

NIQA

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

PAR PHARMACEUTICAL, INC.,

Plaintiff,

v.

GLAXOSMITHKLINE LLC, APTALIS PHARMA
US, INC., APTALIS PHARMATECH, INC., and
APTALIS PHARMA CANADA INC.,

Defendants.

14 6627

Civil Action No. _____

FILED

NOV 19 2014

MICHAEL KUNZ, Clerk
By _____ Dep. Clerk

COMPLAINT

Plaintiff Par Pharmaceutical, Inc. ("Par"), for its Complaint against GlaxoSmithKline LLC ("GSK"), Aptalis Pharma US, Inc., Aptalis Pharmatech, Inc., and Aptalis Pharma Canada Inc. (collectively "Aptalis") (together, "Defendants"), alleges as follows:

NATURE OF ACTION

1. Par seeks declaratory judgment of non-infringement of U.S. Patent No. 7,919,115 pursuant to the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.*, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(5)(C)(i), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq.*

PARTIES

2. Par Pharmaceutical, Inc. is a corporation organized and existing under the laws of Delaware, having a place of business at One Ram Ridge Road, Spring Valley, New York 10977.

3. On information and belief, GlaxoSmithKline LLC is a corporation organized and existing under the laws of the state of Delaware, having a principal place of business at 5 Crescent Drive, Philadelphia, Pennsylvania 19112.

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4. On information and belief, Aptalis Pharma US, Inc. is a corporation organized and existing under the laws of the state of Delaware, having a principal place of business at 100 Somerset Corporate Boulevard, Bridgewater, New Jersey 08807.

5. On information and belief, Aptalis Pharmatech, Inc. is a corporation organized and existing under the laws of the state of Nevada, having a place of business at 790 Township Line Rd., Suite 250, Yardley, Pennsylvania 19067.

6. On information and belief, Aptalis Pharma Canada Inc. is a corporation organized and existing under the laws of Canada, having a principal place of business at 597 Boul Sir-Wilfrid-Laurier, Mont-Saint-Hilaire J3H 6C4, Quebec, Canada.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338(a), and 2201(a); 21 U.S.C. § 355(j)(5)(C)(i)(II); and 35 U.S.C. § 271(e)(5).

8. This Court has personal jurisdiction over Defendants based on, *inter alia*, Defendants' systematic, purposeful, and continuous contacts in this district, including GSK's and Aptalis Pharmatech, Inc.'s registration to do business in this district. On information and belief, GSK has also engaged in the sale of Lamictal ODT[®] in interstate commerce and in this judicial district. On information and belief, Defendants have engaged in the research, development, and sale of pharmaceutical products, which are sold throughout the United States and the State of Pennsylvania. On information and belief, Defendants have purposefully availed themselves of this forum by making and commercializing pharmaceutical products in the State of Pennsylvania, including in this judicial district, and deriving substantial revenues from such activities.

9. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b)-(d) and 21 U.S.C. § 355(j)(5)(C)(i)(II), as Defendants GSK and Aptalis Pharmatech Inc. reside in and have a regular and established place of business in this judicial district, and Defendants transact business in this judicial district.

FACTUAL BACKGROUND

10. United States Patent No. 7,919,115 (“the ’115 patent”) entitled “Orally Disintegrating Tablet Compositions of Lamotrigine,” issued on April 5, 2011. A true and correct copy of the ’115 patent is attached hereto as Exhibit A.

11. On information and belief, the ’115 patent is currently scheduled to expire on January 4, 2029.

12. On information and belief, Aptalis Pharma US, Inc., Aptalis Pharmatech, Inc., and Aptalis Pharma Canada Inc. are the named assignees of the ’115 patent.

13. On information and belief, GSK is the holder of New Drug Application No. 022251 (“NDA 022251”) for orally disintegrating lamotrigine tablets, 25 mg, 50 mg, 100 mg, and 200 mg, marketed under the brand name Lamictal ODT[®]. In connection with NDA 022251, GSK caused the U.S. Food and Drug Administration (“FDA”) to list the ’115 patent in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (“Orange Book”).

14. Par submitted Abbreviated New Drug Application No. 204158 (“ANDA 204158”) to the FDA requesting regulatory approval to engage in the commercial manufacture, use, or sale of orally disintegrating lamotrigine tablets, 25 mg, 50 mg, 100 mg, and 200 mg (“Par’s Lamotrigine ODT Product”), before the expiration of the Orange Book patents listed for Lamictal ODT[®]. Par made a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV Certification”) that the ’115 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Par’s Lamotrigine ODT Product.

15. Pursuant to 21 U.S.C. § 355(j)(2)(B)(ii), on August 28, 2012, Par provided notice to GSK and Aptalis Pharmatech, Inc. of the Paragraph IV Certification that it filed with ANDA 204158, together with an Offer of Confidential Access to ANDA 204158 pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III). This notice included a detailed statement of the factual and legal basis why the '115 patent is invalid, unenforceable, and/or will not be infringed.

16. Par's notification triggered a 45-day statutory period during which Defendants had the first opportunity to initiate patent infringement litigation. Defendants did not assert the '115 patent against Par for Par's Lamotrigine ODT Product during the 45-day statutory period.

17. 35 U.S.C. § 271(e)(5) provides that the Court shall have subject matter jurisdiction under 28 U.S.C. § 2201 for a declaratory judgment claim that an Orange Book-listed patent that is not asserted during the statutory 45-day period is invalid and/or not infringed.

18. Par received tentative approval from FDA for ANDA 204158 on October 30, 2014. A true and correct copy of the FDA letter notifying Par of the tentative approval for ANDA 204158 is attached hereto as Exhibit B.

19. Par has not yet received final approval from FDA for ANDA 204158. The FDA was unable to grant final approval to ANDA 204158 because prior to the submission of Par's ANDA to FDA, "another applicant submitted an ANDA providing for Lamotrigine Orally Disintegrating Tablets, 25 mg, 50 mg, 100 mg, and 200 mg, and containing a paragraph IV certification" to the '115 patent. Exhibit B at 2.

20. The FDA informed Par that ANDA 204158 would be "eligible for final approval, with respect to the other ANDA, 180 days after the first commercial marketing identified in section 505(j)(5)(B)(iv) of the [Federal Food, Drug, and Cosmetic] Act, or that applicant's exclusivity is otherwise resolved." *Id.*

21. On information and belief, commercial marketing under that other ANDA has not yet commenced and, therefore, the other ANDA's paragraph IV certification to the '115 patent remains a barrier to final FDA approval of Par's Lamotrigine ODT Product. This exclusivity barrier exists by virtue of Defendants' maintenance of the listing of the '115 patent in the Orange Book in connection with NDA 022251 for Lamictal ODT®.

22. Par has made substantial preparations for the commercial manufacture, use, and sale of Par's Lamotrigine ODT Product. Par currently has launch quantities of Par's Lamotrigine ODT Product packaged and ready for distribution to customers.

23. A judgment that Par's Lamotrigine ODT Product does not infringe the '115 patent, in view of Par's having been tentatively approved, will commence the period during which commercial marketing of said other ANDA product will be required, the expiry of which without the requisite marketing will remove the aforementioned exclusivity period barrier.

24. Defendants' actions have resulted in a substantial controversy regarding the '115 patent between Par and Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment that the '115 patent is not infringed.

Par's Lamotrigine ODT Product Does Not Infringe the '115 Patent

25. A true and correct copy of Modules 2 and 3 of ANDA 204158, which defines the composition of Par's Lamotrigine ODT Product, is attached hereto as Exhibits C, D, E and F.

26. The '115 patent contains 13 claims, of which claim 1 is independent. Claims 2-13 are dependent on claim 1 and, therefore, incorporate all of the limitations of claim 1. Claim 1 reads as follows:

An ODT consisting essentially of:

lamotrigine microcapsules comprising 25 or 200 mg of lamotrigine crystals having an average particle size of about 1-50 μm , coated with a

taste-masking layer consisting of ethylcellulose, wherein the average coating weight of said microcapsules is about 15% of the total weight of the microcapsules; and

rapidly dispersing granules comprising a granulate of crospovidone and mannitol in a ratio ranging from about 90/10 to about 99/1, wherein the rapidly dispersing granules are about 60% to 70% of the total weight of the ODT; and

an additional disintegrant comprising crospovidone;

wherein after a single oral administration said ODT provides;

a C_{max} in the range of 0.276 to 0.482 ng/mL of lamotrigine, an AUC_{0-24} in the range of 4.87 to 8.17 ng·hr/mL of lamotrigine, or

both a C_{max} in the range of 0.276 to 0.482 ng/mL of lamotrigine and an AUC_{0-24} in the range of 4.87 to 8.17 ng·hr/mL of lamotrigine, if the total amount of lamotrigine in the ODT is 25 mg, or

a C_{max} in the range of 2.21 to 3.95 ng/mL of lamotrigine, an AUC_{0-24} in the range of 36.0 to 63.6 ng·hr/mL of lamotrigine, or

both a C_{max} in the range of 2.21 to 3.95 ng/mL of lamotrigine and an AUC_{0-24} in the range of 36.0 to 63.6 ng·hr/mL of lamotrigine, if the total amount of lamotrigine in the ODT is 200 mg.

27. All claims of the '115 patent require lamotrigine "microcapsules," coated with "a taste-masking layer consisting of ethylcellulose," and "rapidly dispersing granules comprising a granulate of crospovidone and mannitol."

28. Par's Lamotrigine ODT Product does not contain microcapsules of lamotrigine. Exhibit C at 20-25, 29-35; Exhibit E at 20-25, 29-35.

29. Par's Lamotrigine ODT Product does not contain ethylcellulose. Exhibit C at 22; Exhibit E at 22.

30. Par's Lamotrigine ODT Product does not contain crospovidone. Exhibit C at 22; Exhibit E at 22.

31. Par's Lamotrigine ODT Product does not literally infringe any claim of the '115 patent because it does not meet the claim limitation requiring lamotrigine "microcapsules."

32. Par's Lamotrigine ODT Product does not literally infringe any claim of the '115 patent because it does not meet the claim limitation requiring lamotrigine "microcapsules" coated with "a taste-masking layer consisting of ethylcellulose."

33. Par's Lamotrigine ODT Product does not literally infringe any claim of the '115 patent because it does not meet the claim limitation requiring "rapidly dispersing granules comprising a granulate of crospovidone and mannitol."

34. Par's Lamotrigine ODT Product does not infringe under the doctrine of equivalents any claim of the '115 patent because it does not contain microcapsules of lamotrigine, or any equivalent thereof. Exhibit C at 20-25, 29-35; Exhibit E at 20-25, 29-35.

35. Par's Lamotrigine ODT Product does not infringe under the doctrine of equivalents any claim of the '115 patent because it does not contain ethylcellulose, or any equivalent thereof. Exhibit C at 22; Exhibit E at 22.

36. Par's Lamotrigine ODT Product does not infringe under the doctrine of equivalents any claim of the '115 patent because it does not contain crospovidone, or any equivalent thereof. Exhibit C at 22; Exhibit E at 22.

37. During prosecution of the '115 patent, the patentee surrendered all taste-masking layers other than ethylcellulose.

38. During prosecution of the '115 patent, the patentee amended the claims, at the Patent Office's suggestion, to recite a taste masking layer consisting of ethylcellulose in order to distinguish the claims from the art of record. Exhibit G at 2, 6. The Patent Office relied on this amendment in finding the claims to be allowable. Exhibit H at 9.

39. All claims of the '115 patent require lamotrigine microcapsules comprising 25 mg or 200 mg of lamotrigine.

40. Par's 50 mg and 100 mg Lamotrigine ODT Products contain 50 mg and 100 mg of lamotrigine, respectively.

41. Par's 50 mg and 100 mg Lamotrigine ODT Products do not literally infringe any of the claims of the '115 patent because they do not meet the claim limitation requiring 25 mg or 200 mg of lamotrigine.

42. Par's 50 mg and 100 mg Lamotrigine ODT Products do not infringe under the doctrine of equivalents any of the claims of the '115 patent because they do not contain 25 mg or 200 mg of lamotrigine, or any equivalent thereof.

43. The patentee has disclaimed tablets containing 50 mg or 100 mg of lamotrigine by disclosing these dosage strengths in the '115 patent specification, but choosing not to claim them. Exhibit A at 13:55-58.

44. During prosecution of the '115 patent, the patentee surrendered all dosage strengths other than 25 mg or 200 mg.

45. During prosecution of the '115 patent, the patentee amended the claims, at the Patent Office's suggestion, to include the 25 mg and 200 mg dosage strengths in order to distinguish the claims from the art of record. Exhibit I at 1; Exhibit J at 2.

COUNT ONE

Declaratory Judgment Regarding U.S. Patent No 7,919,115

46. Par reasserts and realleges paragraphs 1-45 above as if fully set forth herein.

47. The submission of ANDA 204158 did not infringe any claim of the '115 patent.

48. The commercial manufacture, use, offer for sale, sale, or importation of Par's Lamotrigine ODT Product will not infringe any claim of the '115 patent.

49. An actual and justiciable controversy exists between the parties with respect to the '115 patent, and Par is entitled to a declaratory judgment that the '115 patent is not infringed.

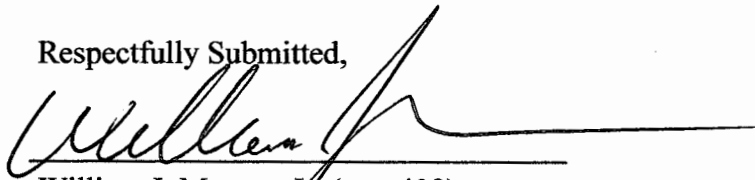
PRAYER FOR RELIEF

WHEREFORE, Par respectfully requests that this Court enter judgment in its favor and against Defendants and grant the following relief:

- A. Declare that the filing of Par's ANDA 204158 did not infringe any claim of the '115 patent;
- B. Declare that the manufacture, use, offer for sale, sale, marketing, distribution, or importation of Par's Lamotrigine ODT Product will not infringe any claim of the '115 patent;
- C. Award Par its costs and reasonable attorneys' fees; and
- D. Award Par such other and further relief as the Court deems just and proper.

Dated: November 19, 2014

Respectfully Submitted,



William J. Murray, Jr. (wm 409)
LAW OFFICES OF WILLIAM J. MURRAY, JR.
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Philadelphia, PA 19110
(267) 670-1818
Williamjmmurrayjr.esq@gmail.com

Attorneys for Plaintiff Par Pharmaceutical, Inc.



CIVIL COVER SHEET

14.0.6627

JS 44 (Rev. 12/12)

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.)

<p>I. (a) PLAINTIFFS Par Pharmaceutical, Inc.</p> <p>(b) County of Residence of First Listed Plaintiff <u>Rockland</u> <i>(EXCEPT IN U.S. PLAINTIFF CASES)</i></p> <p>(c) Attorneys (Firm Name, Address, and Telephone Number) William J. Murray, Jr. Law Offices of William J. Murray, Jr. P.O. Box 22615 Philadelphia, PA 19110 (267) 670-1818</p>	<p>DEFENDANTS GlaxoSmithKline LLC Aptalis Pharma US, Inc.. Aptalis Pharmatech, Inc Aptalis Pharma Canada Inc.</p> <p style="text-align: right; font-size: 2em;">14 6627</p> <p>County of Residence of First Listed Defendant <u>Philadelphia</u> <i>(IN U.S. PLAINTIFF CASES ONLY)</i></p> <p>NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.</p> <p>Attorneys (If Known)</p>
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<p>II. BASIS OF JURISDICTION <i>(Place an "X" in One Box Only)</i></p> <p><input type="checkbox"/> 1 U.S. Government Plaintiff</p> <p><input checked="" type="checkbox"/> 3 Federal Question <i>(U.S. Government Not a Party)</i></p> <p><input type="checkbox"/> 2 U.S. Government Defendant</p> <p><input type="checkbox"/> 4 Diversity <i>(Indicate Citizenship of Parties in Item III)</i></p>	<p>III. CITIZENSHIP OF PRINCIPAL PARTIES <i>(Place an "X" in One Box for Plaintiff and One Box for Defendant)</i></p> <p><i>(For Diversity Cases Only)</i></p> <table style="width:100%;"> <tr> <td style="width:33%;">Citizen of This State</td> <td style="width:10%;"><input type="checkbox"/> 1</td> <td style="width:10%;"><input type="checkbox"/> 1</td> <td style="width:33%;">Incorporated or Principal Place of Business In This State</td> <td style="width:10%;"><input type="checkbox"/> 4</td> <td style="width:10%;"><input type="checkbox"/> 4</td> </tr> <tr> <td>Citizen of Another State</td> <td><input type="checkbox"/> 2</td> <td><input type="checkbox"/> 2</td> <td>Incorporated and Principal Place of Business In Another State</td> <td><input type="checkbox"/> 5</td> <td><input type="checkbox"/> 5</td> </tr> <tr> <td>Citizen or Subject of a Foreign Country</td> <td><input type="checkbox"/> 3</td> <td><input type="checkbox"/> 3</td> <td>Foreign Nation</td> <td><input type="checkbox"/> 6</td> <td><input type="checkbox"/> 6</td> </tr> </table>	Citizen of This State	<input type="checkbox"/> 1	<input type="checkbox"/> 1	Incorporated or Principal Place of Business In This State	<input type="checkbox"/> 4	<input type="checkbox"/> 4	Citizen of Another State	<input type="checkbox"/> 2	<input type="checkbox"/> 2	Incorporated and Principal Place of Business In Another State	<input type="checkbox"/> 5	<input type="checkbox"/> 5	Citizen or Subject of a Foreign Country	<input type="checkbox"/> 3	<input type="checkbox"/> 3	Foreign Nation	<input type="checkbox"/> 6	<input type="checkbox"/> 6
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Citizen or Subject of a Foreign Country	<input type="checkbox"/> 3	<input type="checkbox"/> 3	Foreign Nation	<input type="checkbox"/> 6	<input type="checkbox"/> 6														

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

<p>CONTRACT</p> <p><input type="checkbox"/> 110 Insurance</p> <p><input type="checkbox"/> 120 Marine</p> <p><input type="checkbox"/> 130 Miller Act</p> <p><input type="checkbox"/> 140 Negotiable Instrument</p> <p><input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment</p> <p><input type="checkbox"/> 151 Medicare Act</p> <p><input type="checkbox"/> 152 Recovery of Defaulted Student Loans <i>(Excludes Veterans)</i></p> <p><input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits</p> <p><input type="checkbox"/> 160 Stockholders' Suits</p> <p><input type="checkbox"/> 190 Other Contract</p> <p><input type="checkbox"/> 195 Contract Product Liability</p> <p><input type="checkbox"/> 196 Franchise</p>	<p>TORTS</p> <p>PERSONAL INJURY</p> <p><input type="checkbox"/> 310 Airplane</p> <p><input type="checkbox"/> 315 Airplane Product Liability</p> <p><input type="checkbox"/> 320 Assault, Libel & Slander</p> <p><input type="checkbox"/> 330 Federal Employers' Liability</p> <p><input type="checkbox"/> 340 Marine</p> <p><input type="checkbox"/> 345 Marine Product Liability</p> <p><input type="checkbox"/> 350 Motor Vehicle</p> <p><input type="checkbox"/> 355 Motor Vehicle Product Liability</p> <p><input type="checkbox"/> 360 Other Personal Injury</p> <p><input type="checkbox"/> 362 Personal Injury - Medical Malpractice</p> <p>PERSONAL INJURY</p> <p><input type="checkbox"/> 365 Personal Injury - Product Liability</p> <p><input type="checkbox"/> 367 Health Care/ Pharmaceutical Personal Injury Product Liability</p> <p><input type="checkbox"/> 368 Asbestos Personal Injury Product Liability</p> <p>PERSONAL PROPERTY</p> <p><input type="checkbox"/> 370 Other Fraud</p> <p><input type="checkbox"/> 371 Truth in Lending</p> <p><input type="checkbox"/> 380 Other Personal Property Damage</p> <p><input type="checkbox"/> 385 Property Damage Product Liability</p>	<p>FORFEITURE/PENALTY</p> <p><input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881</p> <p><input type="checkbox"/> 690 Other</p> <p>LABOR</p> <p><input type="checkbox"/> 710 Fair Labor Standards Act</p> <p><input type="checkbox"/> 720 Labor/Management Relations</p> <p><input type="checkbox"/> 740 Railway Labor Act</p> <p><input type="checkbox"/> 751 Family and Medical Leave Act</p> <p><input type="checkbox"/> 790 Other Labor Litigation</p> <p><input type="checkbox"/> 791 Employee Retirement Income Security Act</p> <p>IMMIGRATION</p> <p><input type="checkbox"/> 462 Naturalization Application</p> <p><input type="checkbox"/> 465 Other Immigration Actions</p>	<p>BANKRUPTCY</p> <p><input type="checkbox"/> 422 Appeal 28 USC 158</p> <p><input type="checkbox"/> 423 Withdrawal 28 USC 157</p> <p>PROPERTY RIGHTS</p> <p><input type="checkbox"/> 830 Copyrights</p> <p><input checked="" type="checkbox"/> 830 Patent</p> <p><input type="checkbox"/> 840 Trademark</p> <p>SOCIAL SECURITY</p> <p><input type="checkbox"/> 861 HIA (1395ff)</p> <p><input type="checkbox"/> 862 Black Lung (923)</p> <p><input type="checkbox"/> 863 DIWC/DIWW (405(g))</p> <p><input type="checkbox"/> 864 SSID Title XVI</p> <p><input type="checkbox"/> 865 RSI (405(g))</p> <p>FEDERAL TAX SUITS</p> <p><input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant)</p> <p><input type="checkbox"/> 871 IRS—Third Party 26 USC 7609</p>	<p>OTHER STATUTES</p> <p><input type="checkbox"/> 375 False Claims Act</p> <p><input type="checkbox"/> 400 State Reapportionment</p> <p><input type="checkbox"/> 410 Antitrust</p> <p><input type="checkbox"/> 430 Banks and Banking</p> <p><input type="checkbox"/> 450 Commerce</p> <p><input type="checkbox"/> 460 Deportation</p> <p><input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations</p> <p><input type="checkbox"/> 480 Consumer Credit</p> <p><input type="checkbox"/> 490 Cable/Sat TV</p> <p><input type="checkbox"/> 850 Securities/Commodities/Exchange</p> <p><input type="checkbox"/> 890 Other Statutory Actions</p> <p><input type="checkbox"/> 891 Agricultural Acts</p> <p><input type="checkbox"/> 893 Environmental Matters</p> <p><input type="checkbox"/> 895 Freedom of Information Act</p> <p><input type="checkbox"/> 896 Arbitration</p> <p><input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision</p> <p><input type="checkbox"/> 950 Constitutionality of State Statutes</p>
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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 *(specify)* 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. Sec. 2201(a); 21 U.S.C. Sec. 355(j)(5)(C)(i)

Brief description of cause:
Declaratory judgment of non-infringement of U.S. Patent

VII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND \$ Declaratory Judgment

CHECK YES only if demanded in complaint:

JURY DEMAND: Yes No

VIII. RELATED CASE(S) IF ANY *(See instructions):* JUDGE _____ DOCKET NUMBER S.T.

DATE 11/19/14 SIGNATURE OF ATTORNEY OF RECORD [Signature] NOV 19 2014

FOR OFFICE USE ONLY

UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA — DESIGNATION FORM to be used by counsel to indicate the category of the case for the purpose of assignment to appropriate calendar.

Address of Plaintiff: One Ram Ridge Road, Spring Valley, New York 10977

Address of Defendant: 5 Crescent Drive, Philadelphia PA 19112

Place of Accident, Incident or Transaction: (Use Reverse Side For Additional Space)

Does this civil action involve a nongovernmental corporate party with any parent corporation and any publicly held corporation owning 10% or more of its stock? (Attach two copies of the Disclosure Statement Form in accordance with Fed.R.Civ.P. 7.1(a)) Yes X No

Does this case involve multidistrict litigation possibilities? Yes No X

RELATED CASE, IF ANY:

Case Number: Judge Date Terminated:

Civil cases are deemed related when yes is answered to any of the following questions:

- 1. Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court? Yes No X
2. Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court? Yes No X
3. Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action in this court? Yes No X
4. Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual? Yes No X

CIVIL: (Place ONE CATEGORY ONLY)

A. Federal Question Cases:

- 1. Indemnity Contract, Marine Contract, and All Other Contracts
2. FELA
3. Jones Act-Personal Injury
4. Antitrust
5. X Patent
6. Labor-Management Relations
7. Civil Rights
8. Habeas Corpus
9. Securities Act(s) Cases
10. Social Security Review Cases
11. All other Federal Question Cases (Please specify)

B. Diversity Jurisdiction Cases:

- 1. Insurance Contract and Other Contracts
2. Airplane Personal Injury
3. Assault, Defamation
4. Marine Personal Injury
5. Motor Vehicle Personal Injury
6. Other Personal Injury (Please specify)
7. Products Liability
8. Products Liability — Asbestos
9. All other Diversity Cases (Please specify)

ARBITRATION CERTIFICATION

(Check Appropriate Category)

I, William J. Murray, Jr., counsel of record do hereby certify:
Pursuant to Local Civil Rule 53.2, Section 3(c)(2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of \$150,000.00 exclusive of interest and costs;
X Relief other than monetary damages is sought.

DATE: 11/19/94 William J. Murray, Jr. 73917
Attorney-at-Law Attorney I.D.#

NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.

I certify that, to my knowledge, the within case is not related to any case now pending or within one year previously terminated action in this court except as noted above.

DATE: 11/19/94 73917
Attorney-at-Law Attorney I.D.#

NIQA

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA
CASE MANAGEMENT TRACK DESIGNATION FORM

PAR PHARMACEUTICAL, INC.

v.

GLAXOSMITHKLINE, LLC.
APTALIS PHARMA US, INC.
APTALIS PHARMATECH, INC.
APTALIS PHARMA CANADA INC.

:
:
: CIVIL ACTION NO. **14 6627**
:
:
:

In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a Case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1:03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a Case Management Track Designation Form specifying the track to which that defendant believes the case should be assigned.

SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:

- (a) Habeas Corpus – Cases brought under 28 U.S.C. § 2241 through § 2255. ()
- (b) Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits. ()
- (c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ()
- (d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. ()
- (e) Special Management – Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.) ()
- (f) Standard Management – Cases that do not fall into any one of the other tracks. (X)

11/19/14
Date

William J. Murray, Jr.
Attorney at law

Par Pharmaceutical, Inc.
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NOV 19 2014