William J. O'Shaughnessy
Jonathan M.H. Short
Mark H. Anania
McCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
(973) 622-4444

Of Counsel:
Robert L. Baechtold
Nicholas N. Kallas
Simon D. Roberts
FITZPATRICK, CELLA, HARPER & SCINTO
30 Rockefeller Plaza
New York, New York 10112-3801
(212) 218-2100

Edmund J. Haughey
FITZPATRICK, CELLA, HARPER & SCINTO
975 F Street, N.W.
Suite 400
Washington, D.C. 20004-1462
(202) 530-1010

*Attorneys for Plaintiffs*

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

| | | |
|---|---|---|
| NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS PHARMA AG, and NOVARTIS INTERNATIONAL PHARMACEUTICAL LTD., | : | |
| Plaintiffs, | : | Civil Action No.: |
| v. | : | |
| WATSON PHARMACEUTICALS, INC., WATSON LABORATORIES, INC., and WATSON PHARMA, INC. | : | |
| Defendants. | : | |

**COMPLAINT FOR PATENT INFRINGEMENT AND DECLARATORY JUDGMENT OF PATENT INFRINGEMENT**

Plaintiffs Novartis Pharmaceuticals Corporation, Novartis Pharma AG, and Novartis International Pharmaceutical Ltd. (collectively "Novartis"), for their complaint against Defendants Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., and Watson Pharma, Inc. (collectively, "Watson"), allege as follows:

## NATURE OF ACTION

1. This is an action for patent infringement and declaratory judgment for patent infringement.

## PARTIES

2. Plaintiff Novartis Pharmaceuticals Corporation ("NPC") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 59 Route 10, East Hanover, New Jersey 07936.

3. Plaintiff Novartis Pharma AG is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

4. Plaintiff Novartis International Pharmaceutical Ltd. ("NIP") is a corporation organized and existing under the laws of Bermuda, having an office and place of business at Hurst Holme, 12 Trott Road, Hamilton HM LX, Bermuda.

5. On information and belief, Watson Pharmaceuticals Inc. ("Watson Pharmaceuticals") is a corporation organized under the laws of Nevada, with its commercial headquarters at 360 Mount Kemble Avenue, Morristown, New Jersey 07962 and a place of business at 311 Bonnie Circle, Corona, California 92880.

6. On information and belief, Watson Laboratories, Inc. ("Watson Labs") is a corporation organized under the laws of Nevada, with places of business at 360 Mount Kemble Avenue, Morristown, New Jersey 07962 and 311 Bonnie Circle, Corona, California 92880. On further information and belief, Watson Labs is the holder of various Abbreviated New Drug Applications on file with the U.S. Food and Drug Administration ("FDA"), pursuant to which Watson Pharmaceuticals and Watson Pharma, Inc. manufacture, sell and distribute generic copies of innovative pharmaceutical products.

7. On information and belief, Watson Labs is a wholly owned subsidiary of Watson Pharmaceuticals. On further information and belief, certain officers and directors of Watson Labs are common to Watson Pharmaceuticals.

8. On information and belief, Watson Pharma Inc. ("Watson Pharma"), is a corporation organized under the laws of Delaware, with its commercial headquarters at 360 Mount Kemble Avenue, Morristown, New Jersey 07962. On further information and belief, Watson Pharma is engaged in the business of selling and distributing generic copies of innovative pharmaceutical products.

9. On information and belief, Watson Pharma is a wholly owned subsidiary of Watson Pharmaceuticals. On further information and belief, certain officers and directors of Watson Pharma are common to Watson Pharmaceuticals.

10. On information and belief, certain officers and directors are common to Watson Pharmaceuticals, Watson Labs and/or Watson Pharma.

11. On information and belief, Watson develops, manufactures and sells generic pharmaceutical products. Watson distributes its generic pharmaceutical products throughout the United States and in this District.

12. On information and belief, Watson sells its generic prescription products primarily under the "Watson Laboratories" and "Watson Pharma" labels.

13. On information and belief, Watson Pharmaceuticals has consolidated its activities and financial results, including revenue earned, with, *inter alia*, Watson Labs and Watson Pharma in its most recent SEC filings and Annual Report.

14. On information and belief, Watson Pharmaceuticals and/or Watson Labs earns revenue from the distribution in New Jersey by Watson Pharma of generic pharmaceutical products manufactured by Watson Labs or for which Watson Labs is the named applicant on approved ANDAs.

## JURISDICTION AND VENUE

15. This is an action for patent infringement and for declaratory judgment of patent infringement in a case of actual controversy arising under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202 and the United States Patent Laws, 35 U.S.C. § 1 *et seq*. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

16. This court has personal jurisdiction over Defendants Watson Pharmaceuticals, Watson Labs and Watson Pharma because, *inter alia*, they have purposely availed themselves of the benefits and protections of New Jersey's laws such that they should reasonably anticipate being sued here. On information and belief, Watson Pharmaceuticals, Watson Labs and Watson Pharma have had persistent, continuous and systematic contacts with this judicial district, including, *inter alia*, maintaining a place of business in New Jersey, and either directly or through an agent, deriving substantial revenue from the development, manufacture and/or sale of pharmaceutical products that are sold in New Jersey. In addition, this lawsuit arises from

Watson's imminent patent infringement activities believed to be directed towards the State of New Jersey.

17. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b) and (c) and 28 U.S.C. § 1400(b).

**CLAIM FOR PATENT INFRINGEMENT**
**AND DECLARATORY JUDGMENT FOR PATENT INFRINGEMENT**

18. Plaintiff NPC holds an approved new drug application ("NDA"), No. 20-363, from the United States Food and Drug Administration ("FDA") relating to Famvir® tablets (125 mg, 250 mg, and 500 mg), which tablets contain the active ingredient famciclovir. In the United States, Famvir® tablets are indicated for the treatment of recurrent herpes labialis, the treatment of recurrent episodes of genital herpes, the chronic suppressive therapy of recurrent episodes of genital herpes, the treatment of herpes zoster (shingles), and the treatment of recurrent episodes of orolabial or genital herpes in HIV-infected adults. Famvir® tablets have been shown and are approved to reduce the duration of the painful complication of herpes zoster (shingles) called post-herpetic neuralgia ("PHN"), which is the pain experienced by patients having herpes zoster (shingles) after rash healing. Famvir® tablets are sold in the United States by NPC.

19. The active ingredient in Famvir® tablets, famciclovir, is known chemically as 2-[2-(2-amino-9H-purin-9-yl)ethyl]-1,3-propanediol diacetate or 2-amino-9-(4-acetoxy-3-acetoxymethylbut-1-yl)purine.

20. Plaintiff NIP is the owner of U.S. Patent No. 5,246,937 ("the '937 patent"). The '937 patent was duly and legally issued on September 21, 1993. The '937 patent claims, 2-amino-9-(4-acetoxy-3-acetoxymethylbut-1-yl)purine, pharmaceutically acceptable salts thereof, and pharmaceutical compositions containing them, as well as methods of treating herpesvirus

infections. The '937 patent expired on September 21, 2010, but Novartis has received pediatric exclusivity that extends the regulatory exclusivity for the '937 patent to which Novartis is entitled for, *inter alia*, Famvir® to March 21, 2011. A true copy of the '937 patent is attached hereto as Exhibit A.

21. Plaintiff NIP is the owner of U.S. Patent No. 5,866,581. The '581 patent was duly and legally issued on February 2, 1999. The '581 patent claims, *inter alia*, FDA-approved methods for treating postherpetic neuralgia ("PHN") and treating PHN prophylactically using famciclovir. A true copy of the '581 patent is attached hereto as Exhibit B.

22. On information and belief, Watson submitted to the FDA an abbreviated new drug application ("ANDA") under the provisions of 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, or sale of famciclovir 125 mg, 250 mg and 500 mg tablets ("Watson's generic famciclovir product"). On further information and belief, Watson's ANDA is ANDA No. 78-278.

23. On information and belief, Watson submitted its ANDA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of its generic famciclovir product before the expiration of the '581 patent.

24. On information and belief, on or about September 14, 2010, Watson received FDA approval for its generic famciclovir product.

25. On September 21, 2010, Watson told Novartis that it intended to commercially launch its generic famciclovir product sometime after September 21, 2010, but before March 21, 2011, the expiration of the pediatric exclusivity period associated with the '937 patent.

26. Novartis requested from Watson a copy of Watson's approved product label by both telephonic and electronic means. While Watson agreed to provide its label, it did not do so.

27. On information and belief, Watson engaged in acts constituting infringement of one or more claims of the '937 patent.

28. It is a requirement applicable to all filers of ANDA's under 21 U.S.C. § 355(j)(2)(A) that for any patent listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") that claims a listed drug or a method of using a drug, the applicant must submit a patent certification to the FDA stating:

(I) that such patent information has not been filed;

(II) that such patent has expired;

(III) of the date on which such patent will expire; or

(IV) that such patent is invalid or will not be infringed by the manufacture, use or sale of the new drug for which the application is submitted.

29. The '937 patent claims the drug famciclovir.

30. The '937 patent also claims the use of famciclovir to treat viral infections, and specifically viral infections caused by herpes viruses.

31. On information and belief, Watson knew when it filed its ANDA for famciclovir that the '937 patent claimed that drug and that use.

32. On information and belief, Watson did not submit any of the certifications required by 21 U.S.C. § 355(j)(2)(A) for the '937 patent with ANDA No. 78-278. Instead, Watson filed a statement, pursuant to 21 U.S.C. § 355(j)(2)(A)(viii) (a "section viii statement"), affirmatively representing to FDA that it was not seeking approval for a method of use claimed by the '937 patent.

33. Watson could not have made either the 35 U.S.C. § 355(j)(2)(A) certification of paragraph (I) or the certification of paragraph (II) when it filed ANDA 78-278.

34. An ANDA filer that makes a certification under paragraph (III) of 21 U.S.C. § 355(j)(2)(A) may not have its application approved by FDA until after the expiration of the subject patent and any pediatric exclusivity to which that patent is entitled.

35. An ANDA filer that makes a paragraph (IV) certification must provide notice to the NDA holder and, because a paragraph (IV) certification is an act of patent infringement under 35 U.S.C. § 271(e)(2), the NDA holder may file suit within 45 days of such notice and obtain a 30 month stay of FDA approval of the ANDA. In contrast, an ANDA filer making only a section viii statement does not provide notice to the NDA holder, and the NDA holder does not receive the attendant procedural protections of a paragraph (IV) certification.

36. On information and belief, Watson deliberately and intentionally failed to make either a paragraph (III) or paragraph (IV) certification. Watson did so in order to (i) avoid being barred from approval of its ANDA until after the expiration of the '937 patent and its pediatric exclusivity, and (ii) avoid having to give notice to Novartis and being subject to a suit for infringement and the consequent stay on the approval of its ANDA.

37. On information and belief, Watson's section viii statement was false because, contrary to Watson's representation to the FDA, Watson's ANDA sought approval of the use of famciclovir to treat viral infections, specifically infections caused by herpes viruses, and those uses are claimed in the '937 patent.

38. Watson's intentional failure to submit either a paragraph (III) certification or a paragraph (IV) certification, and its submitting instead a false section viii statement was designed to mislead, and did mislead, the FDA into granting approval of Watson's ANDA 78-278, in derogation and in violation of Novartis's exclusivity rights under the '937 patent.

39. Watsons's ANDA 78-278 does not meet the requirements of 21 U.S.C. § 355 (j) and would not have been approved by the FDA if Watson had not misled that agency, because (i) Watson's ANDA does not comply with the requirements of 21 U.S.C. § 355 (j)(2)(A) and (ii) Watson's ANDA contains material false statements. *See* 21 U.S.C. § 355(j)(4)(K).

40. Watson's false statements and deliberate failure to make the required certification misled the FDA and caused the FDA incorrectly to approve Watson's ANDA 78-278 prior to the expiration of the pediatric exclusivity under the '937 patent to which Novartis is lawfully entitled, and thus has caused or will cause Novartis immediate and irreparable harm.

41. On information and belief, Watson manufactured, used, imported, offered to sell, and/or sold prior to the September 21, 2010 expiration date of the '937 patent. These commercial activities did not fall under the exemptions from infringement provided by 35 U.S.C. § 271(e)(1), and therefore infringed one or more claims of the '937 patent.

42. On information and belief, Watson's generic famciclovir product will be dispensed and used for all of the purposes for which Famvir® tablets are approved, which are set forth in the Famvir® prescribing information. At least some of those uses will constitute direct infringement of one or more claims of the '581 patent. On information and belief, such uses will occur at the active behest of Watson and with its intent, knowledge, and encouragement, and these activities will induce the infringement of one or more claims of the '581 patent under 35 U.S.C. § 271(b).

43. On information and belief, Watson's commercial manufacture, use, offers for sale, sales, and/or importation of its generic famciclovir product will infringe and/or induce infringement of one or more claims of the '581 patent under 35 U.S.C. § 271.

44. On information and belief, Watson's infringement of the '581 patent is imminent, based on Watson's statement that it will launch before the expiry of the pediatric exclusivity period.

45. Thus, an actual controversy exists between Novartis and Watson regarding whether Watson's manufacture, use, offers for sale, sales, and/or importation of its generic famciclovir product will infringe one or more claims of the '581 patent.

46. To avoid legal uncertainty and the threat of infringing importation and sales of generic famciclovir products by Watson, Novartis seeks a declaratory judgment that such importation and sales, and the acts of Watson alleged above relating to such sales, will infringe the '581 patent.

47. Watson's conduct as alleged above will result in irreparable harm to Novartis that cannot be compensated by monetary damages.

48. Novartis 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 any approval of the aforementioned ANDA, relating to Watson's generic famciclovir product, shall be a date which is not earlier than the expiration date of the '581 patent, and the expiration of any exclusivity, and specifically the pediatric exclusivity for the '937 patent to which Novartis is or becomes entitled.

49. This is an exceptional case and Novartis is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

**PRAYER FOR RELIEF**

WHEREFORE, Novartis respectfully requests from the Court the following relief:

A. A preliminary injunction preventing Watson and its officers, agents, attorneys and employees, and those acting in privity or concert with it, and its successors and assigns, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of generic famciclovir products;

B. An order declaring that Watson's commercial manufacture, use, offer for sale, sale, and/or importation of its generic version of famciclovir infringed the '937 patent and will infringe and/or induce infringement of the '581 patent;

C. A permanent injunction restraining and enjoining Watson and its officers, agents, attorneys and employees, and those acting in privity or concert with it, and its successors and assigns, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of generic famciclovir products to the extent such activities will infringe and/or induce the infringement of one or more claims of '581 patent;

D. An order that the effective date of any future approval of the aforementioned ANDA relating to Watson's generic famciclovir product be a date which is not earlier than the expiration date of the '581 patent, the expiration date of Novartis's pediatric exclusivity for the '937 patent, or any later dates of exclusivity to which Novartis is or becomes entitled;

E. Judgment that this is an exceptional case under 35 U.S.C. § 285, and that Novartis is entitled to its costs and reasonable attorney fees; and

F. Such other and further relief as the Court may deem just and proper.

September 24, 2010 Respectfully submitted,

By: /s/ William J. O'Shaughnessy

William J. O'Shaughnessy
Jonathan M. H. Short
Mark H. Anania
MCCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
(973) 622-4444

Attorneys for Plaintiffs
Novartis Pharmaceuticals Corporation,
Novartis Pharma AG and Novartis
International Pharmaceutical Ltd.

Of Counsel:
Robert L. Baechtold
Nicholas N. Kallas
Simon D. Roberts
FITZPATRICK, CELLA, HARPER
& SCINTO
30 Rockefeller Plaza
New York, New York 10112-3801
(212) 218-2100

Edmund J. Haughey
FITZPATRICK, CELLA, HARPER
& SCINTO
975 F Street, N.W.
Suite 400
Washington, D.C. 20004-1462
(202) 530-1010

*Attorneys for Plaintiffs*

**CERTIFICATION PURSUANT TO L. CIV. R. 11.2**

As identified on the first page of the civil cover sheet, there are currently three closely related cases pending in this Court. The first and second related cases are consolidated before Judge Linares, Consolidated Civil Action Nos. 08-cv-2272 & 08-cv-1204 (JLL)(CCC):

Novartis Pharmaceuticals Corp., et al. v. Roxane Laboratories, Inc.
Consolidated Civil Action Nos. 08-cv-2272 & 08-cv-1204 (JLL)(CCC)

These related consolidated cases involve subject matter pertaining to the first of two presently asserted patents (U.S. Pat. No. 5,866,581).

The third related case is before Judge Cavanaugh -- Civil Action No. 08-cv-3853 (DMC)(JAD) -- that involves the same parties and generic drug products as Consolidated Civil Action Nos. 08-cv-2272 & 08-cv-1204 (JLL)(CCC), but a different patent. The complete identification of Judge Cavanaugh's case is as follows:

Novartis Pharmaceuticals Corp., et al. v. Roxane Laboratories, Inc.
Civil Action No. 08-cv-3853 (DMC)(JAD)

This related case involves subject matter pertaining to the second of two presently asserted patents (U.S. Pat. No. 5,246,937).

Dated: September 24, 2010

By: /s/ William J. O'Shaughnessy
William J. O'Shaughnessy
Jonathan M. H. Short
Mark H. Anania
MCCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
(973) 622-4444

Attorneys for Plaintiffs
Novartis Pharmaceuticals Corporation,
Novartis Pharma AG and Novartis
International Pharmaceutical Ltd.

Of Counsel:

Robert L. Baechtold
Nicholas N. Kallas
Simon D. Roberts
FITZPATRICK, CELLA, HARPER
& SCINTO

1290 Avenue of the Americas
New York, New York 10104-3800
(212) 218-2100