000  
Fax: 215.981.4750

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