JS 44 (Rev. 12/07)

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 THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS

LUPIN ATLANTIS HOLDINGS S.A.

(b) County of Residence of First Listed Plaintiff _____
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)

John J. Higson, Dilworth Paxson LLP, 1500 Market St. Ste. 3500E, Phila., PA 19102 215-575-7000

DEFENDANTS

MYLAN INC., MYLAN PHARMACEUTICALS, INC. and ETHYPHARM S.A.

County of Residence of First Listed Defendant _____
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☐ 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)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

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

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury

PERSONAL INJURY
- ☐ 362 Personal Injury - Med. Malpractice
- ☐ 365 Personal Injury - Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 444 Welfare
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 440 Other Civil Rights

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence

Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition

FORFEITURE/PENALTY
- ☐ 610 Agriculture
- ☐ 620 Other Food & Drug
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 630 Liquor Laws
- ☐ 640 R.R. & Truck
- ☐ 650 Airline Regs.
- ☐ 660 Occupational Safety/Health
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 730 Labor/Mgmt.Reporting & Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus - Alien Detainee
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☒ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Information Act
- ☐ 900Appeal of Fee Determination Under Equal Access to Justice
- ☐ 950 Constitutionality of State Statutes

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 ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing **(Do not cite jurisdictional statutes unless diversity)**:
35 U.S.C. §271 (e)(2)

Brief description of cause:
Patent infringement action (ANDA) re Pharmaceutical product under name "Antara"

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER F.R.C.P. 23

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☐ Yes ☑ No

VIII. RELATED CASE(S) IF ANY (See instructions): JUDGE Gene E.K. Pratter DOCKET NUMBER 10-03897

DATE
05/12/2011

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

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: Bachstrasse 56. 8200 Schaffhausen SH, Switzerland

Address of Defendant: 1500 Corporate Drive, Canonsburg, Pennsylvania 15317

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☒ No☐

Does this case involve multidistrict litigation possibilities? Yes☒ No☐

RELATED CASE, IF ANY:
Case Number: 10-cv-03897 Judge Gene E.K. Pratter 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☒
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☒
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☐
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☒

CIVIL: (Place ✔ in 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. ☒ 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, John J. Higson, 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;

☐ Relief other than monetary damages is sought.

DATE: 05/12/2011 _____ 80720
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: n/a see above _____ _____
Attorney-at-Law Attorney I.D.#

CIV. 609 (6/08)

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: Bachstrasse 56. 8200 Schaffhausen SH, Switzerland

Address of Defendant: 1500 Corporate Drive, Canonsburg, Pennsylvania 15317

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☒ No☐

Does this case involve multidistrict litigation possibilities? Yes☒ No☐

RELATED CASE, IF ANY:

Case Number: 10-cv-03897 Judge Gene E.K. Pratter 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☒
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☒
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☐
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☒

CIVIL: (Place ✔ in 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. ☒ 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, John J. Higson, 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;

☐ Relief other than monetary damages is sought.

DATE: 05/12/2011 _____ 80720
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: n/a see above _____ _____
Attorney-at-Law Attorney I.D.#

CIV. 609 (6/08)

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

CASE MANAGEMENT TRACK DESIGNATION FORM

LUPIN ATLANTIS HOLDINGS S.A.,	:	CIVIL ACTION
v.	:	
MYLAN INC., MYLAN PHARMACEUTICALS, INC. and EHTYPHARM S.A.	:	NO.

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.) (X)

(f) Standard Management – Cases that do not fall into any one of the other tracks. ( )

5/12/2011		Lupin Atlantis Holdings S.A.
Date	**Attorney-at-law**	**Attorney for**
215-575-7000	215-575-7200	jhigson@dilworthlaw.com
Telephone	**FAX Number**	**E-Mail Address**

(Civ. 660) 10/02

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

LUPIN ATLANTIS HOLDINGS S.A.,

Plaintiff,

v.

MYLAN INC., MYLAN PHARMACEUTICALS, INC., and ETHYPHARM S.A.,

Defendants.

COMPLAINT

Plaintiff Lupin Atlantis Holdings S.A., by its attorneys, for its complaint against Mylan Inc. and Mylan Pharmaceuticals, Inc. (collectively, "Mylan") and Ethypharm S.A., allege as follows:

THE PARTIES

1. Plaintiff Lupin Atlantis Holdings S.A. ("Lupin Atlantis") is a corporation organized and existing under the laws of Switzerland, with a principal place of business at Bachstrasse 56, 8200 Schaffhausen SH, Switzerland.

2. Upon information and belief, Defendant Mylan Inc. is a company organized and existing under the laws of the Commonwealth of Pennsylvania with a principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317.

3. Upon information and belief, Mylan Inc. is in the business of, among other activities, manufacturing and selling copies of branded pharmaceutical products that are

used and sold throughout the United States, including in the Commonwealth of Pennsylvania and in this judicial district.

4. Upon information and belief, Defendant Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of West Virginia, having its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505 and is a wholly-owned subsidiary of Mylan Inc.

5. Upon information and belief, Mylan Pharmaceuticals, Inc. is in the business of, among other activities, offering for sale, selling and/or importing copies of branded pharmaceutical products throughout the United States, including in the Commonwealth of Pennsylvania and in this judicial district.

6. Upon information and belief, Mylan Pharmaceuticals, Inc. makes regulatory submissions to the United States Food and Drug Administration ("FDA"), including submissions on behalf of Mylan Inc.

7. Upon information and belief, Defendant Ethypharm S.A. ("Ethypharm") is a corporation organized and existing under the laws of France, with its principal offices at 194 Bureaux de la Colline, 922 13 St. Cloud, France.

8. Upon information and belief, Mylan Pharmaceuticals, Inc. and Mylan Inc. collaborated in the research and development of Mylan's Abbreviated New Drug Application ("ANDA") No. 202579 for capsules that contain 43 mg and 130 mg of fenofibrate as the active ingredient ("the Mylan ANDA Product"), continue to collaborate in seeking approval of that application by the FDA, and intend to collaborate in the commercial manufacture, marketing, offer for sale and sale of the Mylan ANDA Product throughout the United States, including in the Commonwealth of Pennsylvania and in this judicial district, in the event the FDA approves the Mylan ANDA.

JURISDICTION AND VENUE

9. This is a civil action arising under the patent laws of the United States, Title 35, United States Code, for infringement of U.S. Patent 7,101,574 ("the '574 patent") and U.S. Patent No. 7,863,331 ("the '331 patent"). This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

10. Upon information and belief, Mylan Inc. is subject to personal jurisdiction in this judicial district because it has purposely availed itself of the benefits and protections of this Commonwealth's laws such that it should reasonably anticipate being haled into court in this judicial district. Mylan Inc. is a Pennsylvania company. Upon information and belief, Mylan Inc. markets and sells generic drugs throughout the United States, and in particular within this judicial district, and therefore Mylan Inc. has engaged in systematic and continuous business within this judicial district. In addition, and upon information and belief, Mylan Inc. controls and dominates Mylan Pharmaceuticals, Inc., and thus the activities of the former entity in this judicial district are attributable to Mylan Inc.

11. Upon information and belief, Mylan Pharmaceuticals, Inc. is subject to personal jurisdiction in this judicial district because, *inter alia*, Mylan Pharmaceuticals, Inc., alone and through its parent Mylan Inc., has purposely availed itself of the benefits and protections of this Commonwealth's laws such that it should reasonably anticipate being haled into court in this judicial district. On information and belief, Mylan Pharmaceuticals, Inc., alone and through its parent Mylan Inc., markets and sells generic drugs throughout the United States, and in particular within this judicial district, and therefore Mylan Pharmaceuticals, Inc. has engaged in systematic and continuous business within this judicial district.

12. Upon information and belief, Mylan Pharmaceuticals, Inc. and Mylan Inc. market Mylan's generic drug products to persons residing within this judicial district, for example, via their website.

13. Upon information and belief, Mylan Pharmaceuticals, Inc. and Mylan Inc. offer Mylan's generic drug products for sale to persons residing within this judicial district on third-party websites that these persons can use to purchase Mylan products for shipment to and within this judicial district.

14. Upon information and belief, persons residing within this judicial district purchase generic drug products, including Mylan products, from Mylan Inc. (itself or through its wholly-owned subsidiary Mylan Pharmaceuticals, Inc.) in this judicial district.

15. Upon information and belief, persons residing within this judicial district purchase generic drug products, including Mylan products, from Mylan Pharmaceuticals, Inc. in this judicial district.

16. Upon information and belief, Mylan Inc. (itself or through its wholly-owned subsidiary Mylan Pharmaceuticals, Inc.) receives revenue from the sales and marketing of generic drug products, including Mylan products, within this judicial district.

17. Upon information and belief, Mylan Pharmaceuticals, Inc. receives revenue from the sales and marketing of generic drug products, including Mylan products, within this judicial district.

18. Upon information and belief, Mylan Inc., or through its wholly-owned subsidiary Mylan Pharmaceuticals, Inc., intends to market and sell the Mylan ANDA Product, if approved, to residents of this judicial district.

19. Upon information and belief, Mylan Pharmaceuticals, Inc. and Mylan Laboratories Inc., the predecessor company to Mylan Inc., did not object to personal jurisdiction or venue in this judicial district in Civil Action No. 2:06-cv-1797-MSG (E.D.Pa.) and its multiple related proceedings.

20. Upon information and belief, Mylan Inc. and Mylan Pharmaceuticals, Inc. did not contest or otherwise object to personal jurisdiction or venue in this judicial district in Civil Action No. 2:11-cv-01939-GP (E.D.Pa.), which action concerns the same Mylan ANDA (No. 202579) and patent that are the subject of this Complaint.

21. Upon information and belief, Ethypharm is in the business of, among other activities, manufacturing pharmaceutical products for importation into and sale throughout the United States and promotes the importation and sale of such products, including in the Commonwealth of Pennsylvania and in this judicial district.

22. Mylan Pharmaceuticals, Inc., Mylan Inc., and Ethypharm are subject to personal jurisdiction in this judicial district.

23. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b).

BACKGROUND

24. Lupin Atlantis is the owner of the approved New Drug Application ("NDA") No. 21-695 for ANTARA® capsules.

25. On information and belief, Mylan Pharmaceuticals Inc. submitted ANDA No. 202579 to the FDA under the provisions of 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of generic copies of ANTARA® capsules.

26. The ANTARA® capsules contain 43 mg and 130 mg of fenofibrate as the active ingredient, and are currently approved for the treatment of hypercholesterolemia and hypertriglyceridemia.

27. Upon information and belief, the Mylan ANDA Product that is the subject of Mylan's ANDA No. 202579 are capsules containing 43 mg and 130 mg of fenofibrate as the active ingredient, for the treatment of hypercholesterolemia and hypertriglyceridemia.

28. On September 5, 2006, the U.S. Patent and Trademark Office ("USPTO") duly and legally issued the '574 patent titled "Pharmaceutical Composition Containing Fenofibrate and the Preparation Method." A true and correct copy of the '574 patent is attached hereto as Exhibit A.

29. On January 4, 2011, the USPTO duly and legally issued the '331 patent, titled "Pharmaceutical Composition Containing Fenofibrate and Method for the Preparation Thereof." A true and correct copy of the '331 patent is attached hereto as Exhibit B.

30. Ethypharm is the owner of the '574 patent, which discloses and claims, *inter alia*, a pharmaceutical composition containing fenofibrate and a method for preparing the composition.

31. Ethypharm also is the owner of the '331 patent, which discloses and claims, *inter alia*, methods of treatment using compositions containing fenofibrate.

32. Lupin Atlantis holds a license from Ethypharm under the '574 and '331 patents that contains provisions granting Lupin Atlantis the right to enforce the '574 and '331 patents in the case of an ANDA filing by a third party.

33. As owner of the '574 and '331 patents and licensor of the '574 and '331 patents to Lupin Atlantis, Defendant Ethypharm is jointly interested with, and contractually obligated to cooperate with, Lupin Atlantis in this cause of action, including without limitation joining this action if necessary. Although requested to file suit as Co-Plaintiff, Ethypharm has not, as of the date of the filing of this action, agreed to do so. For that reason, Ethypharm is named as a defendant.

34. Upon information and belief, Mylan Inc. sent a letter dated February 25, 2011, to Lupin Atlantis, Laboratoires des Produits Ethiques Ethypharm, and Ethypharm S.A. which purported to comply with the provisions of 21 U.S.C. § 355(j)(2)(B) (the "First Notice Letter"). The First Notice Letter purportedly advised Lupin Atlantis and Ethypharm that Mylan's ANDA contains a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") with respect to both the '574 and '331 patents, that no valid and enforceable claim of the '574 patent would be infringed by the manufacture, importation, use, sale or offer for sale of the Mylan ANDA Product containing either 43 mg or 130 mg of fenofibrate, and that no valid and enforceable claim of the '331 patent would be infringed by the manufacture, importation, use, sale or offer for sale of the Mylan ANDA Product containing 43 mg of fenofibrate.

35. Upon information and belief, Mylan Pharmaceuticals, Inc. submitted Mylan ANDA No. 202579 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of a generic copy of the ANTARA® product prior to the expiration of the '574 and '331 patents.

36. Upon information and belief, the Mylan ANDA contains a Paragraph IV Certification asserting that, in its opinion, the '574 and '331 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale and/or importation of the Mylan ANDA Product.

37. By filing ANDA No. 202579 under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the Mylan ANDA Product prior to the expiration of the '574 and '331 patents, Mylan has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, on information and belief, Mylan plans to commercially use, offer for sale,

and/or sell the Mylan ANDA Product, and/or to induce or contribute to such activity, and by such actions Mylan would infringe one or more claims of the '574 patent and the '331 patent under 35 U.S.C. § 271(a), (b) and/or (c).

38. Upon information and belief, Mylan Pharmaceuticals Inc. and Mylan Inc. participated in, contributed to, aided, and/or induced the submission of Mylan ANDA No. 202579 and its Paragraph IV Certification to the FDA. Additionally, upon information and belief, Mylan Pharmaceuticals Inc. and Mylan Inc. will market and/or distribute the Mylan ANDA Product in the United States, and within this judicial district, if Mylan ANDA No. 202579 is approved by the FDA. Mylan Pharmaceuticals Inc. and Mylan Inc. thus are jointly and severally liable for infringement of the '574 and '331 patents.

39. An action was filed in the Eastern District of Pennsylvania within 45 days of receipt by Lupin Atlantis and Ethypharm of the First Notice Letter, which purportedly advised Lupin Atlantis and Ethypharm of Mylan's Paragraph IV Certification with respect to the '574 and '331 patents. This action has been designated Civil Action No. 2:11-cv-01930-GP, and has been assigned to the Honorable Gene E.K. Pratter.

COUNT I FOR PATENT INFRINGEMENT

(Infringement of the '331 patent under 35 U.S.C. § 271(e)(2))

40. Lupin Atlantis incorporates paragraphs 1-39 of this Complaint as if fully set forth herein.

41. Upon information and belief, Mylan Inc. sent a letter dated April 5, 2011, to Lupin Atlantis, Laboratoires des Produits Ethiques Ethypharm, and Ethypharm S.A. which purported to comply with the provisions of 21 U.S.C. § 355(j)(2)(B) (the "Second Notice Letter"). The Second Notice Letter purportedly advised Lupin Atlantis and Ethypharm that Mylan's ANDA contains a Paragraph IV Certification with respect to the '331 patent, and that no valid, enforceable claim of the '331 patent would be infringed by the manufacture, importation, use, sale or offer for sale of the Mylan ANDA Product containing 130 mg of fenofibrate.

42. Upon information and belief, the '331 patent is listed in the FDA publication entitled Approved Drug Products and Therapeutic Equivalence Evaluations ("the Orange Book") relative to ANTARA®.

43. Upon information and belief, Mylan Pharmaceuticals Inc. submitted Mylan ANDA No. 202579 to the FDA for purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of a generic copy of the ANTARA® product prior to the expiration of the '331 patent.

44. Upon information and belief, the Mylan ANDA contains a Paragraph IV Certification asserting that, in its opinion, the '331 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale and/or importation of the Mylan ANDA Product containing 130 mg of fenofibrate.

45. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) requires, *inter alia*, certification by the ANDA applicant that the subject patent, here the '331 patent, is "invalid or will not be infringed by the manufacture, use, offer for sale or sale of the new drug for which the application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to "include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)) specify, *inter alia*, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation."

46. Upon information and belief, at the time the Second Notice Letter was mailed (this letter purportedly serving as a notice of Paragraph IV Certification relative to the '331 patent), Mylan Inc. and/or Mylan Pharmaceuticals Inc. was aware of the statutory provisions and regulations referred to in paragraph 45, *supra*.

47. Mylan's Second Notice Letter is required by statute and regulation to provide a full and detailed explanation regarding all bases for noninfringement of the '331 patent but fails to do so. While providing some information on its noninfringement positions, Mylan fails to provide a full explanation of such bases, stating in its Second Notice Letter that it "*reserves the right to assert additional grounds*, reasons, and/or

authorities that any or all of the claims of these patents are invalid, unenforceable, and/or not *infringed*" by the Mylan ANDA Product (emphasis added).

48. Mylan's Second Notice Letter is required by statute and regulation to provide a full and detailed explanation regarding all bases for invalidity of the '331 patent, but does not allege invalidity of any claims of the '331 patent. Instead, Mylan states in its Second Notice Letter that it "*reserves the right to assert* additional grounds, reasons, and/or authorities that any or all of the claims of *these patents are invalid*, unenforceable, and/or not infringed" by the Mylan ANDA Product (emphasis added).

49. Mylan's Second Notice Letter is required by statute and regulation to provide a full and detailed explanation regarding alleged unenforceability of the patents-in-suit, but does not allege unenforceability or allege inequitable conduct of the '331 patent. Instead, Mylan states in its Second Notice Letter that it "*reserves the right to assert* additional grounds, reasons, and/or authorities that any or all of the claims of *these patents are* invalid, *unenforceable*, and/or not infringed" by the Mylan ANDA Product (emphasis added).

50. Mylan's Second Notice Letter fails to comply with the law, as specified in 21 U.S.C. § 355(j), and FDA rules and regulations, as specified in 21 C.F.R. § 314.95.

51. By filing ANDA No. 202579 under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the Mylan ANDA Product prior to the expiration of the '331 patent, Mylan has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, on information and belief, Mylan plans to commercially use, offer for sale, and/or sell the Mylan ANDA Product, and/or to induce or contribute to such activity, and by such actions Mylan would infringe one or more claims of the '331 patent under 35 U.S.C. § 271(a), (b) and/or (c).

52. Upon information and belief, Mylan Pharmaceuticals Inc. and Mylan Inc. participated in, contributed to, aided, and/or induced the submission of Mylan ANDA No. 202579 and its Paragraph IV Certification to the FDA. Additionally, upon information and belief, Mylan Pharmaceuticals Inc. and Mylan Inc. will market and/or distribute the Mylan ANDA Product containing 130 mg of fenofibrate in the United States, and within

this judicial district, if Mylan ANDA No. 202579 is approved by the FDA. Mylan Pharmaceuticals Inc. and Mylan Inc. thus are jointly and severally liable for infringement of the '331 patent.

53. This action is being filed within 45 days of receipt by Lupin Atlantis and Ethypharm of the Second Notice Letter, which purportedly advised Lupin Atlantis and Ethypharm of Mylan's Paragraph IV Certification with respect to the '331 patent concerning the Mylan ANDA product containing 130 mg of fenofibrate.

54. Upon information and belief, Mylan had actual and constructive notice of the '331 patent prior to filing Mylan's Paragraph IV Certification with respect to the '331 patent concerning the Mylan ANDA product containing 130 mg of fenofibrate, and Mylan's infringement of the '331 patent has been, and continues to be, willful.

55. Lupin Atlantis is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Mylan ANDA No. 202579 be a date that is not earlier than the expiration of the '331 patent, or any later expiration of exclusivity for the '331 patent to which it may become entitled.

56. Lupin Atlantis will be irreparably harmed if Mylan is not enjoined from infringing or actively inducing or contributing to infringement of the '331 patent, as Lupin Atlantis has no adequate remedy at law

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Lupin Atlantis respectfully requests the following relief:

A. A judgment that Mylan has infringed one or more claims of the '331 patent under 35 U.S.C. § 271(e)(2);

B. An order pursuant to 35 U.S.C. § 271(e)(4) providing that the effective date of any FDA approval of Mylan's ANDA No. 202579 be not earlier than the expiration date of the '331 patent or any later expiration of exclusivity for this patent to which it may become entitled;

C. A permanent injunction restraining and enjoining Mylan Pharmaceuticals Inc. and Mylan Inc. and each of their officers, agents, servants, employees and those persons acting in privity or concert with them, from engaging in the commercial

manufacture, use, offer for sale or sale within the United States or its territories, or importation into the United States or its territories, of the Mylan ANDA Product, or any product that infringes the '331 patent;

D. Damages and treble damages from Mylan from any commercial activity constituting infringement of the '331 patent;

E. That Defendant Ethypharm be realigned and named as a Plaintiff in this action;

F. Costs and expenses in this action; and

G. Such other and further relief as this Court determines to be just and proper.

Respectfully submitted,

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